Measuring 'magic': A biopsychosocial feasibility study to measure the effectiveness of a Namaste Care session.

Nicola Kendall

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Nicola Jane Kendall

Doctor of Philosophy

Department of Biosciences

Durham University

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Supervisors:

Professor Paul Chazot, Professor Sarah Atkinson and Dr Leanne Trick

St Cuthbert's Society

Abstract

This doctoral study investigates ways to measure the effectiveness of Namaste Care—a multi-sensory, psycho-social intervention designed for people with advanced dementia—through a biopsychosocial lens. Recognising the challenge of quantifying subjective and relational experiences often described as "magic moments," the research aims to bridge the gap between qualitative accounts and the clinical demand for quantifiable evidence. A three-phase, mixed-methods design was adopted. Phase 1 involved stakeholder consultations to guide the development of a novel observational measure and to co-design the next phase of the study. Phase 2 tested the observational tool, alongside physiological and biological indicators, including resting heart rate, urinary cortisol and dopamine levels, and nasal temperature through thermal imaging during Namaste Care sessions. Phase 3 focused on sharing findings with participants and stakeholders to inform practice.

Results suggest that Namaste Care induces measurable physiological and behavioural changes indicative of improved wellbeing, including reductions in resting heart rate and cortisol levels and observable increases in emotional engagement and relaxation. Resting heart rate proved to be the most simple, accessible and scalable of the biological measures tested. Furthermore, the newly developed Namaste Care Session Outcome Measure (NCSOM) proved acceptable and practical for use by both professionals and trained volunteers. This study contributes a novel, evidence-based framework for evaluating Namaste Care and advocates for the inclusion of relational and sensory care in dementia practice and policy. Findings support Namaste Care's potential to enhance wellbeing in advanced dementia, both within community-based and health and social care settings.

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Ethics Approvals

Phase 1 IRAS Project ID: 310353 Consultation aimed at informing the design of a study into the effectiveness of a psycho-social intervention for people living with advanced dementia called Namaste Care.

Favourable Opinion 2/7/2022 London Camberwell and St Giles Research Ethics Committee

Rec ref 22/OL/0313

Phase 2 IRAS Project ID: 326881 Investigating the potential to validate the reported observable outcomes of Namaste Care by measuring biological, physiological and behavioural responses to the intervention; a mixed methods study.

Favourable opinion 7/6/2023 Northeast- Newcastle & North Tyneside 1 Research Ethics Committee.

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Acknowledgements

I would like to thank my funders, NIHR ARC NENC, who saw the potential for this study and the impact it could have on dementia care practice. Year one of my PhD was peppered with my father's various health emergencies that I needed to respond to, followed by the death of my father in January 2022. Three months after that, my husband was diagnosed with cancer, requiring treatment through year two of my study. To reflect these challenges, I am grateful to NIHR ARC NENC for extending my funding by three months.

My supervisors at Durham University, Professor Paul Chazot, (Biosciences,) Professor Sarah Atkinson (Human Geography/Sociology,) and Dr Leanne Trick (Psychology) provided the range of perspectives I needed to reflect the inter-disciplinary nature of the research. They have been patient with me as I explored areas where I have an interest but have no formal background.

The assistance of Ellie Saunders (Mbiol student) and Dr Jon McPhetre (Molecular Psychology) in exploring the practicalities of the lab methodology were crucial given my lack of laboratory experience.

Throughout my PhD journey, I have been part of the Wolfson Institute Doctoral Training Programme, which has been influential in helping me explore inter-disciplinarity in research.

The support of my family, as I tackle a PhD in my fifties, alongside menopause, significant family changes, diagnosis of a progressive spine condition and reduced income, has meant a great deal to me. They have been enablers and supporters.

Finally, I would like to dedicate this study in memory of my father, Jack St Julien, who died with dementia in 2022 whilst I was conducting this study.

Foreword

An Admiral Nurse once said to me, that trying to evaluate Namaste Care is like asking 'how do we know love is good for us?' I liken evaluating Namaste Care to putting Tinkerbell under a microscope. We are trying to dissect a magical and intangible being. After witnessing first-hand countless 'magic' moments of connection and joy whilst delivering Namaste Care to people, part of me even resents having to evaluate it. But the reality of evidence-based practice, funding streams and National Institute for Clinical Excellence guidelines means that although intuitively, Namaste Care may seem an obviously good thing to offer people with advanced dementia, we are required to evidence the benefit that caregivers report that they see during and following a Namaste Care session. To achieve this, I needed to investigate and learn to understand a range of methods that could add to the evidence base for this intervention and then attempt to measure Tinkerbell's vital statistics.

Namaste Care was originally developed for delivery in care homes and was aimed at improving the quality of life for people living with advanced dementia. Over five years, I led a community-based Namaste Care Project based in a hospice where trained volunteers visited people in their own homes or in an acute hospital ward for up to 2 hours per week. Funding for the project was a constant challenge, being reliant on time-limited charitable grant-giving organisations and having to demonstrate the benefit of Namaste Care both for the person receiving the care, but also for the family carer and the volunteer.

A key moment which motivated this study happened during a community of practice meeting I facilitated in 2021. The Northern Regional Namaste Care Forum was set up by me, and a colleague from Tees, Esk and Wear Valley NHS Foundation Trust, to support the growing interest in Namaste Care in the region and to build good practice. A Consultant Psychiatrist who was attending was having difficulty in engaging the colleagues in his team to introduce Namaste Care into their services because they said there was "no evidence of benefit." This being despite numerous qualitative studies into the benefits of Namaste Care having been published. After exploring this statement further, the issue appeared to be the nature of the evidence gained thus far, and the preference for quantifiable, clinical evidence by members of the medical professions. To meet this need, the idea for this study began to form.

Declaration

I declare that this thesis has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree. Except where states otherwise by reference or acknowledgment, the work presented is entirely my own.

A note on researcher bias and declaration of interest

Given my experience of delivering Namaste Care, my support for the work of Namaste Care International, as well as having 2 published works about Namaste Care, I can acknowledge researcher bias. The approach to be taken in phase 2 will serve to remove that bias, by obtaining rigorous, quantifiable data. However, due to the presence of bias, a reflexive approach, a high degree of self-reflection, as well as robust supervision, was vital throughout the study duration. A further moderating factor was the support of Mbiol student, Ellie Saunders, who assisted with phase 2 data processing and analysis and the assistance of Dr Lydia Kitchen and Dr James Turnbull, who oversaw statistical analysis.

A note on writing style

To best reflect the inter-disciplinary nature of this study, the style of writing aims to be open and accessible across subject boundaries.

Chapter 1: Introduction

1.1 Background

1.2 Literature Review

1.3 Research aims

1.4 Hypothesis

1.Introduction

1.1 Background

With a growing global ageing population and subsequent increase in global dementia numbers (World Health Organisation 2019), and close to 1 million people living with dementia in the UK (dementiastatics.org) there is a growing urgency to optimise dementia care and most especially to improve end-of-life care for people living with advanced dementia (Living Well with Dementia Strategy). For example, Bamford et al, 2018, note that people with advanced dementia very often experience suboptimal end of life care where they are more likely to be hospitalised, have inadequate pain control, and are unlikely to have access to palliative care when compared to people with cancer. From personal and professional practitioner experience, this seems to be in part due to a lack of understanding that dementia is a life limiting condition.

Guidelines from the National Institute for Clinical Excellence (NICE) conclude that non-pharmacological interventions, such as aromatherapy, massage, multi-sensory stimulation, exercise and music should be a first line approach and that anti-psychotic medication for behavioural and psychological symptoms of dementia should be avoided and only prescribed by a specialist (NICE Guidelines, 2020). In practice, however, those with behavioural symptoms are quickly prescribed anti-psychotic medication. At the same time, those more passive “silent residents” with advanced dementia and the associated loss of verbal communication skills, are often under-stimulated (Kaasaleinen, et al, 2020) whether living in care homes or in their own homes.

Living with Dementia

Dementia is a progressive, neurodegenerative condition with over 100 described types. The most common types of the disease are Alzheimer’s Disease, Vascular Dementia, Dementia with Lewy Bodies and Fronto-Temporal Dementia. Dementia most often affects the over 65’s, but young onset dementia is increasingly being diagnosed and now affects over 42,000 people in the UK (The Dementia Guide, Alzheimer’s Society.) Symptoms may include memory changes, difficulties with problem solving, perceptual and spatial changes, challenges with speech and language, mobility problems, behaviour, mood and sensory changes.

Variations in symptom expression and trajectory of the disease across individuals and depending on type of dementia can lead to difficulties with effective advanced care planning and ensuring services are personalised. Instead, the journey with dementia can often be a series of reactive responses to changes in

need. Often described by people living with dementia and their families as a series of losses, the symptoms of dementia can lead to a sense of loss of identity in the person with the disease and a feeling of 'pre-death grief' (Moore, et al, 2020) in their family members.

In the late stages of dementia, severe disabling symptoms, often occurring with co-morbidities and frailty, lead to a significant impact on the wellbeing and quality of life of the person living with dementia. Whilst increasing efforts are being made in research for disease modifying dementia treatments, the likelihood of a curative option is not yet on the horizon. Research can therefore also be focused on effective social care options to ensure the best quality of life is offered to people living with dementia whilst treatment options are in development. Indeed, some of the elements of good care and understanding why they work may serve as clues to the underlying mechanisms at play in dementia as a disease.

What is Namaste Care?

Namaste Care was developed by a social worker called Joyce Simard in the USA in 2003 to meet an obvious gap in services for people in the advanced stages of dementia. Whilst there are a range of approaches used in the mild to moderate stages of dementia, such as Cognitive Stimulation Therapy, 'Singing for the Brain' and social activities, there was no appropriate intervention available at that time that addressed the needs of people living with advanced dementia. Namaste Care was therefore designed to be a very simple, gentle sensory approach to spending time with someone in the late stages of dementia that meets their needs for safety, relaxation and connection. The Namaste Care approach is now practiced across 14 countries, with a community of practice organised by Namaste Care International.

The word 'Namaste' is a Hindu word which Joyce Simard found out meant 'to honour the spirit within.' She thought that this captured her intention for the intervention, which was to help people in the late stages of dementia to express their identity, live with quality and enjoyment in their lives and to promote human connection. The word Namaste has many deeper and more complex meaning, one being that 'the spirit in me honours the spirit in you.' This sense of equality can potentially break down the barrier of care professional – person who needs care, to more of a sense of 2 people spending time together.

A brief outline of a typical Namaste Care session could include:

- Knowledge of the person's life story and sensory preferences
- A pre-prepared, warm, comfortable, and homely environment.
- A warm, genuine, and personal greeting.
- A check on the person's pain levels and mood.

- Moving them to a comfortable chair (ideally a recliner.)
- Tucking them in with a warm, cosy blanket.
- Soothing music playing, favourite music of the person, or music matched to the sensory theme.
- Use of an aromatherapy room spritz or diffuser to introduce pleasant smells.
- Natural objects in the room, such as flowers and houseplants.
- Encouraging the person to take frequent drinks.
- Focussed one to one attention (in a group, this would mean spending one to one time with one person then moving on.)
- Washing hands, face, feet.
- Hair brushing.
- A hand massage, foot massage, scalp massage.
- Applying face cream, favourite perfumes, or aftershave.
- Gentle passive movements to joints and limbs.
- Honouring the seasons and bringing the outside in.
- Looking at pictures in books or photo albums appropriate to the person's interests.
- Exploring tactile objects and objects related to memories.
- Realistic animals and dolls available as a choice to interact with.
- Reading to the person.
- Sharing a snack that the person would consider a treat.

List adapted from Kendall, 2021.

Namaste Care was originally developed to be delivered in a care home environment; however, it has proved to be a flexible approach and has been delivered in the community by St Joseph's Hospice, Hackney, and St Cuthbert's Hospice, Durham. It has now been introduced to hospital inpatient wards (e.g. St John and Koffman, 2017.)

Any activities offered during the session are based on people's life history, preferences, likes and dislikes, so can be adapted to the person and mean that no two sessions are identical. This makes researching the effects of Namaste Care more difficult, as it is impossible to deliver standardised sessions.

In sharing Namaste Care time with individuals, they can be witnessed speaking or smiling for the first time in months. They can be seen joining in with songs and poetry when it was thought that verbal skills were lost. There have been numerous reports of the person with dementia giving a hand massage in return when they have received a hand massage. Namaste Caregivers report improved eye contact, improved appetite and

hydration levels, people looking less anxious and the alertness and engagement that a session evokes often lasts for the rest of the day.

Namaste Caregivers recount memorable 'magic moments' spent with the person they visited. These magic moments were difficult for them to put into words but had felt incredibly special.

Case example: A magic moment captured.

Florence had advanced Parkinson's Dementia. She had been bed-bound and unable to speak for the past year. When I visited, she always looked anxious and worried about her husband, her eyes following him round the room as if aware that he was stressed with caring for her. When her husband left us to have some time together, I played her favourite music and talked softly to her, not expecting any reply. I took her favourite flowers, which were roses, and to add to the rose experience, also added a spray of rose scent to her pillow. Florence turned her head slightly to me with a smile and said clearly "Oooo that's nice." Her husband, who was passing the door as this happened was reduced to tears. "I can't remember the last time I heard her voice or saw her smile" he said. He also looked forward to the sessions as a small form of respite from his caring duties, and due to his desire for his wife to have some 'girlie time.'

She seemed to benefit from the massages I gave her which provided some relief to her tight muscle contractures and improved her skin integrity. She looked less worried by the end of the session. Her husband felt he had someone to check in with if he noticed any changes that were concerning him, and the visits gave him some 'time out' from his caring role.

I visited Florence for two years, having many more magic moments with her until she finally passed away. I was with her right up until half an hour before she died.

Details changed to protect the identity of the individual.

So how can we begin to quantify all the qualitative observations that have been made about Namaste Care and attempt to understand them? How can we enable people living with dementia to give us direct feedback about an intervention when they are unable to verbalise their opinions?

Giving people living with dementia a voice

A key theme in this study is to move away from observation-only research and attempt to involve the person living with dementia as research participant as opposed to merely a subject of research. When thinking about participation in dementia studies, Alzheimer's Research UK points out that:

"Translating academic research into interventions that benefit people with dementia relies on the involvement of people in research. Potential diagnostic tools, preventions and treatments must be tested in clinical trials before they can be approved for public use……The recruitment of people with dementia and their carers for research and clinical trials is therefore vital in ensuring that promising research is focused on the people who will benefit from treatment."

Surveys show that 89% of the UK public would want to take part in clinical research if they were diagnosed with a medical condition or disease. Locally, within Tees, Esk and Wear Valley NHS Trust, patients are being asked at diagnosis if they would be willing to engage in research studies which will provide a clear guide for future research regarding consent as dementia progresses. However, for this study those people who have already indicated willingness will not be in the advanced stages of their condition, and so it will be crucial to feel my way around consent issues and ethical considerations very carefully. Indeed, phase one of the study will focus in on this crucial area.

Strohmeir and Camic, (2017) demonstrated the ability to verbally interview and gain feedback from people in the *earlier stages of dementia* but also flag the absence of direct research on the experiences of people in the *later stages of dementia* who are unable to give that same verbal feedback. Information on the later stages of dementia tends to rely on observational feedback, mainly from caregivers (Mitchell et al, 2009, Kendall, 2019). As Mitchell et al (2009) noted "Despite the growing number of persons with advanced dementia, and the need to improve the end-of-life care, few studies have addressed this important topic."

It will therefore be vital to consider the literature relating to ethics, rights and social justice for people with dementia to inform this study, and gain feedback directly from people with lived experience of dementia to guide research design. The Alzheimer's Society have developed and recently refreshed 'The Dementia Statements and Rights' in consultation with people living with dementia and their families. The statements are grounded in human rights law and are enshrined in the Equality Act, Mental Capacity Legislation, International Human Rights law and health and care legislation. The fourth and fifth dementia statement are most relevant to this study. The fourth states that people with dementia have a right to be respected as partners in care and to receive education, support, services, and training to enable them to make decisions and plans about their care. The fifth states that people with dementia have a right to be involved in research which looks at cause, cure and care for dementia and be supported to take part.

Lepore et al, (2017,) asserted that researchers can maintain the ethical principles of justice, beneficence and respect by assessing the risks and benefits of participation in the research, securing informed consent from proxy-decision makers, but most importantly for this study, that assent is gained from the individual living with dementia. *Assent* can be defined as "an affirmative agreement to participate as expressed verbally (ie. orally) or a non-verbal indication of willingness to cooperate with study procedures, both at the time of enrolment and over the course of the study." (Black et al, 2010.) Berghmans and Ter Meulen (1995) discuss the possibility of involving participants with dementia who are unable to give informed consent by being "very sensitive to verbal and non-verbal signs and signals so that if a participant shows symptoms of distress, then they should be immediately withdrawn from the investigation. Using this approach, researchers can use 'behavioural consent' to monitor continuously a person's willingness to be included in the research." (Berghmans and Ter Meulen, 2002.

1.2 Literature Review

Namaste Care™ (Simard, 2013) provides a potential framework to offer a nonpharmacological, psycho-social, sensory, and relational intervention which could improve the wellbeing of people living with advanced dementia (and potentially other life limiting conditions, such as Parkinson's disease and Cancer.) Research into the benefits of Namaste Care is growing, however it has mainly focussed on Namaste Care in a residential care setting.

Joyce Simard's book, published in 2013, focussed entirely on introducing Namaste Care to a care home environment, although in her updated edition published in 2023, she has included examples of community and hospital-based projects.

In the care home setting, her aim was to offer Namaste Care for two hours in the morning and two hours in the afternoon, seven days per week. Testing out the newly developed Namaste Care programme in a small nursing home in Bennington, Vermont, meant that Simard was well placed to gather data to measure the outcomes from the introduction of the intervention. The research she carried out showed that Namaste Care delivered in a care home setting leads to a reduction in the number of falls, a reduction in urine and chest infections, decreased levels of resident agitation and a decrease in the use of anti-psychotic medication for behavioural symptoms.

The reduction in chest and urine infections could be explained by the focus during Namaste Care sessions of increasing fluid intake and thereby addressing the tendency for people living with dementia to be dehydrated and so prone to such infections. A reduction in the number of falls could be due to residents

being more meaningfully occupied and not wandering. It is perhaps more complex to explain why Namaste Care leads to decreased agitation in recipients. It may be due to an effect on mood and a decrease in feelings of stress and anxiety often described by people living with dementia, but this area warrants further investigation.

The reduction in the use of anti-psychotic medication appeared significant, and so this was examined in more detail by Volicer (2013). In this study offering Namaste Care as an intervention over a 6-month period led to a gradual decrease in the use of anti-psychotic and hypnotic medication such as Quetiapine and Zopiclone. The difficulty with this study however is the small participant group (n=9) and the fact that the change could have been explained by the fact that the study led directly to the medical team reviewing the need for these medications. Some of the research subjects had received anti-psychotic medication for several years without their need for the medication being re-evaluated.

The effect of Namaste Care on behavioural symptoms of dementia was examined by Stacpoole etc al (2014 and 2015) across 5 dementia care homes in South London. Inclusion criteria was a diagnosis of dementia and a Bedford Alzheimer's Nursing Severity Score of >16. Measures used during the study were the Neuropsychiatric Inventory Nursing Homes (NPI-NH) and the Doloplus-II pain behavioural assessment observational scale. They recorded measures at baseline and at 1–2-month intervals after the commencement of Namaste Care. The severity of behavioural symptoms, pain levels and 'occupational disruptiveness' decreased across 4 of the care homes. Increased levels of behavioural distress noted in one care was explained by the researchers as due to poor pain management as evidenced by the higher pain scores and disruptions to management leading to effects on inadequate staffing levels and quality of care. In relation to this study, it should be noted that Min Stacpoole, the lead researcher is a nurse, and that NPI-NH is widely used in healthcare rather than social care. It is not suitable for use as a measure by untrained researchers. A further caution around this study was linking quality of life and a reduction in neuropsychiatric symptoms which were evaluated subjectively by observers. However, of note is that this study also saw evidence of a reductions in the number of infections and falls, like Simard's findings, and staff reported that residents had gained weight since engaging with Namaste Care, possibly due to the care taken to encourage residents to eat and drink during sessions.

Manzar and Volicer, 2015, sought to evaluate the effects of Namaste Care in a pilot study where quality of life was measured over time using the Quality of Life in Late-Stage dementia scale (QUALID.) This measure is used over a 1-week window and looks at observable behaviours which can be rated on a 5-point scale. Pain levels were measured using PAINAD, an observational measure of pain indicators. Qualitative evaluations consisted of questionnaires given out the staff and family members. The study concluded that Namaste Care decreased agitation, improved appetite, reduced pain, reduced residents' rejection of care, improved

engagement, tolerance of touch and communication levels. Amongst family, they found visits to be more enjoyable, interactions with their loved one improved and they seemed more at peace. Feedback from staff members was that they experienced greater job satisfaction and that it made care tasks easier. This study therefore points to a ripple effect of the benefits of Namaste Care, beyond the intended recipient. The difficulty with the use of QUALID as a measure however is that it is intended for use over extended periods and not to measure the outcome across one single Namaste Care session.

In 2017, Stacpoole et al. built on this theme by further exploring the perceptions of families and staff towards Namaste Care in UK care homes. Feedback from both families and staff was that Namaste Care was an antidote to the frequent feeling of chaos, confusion, and hurry in busy care homes, which often leads to resident distress. Again, staff identified Namaste Care as rewarding and leading to improved job satisfaction. One theme discussed was the 'calmness' that Namaste Care provides, and the positive effect that this has on residents, staff, and family. Another key theme was the way Namaste Care encourages connection and shared humanity, leading to relational, person-centred care. The importance of non-functional, caring touch was also noted by respondents. Ultimately, staff and families perceived a greater sense of wellbeing in the residents who had received regular Namaste Care.

A US study (McNeil and Westphal, 2018) used qualitative methods to explore the experiences of care home residents, staff and families who had been involved in a Namaste Care programme. The findings suggested that Namaste Care was suitable for residents who were no longer able to join in with traditional care home activities. They identified six key themes arising from the data; peaceful sanctuary, relating their way, transforming experiences, connections and community, positive moments, and awakened to possibilities. Within the literature we are now therefore seeing commonalities in people's perception of the intervention.

A realist review of Namaste Care (Bunn et al, 2018) added to the growing evidence that Namaste Care seems to trigger feelings of familiarity, reassurance, engagement, and connection for residents and for staff, beginning to hint at mechanisms of how Namaste Care might work to improve quality of life and wellbeing and reduce agitation.

As with many interventions that are developed out of practice and experience, Namaste Care was implemented without clear evidence of effect or without being fully described in terms of an intervention specification. The Medical Research Council guidance Hoffman et al, 2014) advocates for interventions to be fully described so that they can be replicated under research conditions. A feasibility study (Walshe et al, 2019) acknowledged this lack of evidence and set out to refine a specification for Namaste Care in preparation for a feasibility randomised control trial. The study employed a four-stage process to collate existing information into a draft intervention description, explore the usability of the description for those

not familiar with Namaste Care, refine and prioritise Namaste Care materials and then finally to engage in patient and public involvement to refine the materials. The outcome was a sixteen-page booklet with accompanying infographics and a supporting package of training. Consideration would therefore need to be given to a standardised approach to Namaste Care sessions delivered as part of the current study. The approach taken by Walshe et al. also highlights the importance of obtaining evidence to support practice and they acknowledge that any research that determines effect could lead to an adaptation of this agreed practice approach.

A Canadian study (Kaasalainen et al, 2020) used a mixed-method survey to evaluate the Namaste Care programme being delivered in two nursing homes. Looking at pain, quality of life and costs of medication as indicators across 31 care home residents and conducting qualitative interviews to gain views from staff and family about acceptability of the programme, led to an overall picture of satisfaction with the intervention. Participation rates across 5 days of sessions were at 89%. Pain levels observed using the PACSLAC-II score decreased, quality of life measured using the QUALID score improved, and medication costs decreased in comparison to the costing of one month before the Namaste Care intervention. The small sample size provided limited power to produce statistically significant outcomes but again acts as a positive pointer to the positive potential of the Namaste Care intervention to improve the lives of people living with dementia.

Further in-depth studies using qualitative approaches through focus groups and interviews have concluded that Namaste Care improves quality of life for care home residents. For example, Brooker et al, 2019, conducted a 3-year qualitative study into the effects of Namaste Care, producing care home guidance and an information film called 'Seeing is Believing.'

There are only three studies of the use of Namaste Care in a community setting (Dalkin et al, 2019 and Yous, 2020, and Haaksma et al, 2022.) A realist study (Dalkin et al, 2019) concluded that Namaste Care provides personalised and holistic care that improves engagement, provides respite for carers, creates a special relationship between Namaste Caregiver and recipient, and reduces social isolation. The second study focused on training caregivers and measured their quality of life (Yous, 2020.) This study reinforces the need to involve caregivers in developing training interventions.

In the UK/Dutch qualitative study by Haaksma et al, 2022, the team examined the feasibility, experiences, facilitators, and barriers to the delivery of Namaste Care into people's own homes. Results of the study showed that the Namaste Care intervention was feasible to deliver in the community with no major adaptations. They also found that Namaste Care improved the mood of the person living with dementia, as well as showing increased interaction and a calming effect. The researchers concluded that key to the success of the intervention is well-matched, flexible Namaste caregivers. They advocated for multiple sessions of per

week of 1.5 to 2 hours duration to improve quality of life most effectively. Family involvement was encouraged but should be considered in the context of the high carer burden which was uncovered and the frequent strained relationship between family carer and person living with dementia.

Finally, thinking about implementation in more clinical settings, a study of the use of Namaste Care in a hospital setting (St John and Koffman, 2017) concluded that the approach has the potential to improve quality of care for people with advanced dementia in acute hospital care.

All studies on Namaste Care across the various settings have one thing in common, which is that although the person living with dementia is a research subject as a recipient of the Namaste Care intervention, no researchers sought direct feedback from the patient themselves, but instead consulted staff, volunteers, and carers to gain observational data. Again, this reflects the challenges, which are acknowledged in the wider dementia literature, of involving people with dementia, and especially those with advanced dementia when verbal communication skills are being lost and cognitive impairment advancing, in research about care and services.

In early 2024, University College Cork launched their In-Touch Project Funded by a large 5-year Horizon Europe grant and involving an international consortium of 13 partners. The aim of the project is to transform dementia care, prioritising comfort and compassionate support. They will explore the use of Namaste Care in contrast to standard care in a randomised control trial across 56 care homes across 7 countries. The In-Touch team sought guidance directly from this PhD study in deciding on effective and accessible measurement tools for their project.

Comparison with other non-pharmacological interventions

One approach to building the evidence base for Namaste Care could be to examine the research regarding individual components of Namaste Care or other non-pharmacological interventions. As interest in non-pharmacological interventions for people living with dementia has grown, more recent systematic reviews, meta-analyses, and network meta-analyses have provided a richer empirical basis for evaluating the relative strengths, mechanisms of action, and limitations of a variety of psychosocial, sensory, art-based, and relational interventions. To situate Namaste Care more precisely in this landscape, it can be critically compared to evidence for other interventions, especially art and music interventions, sensory stimulation, reminiscence, exercise, and combined interventions. The literature tends to examine outcome domains such as behavioural and psychological symptoms of dementia (BPSD), cognitive function, quality of life, pain and distress, emotional wellbeing, and the durability and feasibility of effects.

Evidence from Recent Reviews: General Non-pharmacological Interventions

A central recent contribution is the rapid review of other systematic reviews by Whear et al (2019), which examined findings from non-pharmacological interventions delivered in residential care settings for people with dementia. They found strongest evidence for music, sensory stimulation, simulated presence, and validation therapies in reducing reactive behaviours. For maintaining or improving activities of daily living they found exercise and light therapy, cognitive stimulation and reminiscence improved cognition. Emotional disorders such as anxiety and depression showed the strongest improvement with music, psychological interventions, and reminiscence. However, the other authors noted wide heterogeneity in such study designs and quality and identified a need for longer-term follow-up. (Meyer and O'Keefe, 2020.)

"An overview of systematic reviews…" (Rosenberg et al., 2024) similarly concludes that non-pharmacological approaches have effect sizes for global BPSD that are *comparable* to pharmacological approaches, but with considerably fewer adverse effects. In that overview, music therapy (a central component of a Namaste Care session) emerges prominently for improving global BPSD.

For pain management, which is a domain often overlapping with distress, there is growing evidence that non-pharmacological interventions can be effective. One systematic review (Liao et al, 2021) of 11 articles (12 interventions) involving 486 participants living with dementia found that interventions such as auricular acupressure, music therapy, reflexology, painting/mark making and singing, cognitive behavioural therapy, play activity sessions, and person-centred environment design showed positive impacts on pain. Painting and singing are creative, strengths-based and expressive interventions that overlap with sensory and relational types of intervention such as Namaste Care.

Evidence from Art-Based Interventions

Art-based interventions (visual arts, painting, art appreciation, museum visits, etc.) have been increasingly studied in recent years. A systematic review 'Creative Art Therapy as a Non-Pharmacological Intervention for Dementia' (Emblad & Mukaetova-Ladinska, 2021) examined 17 studies (2015–2020), with 853 participants, and found that 88% (15/17) reported at least one significant positive outcome in domains such as wellbeing, quality of life, BPSD, or cognition. However, only 17% of those 17 studies demonstrated significant outcomes across all three domains of quality of life, wellbeing, and BPSD. The authors conclude that art therapy can benefit people living with dementia, especially when interventions incorporate being "in the moment" and are person-centred, a significantly similar comparison to Namaste Care.

In another recent and comprehensive assessment, 'Comparative Efficacy of Various Art Therapies for Patients with Dementia: A Network Meta-analysis' (Frontiers, 2023) assessed 39 randomized controlled trials (2,801 participants) involving six types of art therapies: music therapy, reading therapy, painting therapy, horticultural therapy, reminiscence therapy, and calligraphy therapy. It found that calligraphy therapy and reminiscence therapy produced statistically significant improvements in cognitive function compared with traditional dementia care, and horticultural therapy was particularly effective at reducing agitation behaviour compared with music therapy, reading therapy, and reminiscence. Quality of life effects were more variable, with fewer trials and smaller sample sizes.

The literature therefore indicates that art-based interventions are efficacious in several areas: cognition, agitation or behaviour, emotional wellbeing, and sometimes quality of life. However, the size of effects tends to vary, and methodological features (duration, intensity, facilitator skill, active vs passive engagement) moderate the outcomes reported. They are also more applicable to people in the mild to moderate stages of dementia as compared to namaste Care, which is for people in the later stages of dementia.

Sensory, Multisensory, and Relational Interventions

Beyond pure art-based or music interventions, there is evidence for sensory stimulation, multisensory environments, massage/touch, aromatherapy, etc., which often share activities used within Namaste Care. For example:

Sensory stimulation: A rapid review noted sensory stimulation was among the top interventions for improving reactive behaviours. (Meyer and O'Keefe, 2020.)

Massage and touch: Systematic reviews suggest that hand massage and gentle touch may reduce agitation or distress in dementia patients. For example, the 2011 evidence review by the U.S. Department of Veterans Affairs found small, randomised control trials where hand massage was combined with calming music or touch plus verbal interaction showed reduced agitation relative to control or baseline. (O'Neill et al, 2011.)

Aromatherapy & light therapy: Some positive findings show the potential for improving sleep or reducing nighttime agitation, although the evidence is mixed, and effect sizes are small or inconsistent. (O'Neil et al, 2011, Ball et al, 2020, Ting et al, 2023.)

Simulated Presence therapy, (Abraha, 2017) and Validation Therapy, (Feill, 1993,) (the latter which inspired Joyce Simard's approach in developing Namaste Care) are relational, sensory and emotional in nature and here evidence is more mixed. For instance, simulated presence (where audio or video recordings of loved

ones is shared with the person living with dementia) shows inconsistent results in reducing BPSD. Validation therapy (acknowledging emotion and connecting through mirroring) has some indications of benefit for depression and emotional states but overall insufficient high-quality evidence is available to draw strong conclusions. (O'Neill et al, 2011.)

Exercise and physical activity also emerge both in general non-pharmacological reviews and in pain-management and emotional wellbeing domains. Exercise can help maintain or improve activities of daily living and may contribute to mood regulation. However, its applicability for people in very advanced dementia (who are bed- or chair-bound, with loss of mobility) is naturally more limited. (Meyer and O'Keefe, 2020.)

What Namaste Care Offers & How It Compares

Having reviewed the evidence for other interventions, it becomes clearer how Namaste Care maps onto, combines, and in some respects extends what is known, particularly for people with late-stage dementia. Key comparative points are:

Intervention complexity and integration

Namaste Care is not a single modality but a multi-sensory relational programme, combining sensory stimuli (touch, smell, music, lighting, taste,) relational care (presence, gentle communication), comfort, and structured routine. Many arts or music-based interventions focus just on that modality (visual arts, singing, etc.), with limited additional orienting sensory or environmental components. Namaste Care's integration allows for applicability even when cognitive or physical impairments make active participation in arts or exercise more difficult, as in the later stages of dementia. The Dementia and Imagination Research Project, (Windle et al, 2016,) does provide a more integrated view of people living with dementia and the arts, highlighting the importance of relational, sensory and 'in the moment' delivery to encourage people living with a dementia to continue to express themselves. There does therefore appear to be a growing understanding of the need for sensory elements and relational care in all dementia interventions.

Stage of dementia & capacity for active participation

Evidence for art therapy, horticultural therapy, painting, calligraphy etc., tends to involve people with mild to moderate dementia (who can actively engage). For example, in the network meta-analyses previously described, many of the studies of painting or horticultural require physical mobility, attention, ability to follow the tasks. Namaste Care is explicitly designed for those in advanced dementia, including those with

limited verbal or cognitive capacity. Thus, some of art-based interventions benefits are less accessible here, whereas Namaste Care may still deliver benefits through passive sensory, touch, relational presence. This is a critical difference in mechanisms and populations.

Outcomes: Where Namaste Care aligns or diverges

Behavioural/psychological symptoms (agitation, distress, anxiety, hallucinations): Like music therapy and sensory stimulation, Namaste Care shows consistent reports in qualitative studies of reductions in agitation and distress (e.g., Stacpoole et al., 2014; Bunn et al., 2018). These align with findings for massage, music, horticultural therapy, etc.

Cognition: Art-based therapies (especially reminiscence, calligraphy) show improvements in cognitive domains in randomised control trials (RCTs.) Namaste Care's contribution to cognition is less well studied, especially in advanced dementia; cognitive improvement may be less achievable at that stage. However, there is anecdotal evidence in the improvement in cognition throughout the sessions, hypothesised to be due to promoting increased hydration. This is something I have witnessed for myself in delivering Namaste Care sessions.

Quality of life, wellbeing, emotional state: Art and music therapies often report significant improvements in wellbeing, mood, emotional state, and quality of life. Namaste Care also reports improved mood, reduced pain, improved acceptability of care, but fewer rigorous measures of broader quality of life or wellbeing exist to validate these reported improvements.

Mechanisms of effect

Many non-pharmacological interventions share probable or partially uncovered mechanisms of action: sensory stimulation (touch, music, smell) may modulate arousal and activate the parasympathetic nervous system; relational care supports attachment and reduces social isolation; art and music may evoke memories, identity, meaningfulness; regular routines and comfort reduce unpredictability, which in turn reduces anxiety and distress. Namaste Care encompasses most of these: sensory comfort, touch, presence/relationship, routine. Thus, the model likely draws on multiple mechanisms, which may produce more robust or more resilient effects across different domains or in more severe dementia stages than some single-modality interventions.

Duration, intensity, and feasibility

One limitation of many art-based studies is the short duration (often several weeks), small sample sizes, few follow-ups, and therefore limited power. A meta-analysis (Liu et al, 2023) noted that many art therapy studies had small participant numbers, short follow-ups, and sometimes active versus passive engagement wasn't standardised.

Namaste Care studies often report feasibility and acceptability, and some evidence of sustained improvement over multiple weeks or months, especially when adopted as part of care home routine. However, rigorous RCTs absent; many studies are qualitative, mixed-methods, or service evaluations rather than large, randomised trials. Implementation fidelity, staff training, resource costs are also reported as challenges to the study of Namaste Care in practice settings.

Critical reflection on comparative literature

Drawing the comparison with other types of evaluation of non-pharmacological intervention yields both confirming strengths of Namaste Care and gaps that parallel those in other interventions.

Strengths

Namaste Care's multi-modality and relational basis align well with evidence showing that interventions addressing multiple sensory, emotional, relational, and environmental needs tend to have broader effects (e.g., in emotion, behaviour, distress). Its explicit design for late-stage dementia addresses a population often underrepresented in art-therapy RCTs. It also tends to embed interventions into daily care routines, which may enhance feasibility, validity, and acceptability.

Evidence Gaps

1. **Randomised Control Trial (RCT) evidence**: While many art-based interventions and music therapy have multiple RCTs, although often small and heterogeneous, Namaste Care has no high-powered RCTs especially in late-stage dementia with follow-ups for long-term outcomes.
2. **Mechanistic clarity**: For art and music therapies, there is increasing work (as in network meta-analysis) to identify which types (e.g. calligraphy, horticultural, art viewing) are best for which outcomes. For Namaste Care, although qualitative studies often report themes of comfort, relationship and presence, less is known about neurobiological or physiological correlates (e.g. stress hormone reduction, brain activation) especially in advanced dementia.

3. **Quality of life & sustained impact**: Many art therapy studies show improvements in mood and well-being, but long-term effects (beyond the intervention period) are under-studied. Similarly, for Namaste Care, sustaining benefit, and preventing decline or worsening of behavioural and psychological symptoms of dementia over time is less well reported.

Feasibility, training, cost, scalability

Single-modality interventions like art classes and music, may require less structural change to deliver but may not reach those with limited capacity. Namaste Care demands resource input: staff training in relational presence, sensory provision (aromatherapy, tactile items, etc.), timing, consistent delivery. Some of the art interventions also require trained art therapists or museum partnerships, which may limit scalability. Although the review by Emblad & Mukaetova-Ladinska (2021) noted that art therapy sessions need not always be led by licensed therapists meaning that unstructured or staff-led creative activities could have benefit, though possibly smaller effect sizes.

Implications of the comparative literature

Drawing on the comparative evidence, Namaste Care appears especially valuable (or even uniquely beneficial) under some conditions:

Late or advanced dementia: When cognition, verbal communication, and physical mobility are severely limited, many art-based modalities become less feasible. Namaste Care's design with passive sensory input (touch, aroma, music) and relational presence can still provide meaningful comfort, reduce distress, and maintain connection.

Integrated sensory and relational needs: Individuals who not only experience behavioural symptoms but also pain, distress, social withdrawal, or rejection of care may benefit more from a program that addresses multiple senses and fosters relational attunement in the way that Namaste Care explicitly does.

Need for reducing medication use / managing BPSD non-pharmacologically: Given the comparable effect sizes of non-pharmacological interventions vs pharmacological (but safer profiles) in several reviews (e.g., global BPSD effects for music therapy and others; Rosenberg et al., 2024), Namaste Care may serve as a model to reduce reliance on medication, especially for those still living at home, those in care homes, hospital wards or in hospice settings.

Quality of life and emotional well-being in addition to symptom control: While many art and music therapies show improvements in mood, identity expression and satisfaction, Namaste Care may offer

additional benefit in comfort, dignity, human connection, possibly pain relief and reduction of distress associated with care and daily discomforts.

Limitations and evidence gaps

To provide a balanced view, the following limitations and gaps emerge from the literature:

1. **Heterogeneity of studies and outcomes**: Across art, music, sensory, and Namaste Care studies, there is wide variation in intervention duration, intensity, facilitator training, outcome measures, and methods of measurement (such as self-report, proxy, or observational). These variations make cross-study comparisons difficult, and meta-analysis often shows wide confidence intervals or risk of bias.
2. **Short follow-ups and maintenance of effect**: Many art-based studies and music-based ones show benefits during the intervention period, but evidence of longer-term effects (several months post-intervention) is sparse. Namaste Care likewise has fewer studies tracking outcomes beyond the immediate or short term.
3. **Sample sizes and methodological rigour**: Especially for advanced dementia, many studies are small, have no control or weak control condition, lack blinding or randomization, or use only qualitative rather than quantitative outcome measures.
4. **Measurement challenges**: Measuring quality of life, wellbeing, pain and distress in advanced dementia is inherently difficult: self-report is often not possible; proxy measures may be biased; observational measures require careful design; standard scales may not be sensitive to small but meaningful changes. This points to the need for an objective means of measurement.
5. **Implementation issues**: Staff training, cost, resource availability (spaces, materials, time), cultural adaptation, fidelity and consistency of intervention delivery, and the ability to adapt to individual preferences are common challenges across all intervention types. For Namaste Care, setting up sensory resources, consistent staffing, and integrating into routine care are demanding.
6. **Isolating mechanisms**: Because many interventions are multi-modal (e.g. Namaste Care, music + reminiscence, etc.), it is hard to determine which components drive specific effects. For example, is it the touch, the scent, the presence, or the music that alleviates agitation most? To refine practice, and make recommendations, better understanding is needed.

The place of Namaste Care within the wider literature

From comparing Namaste Care to art-based and other interventions, several observations can be made:

- Namaste Care can be conceptualised as a supra-modal intervention that brings together features of sensory stimulation (touch, sound, scent), relational care, routine, relaxation, comfort, and presence. This distinguishes it from single-modality art or music therapies, giving it potential advantages for those with severe impairment.
- Effect sizes in art and music therapies for certain outcomes (mood, agitation) are often moderate, especially in mild-to-moderate dementia, but tend to lessen or become harder to detect as cognitive decline deepens. Namaste Care has fewer studies in mild/moderate, but appears more appropriate for late stage, so there is fewer comparative data in that population; still, qualitative and mixed evidence suggests maintained benefits.
- There is evidence that some art therapies (calligraphy, horticultural therapy) may outperform music therapy for some behavioural symptoms (e.g. agitation), but these may not be accessible or acceptable to people with advanced physical or sensory limitations. Namaste Care may not outperform in those specific symptom domains where active participation (as in calligraphy requiring fine motor skill) is required but may offer broader comfort across many symptom domains for more impaired individuals.
- In terms of quality of life and wellbeing, art and music interventions show consistent benefit; Namaste Care also does, but measurement has often been indirect (e.g. observation, staff or family reports) rather than standard scales. There is a need for studies using validated wellbeing/QOL instruments in Namaste Care, perhaps adapted for very severe dementia.
- For pain and distress, art & music interventions show promise; Namaste Care often includes comfort and touch, which may relieve pain or discomfort, yet studies quantifying analgesic effect (or changes in pain-related physiological stress) are relatively rare. Comparative studies in this domain would be valuable.

In summary, the evidence from recent reviews confirms that multiple non-pharmacological interventions — art-based therapies, music therapy, sensory stimulation, exercise, reminiscence — have demonstrable effects in reducing BPSD, enhancing mood and wellbeing, sometimes preserving or improving certain cognitive and functional domains. Namaste Care, as a composite intervention, seems particularly well suited to people with late-stage dementia, incorporating multiple modalities to offer comfort, relational presence, sensory stimulation, and routine.

While Namaste Care aligns with many of the mechanisms identified in art and sensory therapies, existing evidence remains less rigorous in terms of large RCTs, standardised measures, long-term outcomes, and clear identification of which components are most effective. To strengthen its evidential base and compare

directly with other interventions, further high-quality research is needed and the means to evaluate Namaste Care beyond pure observational feedback is identified.

Taken together, the literature supports the position that Namaste Care is likely to offer unique and additive benefits, especially for populations where single-modality, active interventions are less feasible. It fills a gap in the continuum of care, extending the reach of non-pharmacological interventions into advanced dementia, and arguably offering better holistic coverage (sensory + relational + environmental + comfort) than many isolated art or music activity programmes.

QUALITY OF LIFE AND WELLBEING- Measuring the subjective

Given the fact that quality of life and wellbeing are often used interchangeably in research, consultation activities in phase 1 of this study needed to explore these terms to arrive at a decision about the focus of what is most effective to try to measure in terms of an outcome for a Namaste Care intervention.

Use of observational measures in dementia care

With no cure for dementia on the horizon and treatments still in development, promoting wellbeing and quality of life in people living with dementia is a key driver in health and social care services (Algar et al 2016, Ammaturo et al, 2017, Madso et al, 2021.) In many populations, including in the early stages of dementia, self-report is regarded as the most appropriate and accurate measure of wellbeing (Ferring and Boll, 2010.)

Measuring wellbeing and quality of life outcomes in the case of people living with advanced dementia who are losing their verbal skills and have impaired cognition is however especially problematic. Whether within statutory services or in the case of projects delivered by the voluntary sector, funding often requires outcomes to be measured to show the benefit of the service. However, attempts to engage someone living with advanced dementia to give direct self-report feedback can be extremely difficult, as demonstrated in the following testimony from the former Namaste Support Worker at St Cuthbert's Hospice, Durham.

"*Outcome measures for the Men's Potting Shed Group*

The men's potting shed group consisted of five men all living with advanced dementia, engaging in gardening themed tasks both outside and in a Greenhouse setting.

The men were all different regarding their dementia diagnosis, age, physical and cognitive ability and communication skills.

Staff and volunteers normally gauged outcome measures by using good observation and listening skills. This helped us to get to know the patient; by looking for signs of contentment, calmness, relaxed body language, engagement or whether the men were anxious, unsettled, withdrawing or agitated. This information along with feedback from family members helped us to determine whether the men were happy and if the group was meeting their needs and having a positive impact on their wellbeing.

Under the direction of the Admiral Nurse, we were asked to use a selection of pictures depicting happy or sad faces to see if the men could communicate if they had enjoyed attending the group.

The men were shown the pictures and calmly asked, "Have you enjoyed your day?"

All of the men appeared confused by the pictures of the faces, and none answered the question by pointing to a picture or symbol.

Some of the men responded by becoming agitated and showed signs that they were confused and unhappy.

It's my opinion that the men, due to the advancement in their dementia, memory and attention span, found the pictures and questions stressful, which lead them to feel like they had failed in some way.

As the focus of the group was primarily on making the men feel good about themselves by feeling valued, giving them a sense of achievement and enjoyment, I decided not to use this outcome measure technique again, as it failed to meet the values of the group or be fit for purpose."

Bev Cooke, 2020 (with permission.)

This demonstrates the problem that relying on self-report of wellbeing will exclude people with advanced dementia from providing feedback on services and activities and precludes the opportunity for longitudinal study of the disease progression and its' effects on wellbeing (Madso et al, 2021.)

As dementia progresses, wellbeing is most often measured by proxy reporting of family carers or staff members. Unfortunately, proxy reports have been shown to consistently measure wellbeing as being lower compared to self-report (Kolanowski et al, 2007, Ferring and Boll, 2010, Schulz et al, 2013, Madso et al, 2021.) This could be explained in the case of family carers as they may be comparing the person's present state to their previous state and abilities before their dementia diagnosis. This might suggest the need for a neutral observer for the purposes of a proxy report (Madso et al, 2021.)

A further issue which will reflect the reliability of a self-report measure is that of timescale. Retrospective self-reports have been shown to be open to bias (Shiffman et al, 2008) as they are influenced by current

mood. In the case of people living with dementia, this potentially inaccurate retrospective self-report would be compounded by difficulties with communication, attention, conceptual insight, and memory.

Often in the later stages of dementia, there is a move to using observational tools such as QUALID (Quality of life in late-stage dementia- Weiner, 2000.) The QUALID scoring system asks care home staff to select descriptors from categories that best describes a care home resident over the past week. Lower scores represent a higher quality of life. Categories include smiles, appears sad, cries, appears emotionally calm and comfortable, enjoys eating, enjoy interacting or being with others. Within a care home environment, with regular access, potentially daily. to a Namaste Care session, it would be possible to use QUALID to provide observations of wellbeing over time.

In the case of community visits however which may happen only once weekly, QUALID has not proved useful. The Namaste Care 'dose' is much smaller in terms of time. The Namaste Care visitor is not present to observe across the week. Family carers who have been asked by community projects to complete QUALID found it a negative experience and that it added to their carer burden as being yet another task.

In terms of Namaste Care, no specific measure of outcome has been validated to evaluate whether the intervention has improved the wellbeing of the recipient. Various non-validated measures have been developed by individual Namaste Care projects to capture the outcomes for a particular Namaste Care session. St Joseph's Hospice (SJH) in Hackney, London, were the first hospice in the UK to deliver Namaste Care into people's own homes in the community rather than within a care home, and to develop a training package for the volunteers who would deliver the Namaste Care visits. In consultation with their volunteers, they developed a session record aimed at gathering qualitative and quantitative outcome data they could use to evaluate the project and as feedback for their funders (see appendix **A1**- provided by SJH.)

With the aim to capture any change of emotional state from the start of the session to the end, the session record asks the Namaste Caregiver (NCG) to tick which descriptors applied at the beginning and then again at the end of the session for comparison. This has enabled a summary of project outcomes to be generated as follows.

<u>St Joseph's Hospice - Namaste Care East London Project- July 2018- June 2019</u>

Number of service users= 274

Number of sessions delivered by volunteers= 1034

Service user at the start of the session	
Mood and Mobility	**Occurrence (pre)**
Aggressive	10
Anxious	74
Frustrated	30
Confused	87
Engaged	198
Motivated	59
Relaxed	284
Emotional	40
Happy	177
Sad	61
Restless	90
Content	163
Sleepy/tired	232

Table 1 St Jospeh's Hospice record of service user mood

Service user at the end of the session			
Mood and Mobility	**Occurrence (post)**	**Outcome**	**Change***
Aggressive	4	-6	**-60%**
Anxious	83	9	**11%**
Frustrated	17	-13	**-43%**
Confused	48	-39	**-45%**
Engaged	221	23	**11%**
Motivated	86	27	**46%**
Relaxed	493	209	**74%**
Emotional	40	0	**0%**
Happy	340	163	**92%**
Sad	29	-32	**-52%**
Restless	28	-62	**-69%**
Content	422	259	**158%**
Sleepy/tired	249	17	**7%**

* % change between pre and post occurrence

Table 2 St Jospeh's Hospice calculations on mood change during a Namaste Care session

With a group of indicators which could identify positive wellbeing scoring well in this summary (e.g. 158% more content, 92% appearing happy and 74% more relaxed) this has been sufficient evidence to ensure important continuation funding for the project. However, analysis of the results raises several questions, including an apparently contradictory figure of 11% of people being more anxious, in comparison to the score for 'content' or 'relaxed' for example. Another key question is how we are to define each category and ensure that all observers are interpreting what they see in the same way.

The same difficulty was encountered at St Cuthbert's Hospice in Durham. Their community-based Namaste Care Project devised several formats to record the outcome of sessions, with volunteers finding some too time consuming and wanting a quicker and easier checklist format. Some volunteers did not like filling in the form at all, seeing at as not important to them or the person they visited.

Both of these community projects trialled the use of the QUALID measure (Weiner et al, 2000) but found that this was not useful in the case of a progressive illness, where visits were once weekly and therefore the 'dosage' of Namaste Care was much reduced as compared to a care home environment where Namaste Care could be delivered daily and outcomes measured daily by care staff. Therefore, the need for a consistent observational measure which captures the outcome of a Namaste Care intervention in the timeframe of one session would seem to be needed.

A 3-year study carried out by the Association for Dementia Studies at Worcester University (Brooker et al, 2019) resulted in an online toolkit of resources aimed at supporting care homes to implement Namaste Care. The session evaluation form within the toolkit includes a sheet to document activities carried out in the session and some space for narrative, as well as a wellbeing scaling section, asking observers to rate from 1 (poor) to 5 (good) across 3 domains:

1. Physical wellbeing
2. Emotional Wellbeing
3. Awareness/alertness

The observer is asked to rate these domains at the start and end of the session. There is a short explanation of what each domain might include, eg "Physical well-being- This includes anything to do with the person's body and physical sensations eg level of comfort; pain; warmth/cold etc." The form is very user friendly, however could be argued to leave a wide margin for individual interpretation of each domain and therefore lack of consistency across different users.

(See the toolkit at https://eprints.worc.ac.uk/8987/1/Guidance-for-Care-Homes-V3-updated.pdf)

The toolkit also includes a copy of the Pain Assessment in Advanced Dementia Scale (PAINAD) developed by Warden et al, 2003. PAINAD asks observers to score certain observable behaviours which indicate pain and definitions are provided. The scoring system is simple and self-explanatory, and as the observer is being asked to notice a specific behaviour it is much less open to interpretation and therefore more reliable as a consistent measure.

Issues affecting reliability of an observational measure therefore require exploration prior to attempting to develop a new format. Arriving at a manageable group of indicators will obviously need a decision about what to measure. Phase 1 of this study attempts to arrive at a consensus view about important indicators to include. Another issue to consider is whether there is a need for training for users to ensure consistency, or whether the measure can be neutral and specific enough to allow ease of use without training. This would make the measure more user friendly and accessible. What people observe can be influenced by many things, such as observer emotional state, bias and prejudice, expectations of what response they are hoping for, cultural values and so on, leading to the possibility of differences in interpretation of an indicator. For example, if an observer reports that a person is more relaxed by the end of a Namaste Care session, what is it that leads them to say that? Has their breathing slowed, muscle tension reduced, and posture changed, for example? If they are reported as more anxious, are they frowning, has their breathing rate increased, perhaps looking flushed, tense and restless? Simply having an indicator of 'relaxed' or 'anxious' could be too open to interpretation and bias.

Clark et al (2020) conducted a scoping review of outcome measures for wellbeing in people living with dementia. They note that research into psycho-social interventions has often focussed on cognitive function or symptom reduction, and in so doing they fail to capture a full range of psycho-social outcomes, such as humour or autonomy. Their review therefore aimed to take a positive psychology/positive aging approach to develop a more asset/strengths-based framework for measurable outcomes. Searching the literature for key conceptual domains of wellbeing and currently used measures, they discovered only 6 instruments designed specifically for people living with dementia, another 5 from gerontological literature and a further 24 from general wellbeing literature.

Several relevant themes emerged from the Clark study which will need to be considered in planning the phase 1 consultation. Firstly, the Clark study uses the definition of Dodge (2012) which describes wellbeing as "a state of equilibrium existing between personal resources and life challenges that, when achieved, gives rise to positive emotions and psychological health." This highlights the issue that defining wellbeing and quality of life in a meaningful way for people in the advanced stages of dementia and other life limiting conditions who may not be able to express how they feel about personal resources and life challenges requires further exploration.

Another relevant consideration is again, the emphasis on self-report. Clark et al claim that "Self-report measures of wellbeing should be acceptable and easy to complete for the majority of people with dementia." As demonstrated earlier in the chapter, aiming for self-report excludes people with severe cognitive impairment, and therefore work is required to develop reliable observational measures of wellbeing.

The Clark review arrives at a conceptual framework derived from a study of the various measures and wellbeing literature which although relating to self-report, can be analysed in relation to applying the concepts to observational measures of wellbeing to consider whether they would be applicable in late-stage disease. The conceptual framework can be summarised and analysed as follows:

Conceptual Theme (Clark et al, 2020)	**Domain (Clark et al, 2020)**	*Possible to observe in advanced dementia?*
Emotional Wellbeing	**Positive states:** positive affect such as pleasure, enjoyment, contentment, humour.	*Yes: smiles, laughter, eye contact, showing interest.*
Psychological Wellbeing	**Going Beyond:** personal strengths, hope, personal growth, transcending challenges, spirituality and meaning making **Agency and purpose:** continued engagement in meaningful activities, self-determination, autonomy, goals. **Positive sense of self:** positive attitude to self and	*Yes: demonstrating use of a retained skill, positivity in trying things, 'magic moments.' Some aspects could be measured: making simple choices,*

	self-hood, self- esteem, sense or identity and dignity	*choosing to interact. Difficult to measure from observation other than noting the person interacting with some relevant activity related to their life history.*
Social Wellbeing	**Connection and belonging:** love, support, connection, social participation	*Yes: often described as a strong aspect of Namaste Care- mutual warmth and affection.*
Life satisfaction	**Valuing Life:** sense of feeling well and satisfied with life	*Yes: possibly the absence of agitation and distress*

Table 3 Summary of Clark et al, 2020, conceptual framework for wellbeing in people living with dementia.

In an earlier study, Algar et al (2016) also acknowledged the dynamic nature of psychosocial interventions and argued that many existing standardised clinical measures were not good at capturing their effectiveness. 11 observational tools were reviewed in relation to use in capturing wellbeing outcomes for a visual arts intervention. The review concluded that the Greater Cincinnati Chapter Wellbeing Observational Tool (Rentz, 2002) was most effective at capturing an arts-based activity across seven domains: interest, sustained attention, pleasure, negative affect, sadness, self-esteem, and normalcy. This measure can be used to observe up to 3 participants, with observations recorded every 10 minutes during and after the intervention

using an indicator score from 0 (never demonstrates) to 4 (always demonstrates.) However, in another study (Gross et al, 2013) it was found that the Greater Cincinnati Chapter Wellbeing Observational Tool had methodological flaws due to use of different observers during and outside of sessions and inconsistent timing. Frequency of observation and who is doing the observing would also need to be considered in terms of a Namaste Care session where the people living with dementia and NCG may well be alone and so the NCG would be the observer. Ease and lightness of use would again seem important, as well as a clear definition of what is being measured.

A recent study (Turel et al, 2025) examined meaning-based wellbeing, advocating that wellbeing in people living with a dementia goes beyond the management of symptoms and care tasks, and needs to prioritise social connections, dignity and personalised care. The researchers developed a tool to measure wellbeing across 6 domains, the Wellbeing in Dementia Inventory (WiDi.) The Widi tool is validated and has good inter-rater reliability, so would be a potential contender for use in this study. The domains of self-sufficiency, functional mastery, goal-based mastery, purposeful engagement, positive interactions and constructive self-perspective are however more appropriate for the earlier stages of dementia and a more global assessment of wellbeing than could represent the outcome in one Namaste Care session. Moreover, this tool was not available at the time of study design and data collection.

In conclusion to this review of some of the literature relevant to dementia and wellbeing scores, there is a shortage of appropriate measures to capture psycho-social interventions such as Namaste Care when the person living with dementia is not able to self-report, the aim is to capture outcomes of one particular session and furthermore there is a lack of agreement about suitable observational tools for use in advanced dementia. Brooker (2008) suggests that quantitative observational measure data should be complimented with qualitative interviews of participants and practitioners to gain a fuller perspective and understanding of an intervention. This may indicate the need for space to allow for some narrative alongside some user-friendly scoring when developing the observational tool during this study. Arguably, the most important people to consult about the structure of this tool are the people who will use it and those that it matters to. For this reason, the target group for consultation in phase 1 of this study will be care professionals, Namaste Care volunteers, family carers and those living with dementia and other life limiting conditions who are in the mild to moderate stages of disease and therefore able to consent to participate.

It is therefore an objective of this study to devise and test a new observational tool which could be used as a standardised evaluation measure for an individual Namaste Care session. This would need to be user friendly, quick, and easy to score, given the pressures on NHS and social care staff in terms of time and workload.

Use of other potential means to measure quality of life/wellbeing in dementia.

The idea for this current study originally came about after I had read an article which explored the use of essential oils to reduce pre-operative anxiety in gall bladder surgery (Pasyar et al, 2021) and the use of saliva sampling to measure cortisol levels. I wondered if this testing procedure would provide a potential way to explore responses to Namaste Care.

One study by Kovach et al, 2011, looked at diurnal variation of cortisol in people with dementia and the relationship to cognition and illness burden. Saliva was sampled 4 times over a 24-hour period in care home residents, over a 2-week period and at the same times of day. Results showed that in 50% of participants, cortisol levels decreased from morning to evening in a negative slope pattern. However, 38% had a flat cortisol rhythm, potentially suggesting dysregulation in the HPA axis function. Of the participants, 7% exhibited an afternoon increase, which could be an area for future study to explore if this correlates with the phenomenon of 'sundowning' experienced by some people living with dementia. Their study demonstrated evidence of individual variations in the diurnal pattern of cortisol secretion but showed the stability of the pattern in an individual over time. The study therefore highlights the need to establish a normal baseline reading for any individual I collect samples from in this study. I also plan to test groups of people without a diagnosis of dementia, to provide a comparison, as it may be the case that the HPA axis is disrupted in people living with dementia.

Bourne et al, 2019, used saliva sampling alongside self-report visual analogue scales and heart rate variability via wearable sensors to measure outcomes following arts-based activities in people living with mild to moderate dementia in a feasibility study. They acknowledge that the self-report scales would not be possible in the later stages of dementia and so advocate the use of wearable sensors to provide physiological data direct from the patient which would give insight into any reported observations of outcome by caregivers. Despite having difficulties with their saliva samples, they recommend further investigation into the potential window that saliva assays offer into the patient's psychophysiological functioning.

Possible outcomes from this current study therefore could be either the confirmation of usefulness or elimination of the use of saliva assays in the late stages of dementia, as the studies to date were carried out with participants in the mild to moderate stages of dementia. Wearable sensors appear to be a non- intrusive and more widely accepted option, and it may be necessary to explore novel approaches such as facial scanning should the saliva sampling prove to not be acceptable, feasible or effective.

Theoretical approach and inter-disciplinarity

Namaste Care is a seemingly simple sensory activity and yet in practice it is multi layered and relational. To take a reductionist approach to only investigate biological responses to a session, without exploring in a more holistic way the behavioural, psychological, and social interplay that occurs would be doing a disservice to the intervention and to the recipients and caregivers spending Namaste Care time together.

The ideology of a biopsychosocial model of health was first proposed in the 1970's by George Engels as a wider way of thinking about an individual's experience, as opposed to the prevailing biomedical model. "George Engels most enduring contribution was to broaden the scope of the clinician's gaze." (Carrio et al, 2004.) In their paper 'The Biopsychosocial model 25 years later: Principles, Practice and Scientific Enquiry,' Carrio et al proposed pillars of practice which would seem very applicable to this study. These pillars include self-awareness and active cultivation of trust. Researcher reflexivity will therefore be a theme throughout this study, as I move forward as both researcher and Namaste Care caregiver. Building trusting relationships with research participants is vital to all studies, but especially so when there will be issues of mental capacity, consent, and discussions about a progressive illness. An emotional style characterised by empathic curiosity alongside self-calibration to reduce bias are also a guiding principle to adopting this biopsychosocial approach to research.

The nature of this study therefore demands an inter-disciplinary approach to gain a holistic picture of a potentially useful intervention. This will be explored in more detail in chapter 2 and 3. When it comes to thinking about inter-disciplinarity, Klein, 1990, argues that there is no agreed and universal inter-disciplinary methodology. Rather the inter-disciplinary method will be influenced by the purpose of the study, the research questions being addressed, the researchers involved and their allegiances to paradigms. Inter-disciplinary projects list collaborators with their own specialisms all having input into an overall study synthesis. This is an area that has been a struggle throughout my study, given that I cannot embody all the specialisms required for the range of measures I wish to explore. This central struggle will therefore be a developing theme throughout. Indeed, it could be argued that a biopsychosocial model is transdisciplinary in nature, and to achieve this, my study will require an integrated and collaborative approach. Engaging experts by experience and various stakeholder groups will be key to informing the direction and complexion of the study, and I will be tasked with drawing together these strands in a cohesive way, as well as using experts with specialisms I do not possess to adequately treat the quantitative data with the respect it deserves.

RATIONALE FOR THE STUDY

With a key theme of social justice and equality of access, this study will attempt to integrate biological and social sciences to address a widespread health inequality which affects people living with advanced dementia. From initial qualitative studies as discussed, Namaste Care shows potential for responding to the needs of these groups and yet access to Namaste Care is unequal and sporadic across the UK and abroad, as witnessed during my 7 years of developing Namaste Care in the Northeast of England. Evidence of efficacy gained from measuring biological, physiological and behavioural responses will aim to inform the medical profession about this psycho-social intervention and potentially lead to the promotion of the use of Namaste Care across clinical as well as health and social care settings and may promote the inclusion of Namaste Care within National Institute of Clinical Excellence (NICE) guidelines.

Although research into the effectiveness of Namaste Care is growing, it is mainly being conducted in a care home environment where access to Namaste Care is frequent and can be measured over time. In the case of community visits where the visits may be once weekly for 1 to 2 hours, to show effectiveness, then the benefit needs to be measured in the timescale of *one visit*. This will better reflect the flexibility of Namaste Care delivery in an expanding number of settings. This leads to the following summary of aims for the study to achieve.

1.3 OVERALL RESEARCH AIMS

To test ways to objectively measure responses to a Namaste Care session using a range of biological, physiological, and behavioural measures to provide quantitative data for analysis.

a. To involve key stakeholders in the design of the study.
b. To develop an observational measure for Namaste Care to capture outcomes of a single session.
c. Test the use of resting heart rate as a potential measure.
d. Test the use of urinary biomarkers as potential measures.
e. Test the use of facial nasal temperature measures.
f. Test the refined version of an observational tool designed in response to phase 1 consultation and correlate quantitative results to the qualitative data.
g. Share the results with participants and key stakeholders.

The various methods of data collection will be considered for:

- Acceptability of method
- Ease of data collection
- Cost
- Ability to scale up to larger studies

OUTCOMES OF STUDY

a. A process will be tested to enable people living with dementia to give researchers their direct physical feedback about a psycho-social intervention that may benefit them.
b. The Namaste Care Approach has a stronger evidence base.
c. An observational tool is available that has been validated and is available to aid the evaluation of services and individual experience for people living with dementia.

1.4 HYPOTHESIS

1. **Namaste Care induces a relaxation response.**
   a. Resting heart rate expected to *decrease* during Namaste Care.
   b. Cortisol levels expected to *decrease* during Namaste Care.
   c. *Increase* in outcome measure scores.

2. **Namaste Care produces positive mood changes.**
   a. Dopamine levels expected to *increase*.
   b. Facial nasal temperature *changes* in response to Namaste Care will be evident.
   c. *Increase* in outcome measure scores.

Chapter 2

Perspectives on dementia- the rationale for a biopsychosocial approach

Chapter 2: Perspectives on dementia; Rationale for a biopsychosocial approach

2.1 Introduction

If you want to watch a sunrise, you could choose to view it from between two office buildings, or you could choose to climb a hill and view the sunrise in the context of the whole landscape. Similarly, dementia exists in a broad landscape, and I would argue deserves to be viewed with a wide lens. During community visits in my time leading the hospice Namaste Care Project, I was frequently asked if dementia was a modern disease. People would comment that it was never heard of in the past, or that it would be referred to as someone 'going senile.' This confusion and lack of understanding adds to the fear of the unknown that we witnessed families battling with as they tried to support their loved one. Indeed, dementia is still not fully understood as a disease by the medical profession, and research into causes and potential treatments has lagged far behind the advances in cancer treatment. It will be important therefore in this chapter to give this study it's context within a historical, scientific, social and policy landscape, to emphasise why an inter-disciplinary approach is required.

2.2 Historical view

Searching the ancient texts, references can be found to dementia in ancient Greece, Egypt, Byzantium and Rome as far back as 2000 BCE (Papavramidou, 2018, Boller, 1998.) Various terms were used to describe dementia symptoms, such as 'morosis', delirium and 'anoia.' Often seen as a natural consequence of old age, attempts to differentiate causation were made. For example, 'anoia' was believed to be caused be poor nutrition and 'humidity' within the body. Symptoms of dementia were described, including memory loss, poor reasoning, confusion, lethargy and melancholy.

During the second century CE Galen studied the symptoms of dementia and Aretheus of Cappadocia introduced the term 'organic mental disorder.' He was the first to write about a distinction between acute and chronic psychiatric and neurological disorders.

Into the Middle Ages, dementia does not seem to have been studied or often written about, potentially due to the more pressing issues of the deadly plague epidemics of the time (Boller, 1998.)

It was into the nineteenth century that Philippe Pinel (the French founder of modern Psychiatry) first provided a clear description of symptoms and used the term dementia ('demence') as a label. Another

Frenchman, Jean Etienne Esquirrol, produced a list of causes of dementia which is now widely ridiculed for the inclusion of such causes as 'unhappy in love' and 'political upheavals.' However, such a list reflected the thinking of medicine at the time and does include some well observed causes, such as 'wine abuse.'

It was well into the twentieth century when we begin to see a clear evolution of thinking and refining of terminology with the introduction and updating of the Diagnostic and Statistical Manual of Mental Disorders (DSM) produced by the American Psychiatric Association. The first edition of the DSM did not mention dementia, instead detailing 'Organic Brain Syndrome' which was irreversible. Across successive updated editions of the DSM, the understanding of causes of dementia and description of a growing number of 'types' of dementia can be tracked. The constantly evolving landscape brings us to a current understanding that there are over 100 distinct types of disease which cause varying dementia symptoms. How the disease manifests in everyone can vary, and so a complex picture emerges that makes the search for a disease modifying treatment extremely challenging.

2.3 Medical model versus Social Model- towards compassionate healthcare

How we seek to understand dementia starkly highlights differences between the Medical Model and Social Model of disability (Szasz, 1956.) With a growing number of studies evidencing social, behavioural, and psychological benefits of Namaste Care, as well as a list of medical outcomes as discussed in chapter 1, it could be argued that this intervention *should* have the medical profession interested. What the medical profession however seems to need is physiological evidence, 'hard science' type data and an explanation for why the intervention works.

Engel however was advocating for an integration of the medical, psychological, and social view of disease in the 1970s (Engel, 1977.) He argued that the scientific model of medicine was reductionist and physicalist, with a specific scientific language that limited potential research to a physical experiment with biological systems. He believed that there was a need to broaden the approach to include human experience and meaning; to include a psycho-social element to the study of disease, without losing the knowledge and advances made in the bioscientific approach. Considering the patient's personal characteristics and beliefs, their social, cultural and relational context, as well as the causation of illness would lead to a more robust treatment plan than medical intervention alone. Engels concludes by arguing that the biopsychosocial model should be the framework for research, teaching and 'real world' healthcare.

Six decades later, how are we progressing with an attempt to counteract a biomedical attempt to reduce disability and disease down to physiochemical causes? Through the 1990's, there was a movement proposing that illness disability was a political and societal issue, not a health issue (Oliver, 1990, Crow, 1996.) This

drive did not appear to make a dent in the medical model approach but rather set up an either/or which was not Engels' intention, which instead was more an intended synthesis.

In 2021, a study looked at the perceptions and views of medical students towards patients diagnosed with depression. 1652 medical student between the ages of 18 and 32 from the faculty of Medicine in Belgrade were involved in the study. The results showed a prevailing tendency to think of the biological causes of depression and to treat with medication, rather than consider social causes and to refer the patient for therapy. The study showed that the minds of medical students are shaped from the very start of medical school, and that this is the opportunity to influence their view of disease and treatment.

Of note in this section is the individual experience I have had in conducting this study. I was registered within the biosciences department since some laboratory work would be required as a part of the study. Given the overall nature of the research, I could have equally been placed in psychology, sociology, or anthropology. The reaction from colleagues who heard the nature of my study ranged from encouraging and helpful, to curious, to outright hostile and challenging. The defence of the purist scientific paradigm appears alive and well within our academic institutions.

Namaste Care was not developed in a scientific way. It was designed based on what Joyce Simard had learned from experience that a person in the later stages of dementia needed. It developed organically from a base of good practice, careful observation, and a healthy dose of intuition. However, within the elements of Namaste Care, lie components which directly address a biological need, such as addressing hydration and pain. These are weaved with an approach which is social, relational, sensory, and compassionate. To understand the intervention purely from a biological standpoint would therefore make no sense.

2.4 A biological understanding of dementia

That is not to say that a biological understanding of dementia is not important. If we are to integrate our perceptions of dementia, as a non-scientist I must embrace and seek to consider the evolving science of dementia and how it may interact with the mechanisms of Namaste Care.

Research into the causes and potential treatment options of dementia types is ongoing. Taking Alzheimer's Disease (AD) as an example, given that it is the most common type of dementia, the Global Burden of Disease Study identified AD as one of the fastest growing diseases and is among the leading causes of death globally (Calabro et al, 2021.) Postmortem examinations of AD patients show a pattern of synaptic loss, an accumulation of neuritic plaques (Amyloid B Peptide) and the presence of neurofibrillary tangles (Tau proteins.) The pro-dromal phase of the disease is believed to begin with the gradual accumulation of lesions up to 15 years before the onset of cognitive symptoms. Looking at disease progression, the neurofibrillary

tangles start to form within the trans entorhinal cortex, before spreading to the hippocampus and later progressing to cover the cerebral cortex in later stages of the disease. It is clear to understand from this progression how patients will struggle to lay down new memories and as the disease progresses it effects the entire biological system.

A genetic component has been identified in some cases of AD, with 3 genes affected: APP, PSEN1 and PSEN2. Those inheriting the mutated APP and PSEN1 genes are guaranteed to develop AD and those with the PSEN2 mutation are 95% likely to develop the disease. Incidences of AD within a family are therefore a potential risk factor for others to consider.

Other factors influencing the development of AD include oxidative stress. Cigarette smoking and high alcohol consumption for example are high risk factors, and so a social and psychological component exists in causation due to lifestyle. There is also an awareness that energy metabolism dysfunction such as diabetes can be implicated in AD development due the neuroinflammatory and neurodegenerative nature of increased amyloid and tau protein concentrations.

Vascular dysfunctions are potentially implicated in the development of AD due to the increased risk of neuroinflammation and increased neuronal death. Amyloid B accumulations are seen in areas with reduced cerebral blood flow. The role of cardiovascular health promotion is therefore one area that preventative work is currently focussing.

An emerging area of study is that of autophagy impairment. The importance of this complex system is still being investigated but it is an important adaptive process when a person is under stress such as infection or nutrient deprivation. The importance of this process in relation to neuronal health is a promising area of investigation.

Numerous other areas of study, including metal balance impairments, the role of mitochondria, protein misfolding and protein clearance systems and the role of exosomes are all potential candidates for causation. However, there is an awareness amongst dementia researchers that a complex interplay of many of these components may be at work, making the task of finding disease modifying treatment particularly challenging.

Adding to the complexity of understanding dementia is what Kua et al, 2014, refer to as the ‘natural history of dementia.’ The progression of dementia is a difficult conversation to have with people living with the condition and their families from professional experience. The individual nature of how the disease is expressed in each person compounds the complexity of planning for changing needs.

There have been various attempts to categorise the stages of dementia. Most widely used in clinical settings are the 3 generic stages of mild, moderate and advanced dementia. A more detailed scale of progression has been proposed by Reisberg, 1982.

Global Deterioration Scale- *free online access*

Global Deterioration Scale (CGS)/Reisberg Scale			
Diagnosis	*Stage*	*Signs and Symptoms*	*Expected duration*
No dementia	Stage 1: No cognitive decline	In this stage, the person functions normally, has no memory loss, and is mentally healthy. People with NO dementia would be considered stage 1.	N/A
No dementia	Stage 2: Very mild cognitive decline	This stage is used to describe normal forgetfulness associated with aging. For example, forgetting names and where familiar objects were left. Symptoms of dementia are not evident to the individual's loved ones or their physician	Average duration of this stage is between 2 and 7 years
No dementia	Stage 3: Mild cognitive decline	This stage includes increased forgetfulness, slight difficulty concentrating and decreased work performance. People may get lost more frequently or have difficulty finding the right words. At this stage, a person's loved ones will notice a cognitive decline.	Average duration of this stage is 2 years
Early stage	Stage 4: Moderate cognitive decline	This stage includes difficulty concentrating, decreased memory of recent events, and difficulty managing finances or travelling alone to new locations. People have trouble completing complex tasks efficiently or accurately and may be in denial about their symptoms. They may also start withdrawing from family or friends because socialization becomes difficult. At this stage, a physician can detect clear cognitive problems during a patient interview and exam.	Average duration of this stage is 2 years
Mid-stage	Stage 5: Moderately severe cognitive decline	People in this stage have major memory deficiencies and need some assistance to complete their daily living activities (dressing, bathing, preparing meals, etc.) Memory loss is more prominent and may include major relevant aspects of current lives. For example, people may not remember their address or phone number and may not know the time or day or where they are.	Average duration of this stage is 1.5 years
Mid-stage	Stage 6: Severe cognitive decline (middle dementia)	People is stage 6 require extensive assistance to carry out their Activities of daily Living (ADLs.) They start to forget names of close family members and have little memory of recent events. Many people can remember only some of earlier life. Individuals also have difficulty counting down from 10 and finishing tasks. Incontinence (loss of bladder or bowel control) is a problem in this stage. Ability to speak declines. Personality/emotional changes, such as delusions (believing something to be true that is not), compulsions (repeating a simple behaviour, such as cleaning), or anxiety and agitation may occur.	Average duration of this stage is 2.5 years

Late stage	Stage 7: Very severe cognitive decline (late dementia)	People in this stage have essentially no ability to speak or communicate. They require assistance with most activities (eg. Using the toilet, eating.) They often lose psychomotor skills. For example, their ability to walk.	Average duration of this stage is 1.5 to 2.5 years.

Table 4 Summary of the Reisberg scale for stages of dementia progression

Namaste Care was originally designed for people in stage 7, although in practice many settings using Namaste Care find it beneficial introducing it in earlier stages.

To add to the complexity however, someone may have a low score on a cognitive test, such as the Cognitive Impairment Test (Kingshill, 2000) or the ACE III (Addenbrooke's Cognitive Examination-III,) but still be functioning reasonably well in activities of daily living. Therefore, some dementia care professionals look at how a person is functioning as part of an assessment. The Functional Assessment Staging Test (FAST), by Reisberg 1988, details 7 stages of functioning. A person may be at a different stage cognitively and functionally.

Functional Assessment Staging Test (FAST)			
Stage	***Patient Condition***	***Level of Functional Decline***	***Expected Duration of Stage***
Stage 1	Normal adult	No functional decline	N/A
Stage 2	Normal older adult	Personal awareness of some functional decline	Unknown
Stage 3	Early Alzheimer's Disease	Noticeable deficit in demanding job situations	Average duration of this stage is 7 years
Stage 4	Mild Alzheimer's	Require assistance in complicated tasks such as handling fiancés, travelling, planning parties etc.	Average duration of this stage is 2 years
Stage 5	Moderate Alzheimer's	Requires assistance in choosing proper clothing	Average duration of this stage is 1.5 years
Stage 6	Moderately severe Alzheimer's	Requires assistance with dressing, bathing, and toileting. Experiences urinary and faecal incontinence.	Average duration of this stage is 3.5 months to 9.5 months
Stage 7	Severe Alzheimer's	Speech ability declines to about half a dozen intelligible words. Progressive loss of ability to walk, to sit up, to smile, and to hold head up.	Average duration of this stage is 1 year to 1.5 years

Table 5 Summary of Reisberg's' functional assessment staging test

This issue highlights the ongoing difficulty of viewing dementia through a predominantly medical lens. More recently Teepa Snow has attempted to redress the negative approach of loss of function and deterioration by proposing her GEMS Model. ™ She attempts to describe progression in terms of the strengths people have left at each stage and how to work with the characteristics of each stage to meet the needs of the person. This moves us from a deficit approach to an asset-based model.

Attempts to give guidance on life expectancy has resulted in varied and broad-brush stroke results from various longitudinal studies and across different countries. For example, Hier et al in 1989, (USA) estimated the mean survival for both Alzheimer's Disease and Vascular dementia at 4.5 years. Compare that to McGonigal et al, 1992 (Scotland) estimated the mean survival rate of Alzheimer's Disease as 7.4 years, and that of Vascular Dementia as 5.8 years. By 2013, Go et al (South Korea) found a mean survival rate of 12.6 for Alzheimer's patients. This variation could indicate an improvement in health care, a social and cultural variation such as diet or views on care of older people, or differences in dementia care specifically. This therefore leads us to the need to consider the social context of dementia.

2.5 A social understanding of dementia

The word dementia comes from the root, *dement* (from the Latin, '*dementare*,') which means 'without mind,' 'mad' or 'out of one's mind.' Therefore, the stigma of a dementia diagnosis is encapsulated in the very terminology used to describe the disease. In the UK, the Alzheimer's Society and Dementia UK are charitable organisations attempting to challenge the stigma and discrimination often experienced by people with the condition.

In their publication 'Understanding and challenging stigma and discrimination' (2023,) Dementia UK describe how a lack of understanding about dementia can often lead to the person being dehumanised and assumptions being made about them. Friends and family are very often anxious about what to say and do around the person, seeing the diagnosis front and centre instead of the person. This can lead to a progressive isolation of the person and their main carer as friends and family begin to avoid contact. Given that dementia is often viewed as an 'old person's disease', people with young onset dementia can experience problems with people around them lacking empathy and judging them harshly. Stigma can be a particular problem in certain minority ethnic communities due to cultural beliefs, myths and taboos. There may also be cultural beliefs about family duty leading to the person with dementia being cared for by the family without external support services.

For the purposes of this study, it is worth exploring the prevalence and social context of dementia In County Durham, which is the location for participant recruitment.

In the 'Dementia in County Durham' Factsheet produced by Durham Insight, it is noted that dementia prevalence is significantly higher than England. This report represents recorded prevalence and not actual prevalence and therefore under-reports groups who are less likely to be registered with a GP, such as ethnic minority populations, the homeless, migrants and travellers. In 2014/15 within a total population of 517,800, the total number of people being registered as having dementia in Durham was 4800, although as previously noted, the actual number is expected to be higher and is estimated at 6625. The figures show that age is the greatest risk for dementia, with a huge prevalence of 92% for those aged over 85 years old. Looking at the local analysis of hospital admissions in County Durham in 2015/16, it was noted that co-morbidity was a key factor and influenced the care and recovery of the person living with dementia.

It is noted that anyone can develop dementia, but some risk factors and social determinants are emerging from data, such as.

- Age
- Gender
- Ethnicity
- Hearing loss
- Cigarette use
- Alcohol abuse
- Social class and educational attainment
- Unhealthy lifestyles
- High blood pressure and diabetes
- Having a learning disability

In practice, any discussion about risk factors for people already diagnosed with the disease needs extreme caution to avoid the person feeling 'blamed and shamed.'

Of interest in this study therefore will be the context in which the Namaste Care sessions are delivered (i.e. the person's own home.) Dementia places a significant responsibility on family members (usually a spouse) to take on the role of carer. Those caring for people with dementia often have poor mental and physical health, feel lonely and stressed, often describing life as like 'Groundhog Day.' Other studies (eg Dalkin et al, 2019) have suggested that family carers experience the Namaste Care visit as some respite from their caring role and as an opportunity for social connection for themselves, as well as the person they care for. This aspect of enquiry will be noted from carer comments during visits. The acceptability of Namaste Care as a

non- medical intervention, what the person with dementia and their family hope for from the sessions and the context of the sessions being offered for a short period as part of research project will all be relevant areas to explore.

2.6 The psychological impact of dementia

The psychological impact of dementia is intertwined with the biology of dementia and the social effects each person and their family may be experiencing.

People living with dementia who are writing about their experiences (Bryden 2012, Mitchell, 2019) tell us that anxiety is a key feature of the disease. The inflammatory consequences of chronic stress have been explored as potentially causative in relation to cognitive decline (eg. Justice 2018.) However, the high anxiety experiences of people living with the disease could indicate a dysregulation in the sympathetic/parasympathetic nervous system, the dopaminergic system, and the Hypothalamus/Pituitary Axis (HPA) among others, as a feature of the disease. Add to this, the fear, confusion and uncertainty that the person will feel as they negotiate daily life with dementia, there is frequently accompanying symptoms of depression, feelings of frustration and agitation. All these mood changes will necessarily have an impact on the meaningful relationships surrounding that person and potentially how they interact with those offering care.

The sensitive balance between the sympathetic and parasympathetic nervous system producing autonomic regulation appears dysregulated in people living with dementia. (Chou, 2023.) A chronic lower parasympathetic activity level (rest and digest state) and a higher sympathetic-vagal (alert, stress response) state were associated with a risk of dementia.

As dementia progresses, some of the behavioural and psychological symptoms being experienced by the person are related to perception, mood and emotion, which are influenced by Dopamine. (Martorana and Koch, 2014.) Regulated through the mesolimbic system, Dopamine is produced in the substantia nigra, ventral tegmental area and hypothalamus of the brain. (Lewis et al, 2021.) Changes within the dopaminergic system have been identified as present in dementia cases (e.g. Sweet et al 2001, Caminiti, 2020.) This is especially notable in Alzheimer's Disease and most especially in the later stages of the disease (Ceyzeriat, 2020.)

Similarly, a dysfunction of the HPA axis in dementia, (as compared to the normal function shown in figure 1) particularly Alzheimer's Disease, is evidenced by elevated basal levels of circulating cortisol (Ahmad et al, 2018) which would back up the reports of stress and anxiety by people living with dementia.

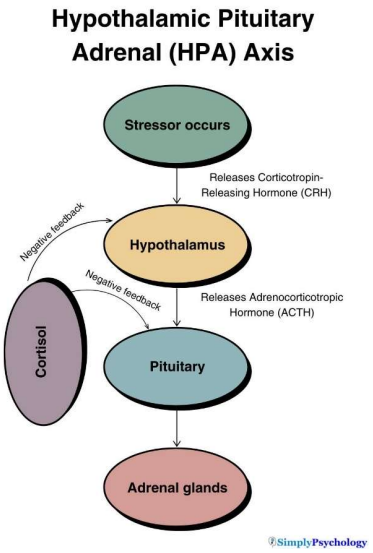


Figure 1 The normal functioning of the HPA axis (Simply Psychology)

Another consequence of advancing dementia symptoms is the prevalence of pain, and the difficulty with gradual loss of verbal skills is that pain is difficult for the person with dementia to self-report. Pain assessment by observation of the person becomes essential at this stage (Achterberg et al, 2020.) It is estimated that in nursing homes, 60-80% of people with dementia experience daily pain, and this must logically have an impact on mood and behaviour. Pieper et al (2013) noted that non-pharmacological interventions such as music therapy, massage and human interaction could be effective in reducing pain in this population, but that evidence of efficacy was limited. This approach is of very great relevance to the evaluation of Namaste Care.

2.7 Implication for care services and policy.

As a life limiting condition, a dementia diagnosis should in theory lead to a referral to palliative services. This would open the person to Palliative Services and more frequent GP review. In practice this does not happen. Following diagnosis, if a person's symptoms are stable, they are very often discharged from specialist dementia services back to the care of general practice. It is very likely that the resource implications of opening palliative care to people living with dementia would stretch services beyond its current capacity.

As dementia progresses, people living with dementia have frequent hospital admissions with issues such as falls and infections, which for someone without dementia would often not require an admission. 25% of

hospital beds are estimated to be taken at any one time by people living with dementia and their stays are longer than for those without dementia with the same condition. ('Dementia- A state of the nation report on dementia care and support in England', Department of Health, 2013.) Finding a suitable place to discharge to safely often results in discharge delays and the person being moved into residential care, with a prescription of anti-psychotic drugs to manage behavioural symptoms. People living with dementia are more likely to be re-admitted, and long hospital stays are associated with a deterioration of dementia symptoms and poorer longer-term health.

Given the increasing prevalence of dementia, care homes and nursing homes are often seen as the primary service for people with the condition. However, as the Alzheimer's Society (2013) report showed, 63.4% of people with dementia still live at home, meaning that the burden of care often sits with family members and home care agencies. Worryingly, only 41% of relatives questioned for this same report consider their loved ones with dementia enjoys a good quality of life**.** This brings into focus how we perceive quality of life and who is doing the perceiving. For example, it is very easy to understand that a family member may well be judging a person's current quality of life as compared to their past quality of life and based on their own value judgements about what constitutes a good quality of life. Encouraging family members and care staff to 'be in the moment' with people living with dementia and to be willing to 'enter their reality' is what Christine Bryden advises from her own experience of living with the condition.

If care home provision is sought, there is often sub-optimal care for people living with dementia, especially in the late stages of the disease (Latham et al, 2020.) This suggests the need for improved care practices in residential care, and better training in how to meet the needs of people living with dementia. Latham et al, among other similar papers, argue that the focus on physical care tasks needs to shift to also include social, sensory, emotional and person-centred approaches.

Hospice care is still commonly associated with cancer care and from professional experience of working with hospices across the country, some of them still have an attitude of 'we don't *do* dementia.' However, hospices are ideally placed to offer advanced care planning services to families still living in the community, and some hospices offer a 'hospice at home' or 'rapid response end-of-life' care model to support people who are still living at home (Bosco, 2023.) Hospices are therefore being guided by Hospice UK (2015) to ensure their services can meet the needs of people living with dementia.

From a policy framework perspective, health and social care providers look to National Institute of Clinical Excellence (NICE) guidelines, the Gold Standard Framework (GSF) and the Care Quality Commission Inspection framework (CQC) for standards of practice. None of these national policy bodies refer to Namaste Care. The evidence required for inclusion of an intervention or technology has been called into question for the fairness and transparency of processes (eg. Charlton, 2020) and there has been a drive for more of a

patient voice in decision making for NICE (Quennel, 2001.) NICE looks at efficacy and cost effectiveness of interventions and technology. Cost effectiveness will be beyond the scope of this study. But finding ways to evaluate effectiveness will very much be the focus.

2.8 Differing ways to understand dementia- consequences for evidence gathering

From the summary of perspectives on dementia presented in this chapter, it is possible to identify various stakeholders with differing needs for whom the evidence provided by this study needs to make sense. This ranges from dementia specialist clinicians, to care staff, to allied health professionals, national and local policy makers, to people living with dementia and their families. Meeting the needs of this broad audience demands both qualitative and quantitative approaches and has resulted in a panoramic lens with which to view the landscape that Namaste Care sit within. The study has therefore required inter-disciplinarity, the assistance of experts, and extreme flexibility of thought.

Chapter 3

A mixed methodology approach

Chapter 3- Mixed Methodology Approach

3.1 Introduction

The broad scope of this study and the interdisciplinary approach being taken naturally suit a mixed method approach. This chapter outlines and critically discusses the over-arching mixed methodology adopted to explore ways to measure the biopsychosocial impact of Namaste Care on people living with advanced dementia. Each phase of the study then also has a methodology protocol description, specific to that phase of study.

A mixed-methods approach was chosen to bridge the gap between qualitative, relational accounts of Namaste Care and the biomedical demand for quantifiable evidence. This study recognises that Namaste Care—an intensely sensory and relational intervention—cannot be fully understood through any single methodological lens. Accordingly, the study attempts to integrate qualitative and quantitative strands to illuminate the "magic" of Namaste Care both as lived experience and as measurable physiological change.

A **three-phase sequential design** was implemented. *Phase 1* comprised qualitative consultation with key stakeholders to co-design the research and develop a new observational tool—the Namaste Care Session Outcome Measure (NCSOM). *Phase 2* used quantitative physiological and biological measures, including resting heart rate, urinary biomarkers, and thermal imaging, to evaluate responses to Namaste Care sessions. *Phase 3* brought participants and stakeholders together to interpret and validate findings collaboratively. Together, these phases created an iterative cycle of exploration, testing, and reflection consistent with a pragmatic mixed-methods paradigm (Creswell & Plano Clark, 2018; Tashakkori & Teddlie, 2010).

This chapter therefore articulates the philosophical stance underpinning the study, the rationale for combining methods, summarises the design structure, procedures for data collection and analysis, and how integration was achieved. It concludes with reflections on validity, trustworthiness, ethics, and reflexivity.

3.2 Ontology

The mixed-methods design adopted in this research is rooted in pragmatism and the biopsychosocial model. Ontologically, the study assumes that reality is complex and multi layered, encompassing measurable physiological responses and experiential meaning simultaneously. Pragmatism provides an overarching

philosophical foundation that prioritises research questions and practical solutions over allegiance to a single paradigm (Biesta, 2010; Morgan, 2014). It accommodates the coexistence of multiple forms of truth and knowledge—both subjective and objective—aligning closely with Engel's (1977) biopsychosocial framework, which recognises that human health is shaped by biological, psychological, and social systems in constant interaction.

Pragmatism accepts methodological pluralism and rejects the perceived divide between positivism and constructivism (Johnson & Onwuegbuzie, 2004). It encourages researchers to "use whatever works" to answer the research problem effectively. In this study, pragmatic thinking allowed for an integration of laboratory-based quantitative measurements with interpretive, participatory qualitative data. This pluralism mirrors the holistic nature of Namaste Care itself—a practice combining physical touch, sensory engagement, and emotional connection.

Reflexivity was essential throughout. As both a Namaste Care practitioner and researcher, I acknowledged the potential for interpretive bias. Maintaining a reflective journal, peer debriefing, and supervisory triangulation were strategies used to ensure transparency and critical self-awareness (Finlay, 2021).

3.3 Epistemology- Rationale for a Mixed-Methods Design

Epistemologically, the study recognises that knowledge of wellbeing in advanced dementia is co-constructed among researchers, participants, and caregivers. The adoption of an integrative stance enabled the exploration of both dimensions as equally valid representations of wellbeing (Fetters et al., 2013).

The rationale for employing a mixed-methods approach was threefold.

First, the research problem itself was multidimensional. Namaste Care encompasses sensory, relational, and physiological dimensions that no single method could capture comprehensively. Quantitative measures could reveal biological or behavioural changes—such as heart-rate changes or cortisol reduction—but not the subjective "magic moments" of connection frequently reported by caregivers. Conversely, purely qualitative accounts risked being dismissed as anecdotal within clinical contexts seeking quantifiable evidence. A mixed methods approach therefore provided methodological complementarity (Greene et al., 1989), enabling exploration of both meaning and mechanism.

Second, the approach addressed a gap in existing research. Previous studies of Namaste Care (e.g., Stacpoole et al., 2014; Brooker et al., 2019; Kaasalainen et al., 2020) relied primarily on qualitative data or proxy

observational tools, limiting generalisability. This study sought to move beyond observation to obtain direct physiological feedback from people with advanced dementia, offering a new layer of evidence.

Third, mixed methods aligned with the ethical and emancipatory goal of giving people with dementia a voice. By integrating biological and behavioural indicators with co-produced qualitative insights, the study allowed individuals unable to verbalise feedback to participate through measurable bodily responses. In this sense, mixed methods served both epistemic and moral purposes—supporting inclusivity, dignity, and participation consistent with the Dementia Statements (Alzheimer's Society, 2017).

Thus, the chosen design enabled triangulation across biological, psychological, and social domains—reflecting the biopsychosocial model underpinning the intervention.

3.4 Research Design

A sequential exploratory mixed-methods design (Creswell & Plano Clark, 2018) was employed, comprising three interconnected phases representing a cyclical flow between exploration, measurement, and reflection.

Phase 1 – Qualitative Exploration and Tool Development
Stakeholder consultations were undertaken to identify observable indicators of wellbeing relevant to Namaste Care and to co-design a new observational outcome tool (NCSOM). The NCSOM was tested by front line NHS staff in 2 local NHS Trust (CNTW and TEWV.) Feedback from this live testing led to refinement of the measure ready for use in phase 2. Insights from phase 1 informed the development of the quantitative measurement framework felt appropriate by stakeholders to employ as the approach in phase 2.

Phase 2 – Quantitative Measurement and Testing of varied measure types
Using some of the indicators identified in Phase 1, this phase tested biological and physiological responses to Namaste Care. Data was collected on resting heart rate, urinary cortisol and dopamine, and facial temperature via thermal imaging. The NCSOM was simultaneously piloted to evaluate observable behavioural change, and some inter-rater scoring was undertaken to check reliability.

Phase 3 – Participatory Interpretation and Validation
Findings from Phases 1 and 2 were presented to participants and stakeholders in a workshop designed to foster shared interpretation, validate results, and discuss implications for practice.

Integration occurred at three key points: (1) *design integration*, where qualitative results shaped quantitative instrument development; (2) *methods integration*, through concurrent behavioural observation alongside physiological measures; and (3) *interpretive integration*, where quantitative findings were contextualised through participant feedback (Fetters et al., 2013).

This design facilitated both **developmental** (qualitative → quantitative) and **complementary** (quantitative ↔ qualitative) linkages, yielding a more cohesive understanding of ways to measure Namaste Care's biopsychosocial effects. The transition between study phases is achieved by way of a summary of researcher reflexive notes to provide a bridge between phases.

3.5 Phase 1: Qualitative Consultation and Co-Design

Purpose and Participants

Phase 1 aimed to capture expert and experiential perspectives to guide measurement design. Participants included Namaste Care volunteers, family carers, health professionals, and people with mild-to-moderate dementia capable of providing informed consent. This inclusive sampling reflected a commitment to co-production (Hickey et al., 2018) and ensured that the resulting tool would be meaningful and practical across settings.

Data Collection

Data was collected through semi-structured focus groups and interviews, conducted face-to-face and online via a Qualtrics questionnaire which asked the same questions posed in the focus groups and interviews. Discussion topics included perceptions of wellbeing, observable signs of positive or negative emotional states, and reflections on current measurement challenges. Sessions were audio-recorded, transcribed verbatim, and anonymised. Field notes captured non-verbal cues and contextual observations.

Analysis

Thematic analysis followed Braun and Clarke's (2022) six-phase framework: familiarisation, coding, theme development, review, definition, and reporting. Due to the large amount of data, the themes were identified intuitively and rapidly by highlighting key descriptors and organising them into categories. This process could have been much more thoroughly explored for finer detail data if this had been the sole focus of the study. However, in this study it was one part of a much larger whole and so required a rapid analysis to inform movement to phase 2. Themes identified included *relaxation and calm*, *connection and engagement*,

expression and responsiveness, and *comfort and dignity*—each later operationalised as observable indicators within the NCSOM.

Outcome: Development of the NCSOM

Findings were synthesised alongside review of existing observational frameworks (QUALID; PAINAD; Brooker et al., 2019) to create the **Namaste Care Session Outcome Measure**. The draft NCSOM featured concise descriptors of observable behaviours (e.g., eye contact, facial expression, posture, vocalisation) scored on a Likert-type scale at session start and end. Pilot testing by staff from Tees Esk and Wear Valley NHS Trust (TEWV) and Cumbria, Northumberland, Tyne and Wear NHS Trust (CNTW) confirmed its usability with minimal burden and without the need for training in its use. This testing also identified elements of the measure which required modification and the NCSOM format was re-designed in consultation with NHS staff.

The co-design process exemplified participatory action research principles, fostering ownership and ecological validity (Reason & Bradbury, 2008). Qualitative insight thus directly informed instrument creation—demonstrating *developmental integration* of methods. Of note is the decision to collaborate with dementia specialist nurses, occupational therapists and support workers in the development of the NCSOM as opposed to consultant psychiatrists. This was due to the more ongoing and relational contact to people living with dementia that nurses and allied health workers have, as compared to the shorter duration contact that consultant psychiatrists have in clinic.

3.6 Phase 2: Quantitative Measurement of Physiological and Behavioural Responses

Purpose and Design

Phase 2 sought to test whether measurable physiological changes occur during Namaste Care sessions and to assess the sensitivity of the NCSOM to behavioural change. A repeated-measures design captured pre- and post-session data across four sessions delivered per participant, enabling within-subject comparison over time. Data was collected in session 1 and session 4, due to cost restraints in using ELISA kits. The consistency of session delivery across 4 sessions however was important to assess whether effects differed over an extended period. It would have been beneficial to assess this over a much longer period to validate Namaste Care as an intervention, but to test the measures, it was felt that 4 sessions was adequate.

Participants and Sampling

Participants comprised people living with dementia (n = 8) and a control group of cognitively healthy adults (n = 8). The session outcome for Namaste Caregivers was also tested (n=4.) Recruitment occurred via hospice and community Namaste Care programmes. Proxy consent was sought where appropriate on a case by case basis. Ethical approval was obtained from the North East –Newcastle & North Tyneside 1 Research Ethics Committee (Ref 23/NE/0091). Co-morbidities and medication taken by participants were not recorded in this study due to the main aim being testing of measures, however these factors could impact on and explain results and so would be important to include in any study looking to validate Namaste Care as an intervention.

Data Collection Procedures

Resting Heart Rate.

Pulse oximeters and wrist sensors were tested to record resting heart rate at the start and end of the session.

Urinary Cortisol and Dopamine.

Mid-stream urine samples were collected pre- and post-session in sterile sample containers. Samples were processed in Laboratory 9, Biosciences department, Durham University, following standard ELISA assay protocols.

Thermal Imaging.

Facial thermal images were captured using a calibrated FLIR T540 camera, focusing on nasal-tip temperature as a proxy for autonomic arousal (Ioannou et al., 2014).

Behavioural Observation.

During sessions, NCSOM scores were recorded by observers. Observers were blind to physiological results to minimise expectancy bias.

Data Analysis

Quantitative data were analysed using PRISM software. Descriptive statistics summarised central tendencies and variability. Inferential analyses included paired t-tests, Wilcoxon matched-pairs signed-rank tests, and one-way ANOVAs to examine within-subject and between-group differences. Significance was set at $p < .05$.

Preliminary results indicated reductions in resting heart rate and urinary cortisol, alongside increases in NCSOM wellbeing scores—suggesting a measurable relaxation response congruent with qualitative descriptions. Resting heart rate emerged as the most accessible and scalable indicator.

Integration with Qualitative Insights

The quantitative findings would have the potential to be contextualised using the Phase 1 themes. For example, does decreased heart rate corresponded to the thematic code *calmness*, while does elevated nasal temperature align with *emotional warmth and engagement*? These patterns could reinforce interpretive complementarity and validate the multi-layered nature of wellbeing observed in Namaste Care sessions.

3.7 Phase 3: Results-Sharing and Co-Interpretation

Phase 3 operationalised the participatory ethos of the study by re-engaging stakeholders to discuss and interpret results collaboratively. One half-day workshop was held with study participants, caregivers, health professionals, and Namaste Care volunteers. Visual summaries of findings were presented through accessible infographics and anonymised case vignettes.

Discussions explored the resonance of quantitative outcomes with experiential observations. Participants reflected that those measurable physiological changes "gave voice" to the individuals receiving care, confirming what practitioners had intuitively known. Feedback informed final refinements to the NCSOM and identified priorities for future implementation, including Namaste Care training needs and integration within routine care documentation.

This phase exemplified interpretive integration (Fetters et al., 2013), merging numerical data with narrative meaning to form a coherent, actionable understanding. It also reinforced ethical reciprocity by returning findings to those who contributed knowledge—an important principle in participatory dementia research (Wilkinson et al., 2020).

3.8 Integration of Qualitative and Quantitative Data

Integration is the defining feature of mixed-methods research and represents the point at which qualitative and quantitative strands combine to generate a more comprehensive understanding than either could yield alone (Creswell & Plano Clark, 2018; Fetters, Curry, & Creswell, 2013). In this study, integration occurred both *within* and *across* the three phases, producing layered insight into the biopsychosocial effects of Namaste Care.

Points and Forms of Integration:

Design integration occurred when themes from Phase 1 guided the selection of quantitative indicators in Phase 2. For instance, the qualitative finding that "calmness" and "connection" signified wellbeing informed the choice of heart rate and cortisol as physiological proxies for relaxation and stress reduction.

Methods integration was embedded in the concurrent collection of NCSOM behavioural data alongside biological samples, enabling real-time cross-validation between observed and physiological responses.

Interpretive integration took place during Phase 3, when stakeholders compared patterns in the quantitative results with experiential narratives. The triangulation of findings through participatory dialogue provided an interpretive synthesis—what Greene (2007) calls "integrative legitimation."

Complementarity and Convergence

Complementarity was achieved when different data types illuminated distinct facets of the same phenomenon. For example, reductions in cortisol (quantitative) complemented descriptive accounts of "relaxation" (qualitative). Convergence was evident when both data types corroborated each other—such as simultaneous declines in heart rate and observers noting slower breathing and softened posture.

Where divergence occurred—such as cases where physiological data indicated stress but observers recorded engagement—these instances were not dismissed as error but analysed for contextual meaning. Sometimes heightened arousal reflected emotional stimulation rather than anxiety, demonstrating the nuanced, non-linear relationship between physiological and emotional states. These dissonances underscored the importance of interpretive integration rather than statistical dominance (Bryman, 2006).

Joint Displays and Interpretation

Data integration was visualised through *joint displays* (Fetters et al., 2013), combining statistical outputs and thematic summaries as an example of how results may have more meaning when presented by individual participant rather than as group data. This could more effectively help to identify recurring patterns, such as consistent physiological and behavioural improvements during sessions involving personalised sensory stimuli (music, fragrance). These example integrative matrices strengthened interpretive coherence and enhanced the transparency of analytic reasoning.

3.9 Ethical Considerations

Ethical Framework

Given the vulnerability of participants living with advanced dementia, ethical integrity was central to this approach. The study complied with the UK Health Research Authority framework and gained favourable opinions from two NHS Research Ethics Committees (Refs 22/OL/0313 and 23/NE/0091). Ethical decision-making was guided by the principles of autonomy, beneficence, non-maleficence, and justice (Beauchamp & Childress, 2019), alongside a human-rights orientation consistent with the Alzheimer's Society's *Dementia Statements*.

Consent, Assent, and Capacity

For participants unable to provide informed consent, assent procedures were employed in accordance with the Mental Capacity Act (2005). Family carers acted as consultees, while participants' ongoing willingness was continuously monitored through behavioural cues—an approach sometimes termed *behavioural consent* (Berghmans & Ter Meulen, 2002). Signs of distress or withdrawal would have triggered immediate cessation of data collection. This sensitive monitoring ensured that participation remained voluntary and respectful throughout.

Minimising Risk and Burden

All procedures were designed to be non-invasive and minimally disruptive. Urine sampling was felt by phase 1 participants to be a routine, low burden task; thermal imaging required no physical contact; and heart-rate monitoring employed comfortable sensors (wrist or finger.) Sessions were conducted within familiar care environments to reduce anxiety. Debriefing conversations with caregivers occurred after each session to identify any unforeseen stress or discomfort.

Confidentiality and Data Governance

Data were pseudonymised using coded identifiers and stored on encrypted, password-protected systems in compliance with GDPR (2018) regulations. Biological samples were destroyed after laboratory analysis in accordance with the Human Tissue Act (2004). Only the researcher and supervisory team had access to identifiable information. Details of participants prescribed medications were not recorded for the purposes of this feasibility study but would provide useful information in a larger scale study to understand and individual's responses to a Namaste Care session more fully.

Reflexivity and Researcher Wellbeing

The researcher's dual role as Namaste Care practitioner and academic demanded a high degree of reflexive awareness. Regular supervisory discussions and reflective journaling were used to monitor emotional impact and maintain boundaries. Ethical reflexivity was considered an ongoing process rather than as a single requirement for ethics approval (Guillemin & Gillam, 2004).

Validity, Reliability, and Trustworthiness

Quantitative Validity and Reliability

For physiological and biochemical data, internal validity was supported through consistent timing of sample collection and standardised environmental conditions (lighting, music volume, session content). Due to sessions being conducted in a variety of environments, usually the person's home, standardising temperature was not achieved.

Instrument reliability was ensured via equipment calibration and duplicate assay runs for urine samples. External validity was limited by small sample size, but the primary goal was feasibility rather than generalisability. Statistical significance ($p < .05$) was interpreted alongside effect sizes to estimate practical relevance (Field, 2018).

Qualitative Trustworthiness

The qualitative strand's rigour was addressed through the four criteria of credibility, transferability, dependability, and confirmability (Lincoln & Guba, 1985).

- **Credibility** was enhanced through stakeholder review during Phase 3 and triangulation across data sources.
- **Transferability** was facilitated by testing measures in a variety of environments.
- **Dependability** was supported by peer discussion with dementia care professionals in Tees, Esk and Wear Valley NHS Trist and Cumbria, Northumberland, Tyne and Wear NHS Trust to ensure themes identified in phase 1 were relevant to their practice experience.
- **Confirmability** was strengthened through reflexive journaling and peer debriefing within the supervisory team.

3.10 Integration Quality

Fetters et al. (2013) propose three criteria for high-quality integration—*connectedness*, *coherence*, and *completeness*. Connectedness was achieved by clearly linking qualitative themes to quantitative variables. Coherence emerged through convergent interpretation demonstrating logical consistency across strands. Completeness was realised by ensuring that the final synthesis addressed all aspects of the biopsychosocial research question. Together, these criteria demonstrate *meta-inference validity*—the credibility of the overall mixed-methods conclusion (Venkatesh et al., 2013).

3.11 Limitations of the Mixed-Methodological Approach

While mixed methods offer a powerful framework for this research, several limitations must be acknowledged.

Sample size and representativeness.
The small participant number limits statistical generalisability. Recruitment of individuals with dementia is inherently challenging due to consent, frailty, and fluctuating health status. Nevertheless, the study's aim was exploratory feasibility rather than hypothesis testing.

Temporal and logistical constraints.
Collecting multi-modal data required considerable coordination among clinical, volunteer, and laboratory partners. Biological assays, though rigorous, were resource-intensive and at times constrained by the researchers' limited laboratory experience.

Observer bias and interpretive subjectivity.
Although the NCSOM reduced reliance on purely subjective judgement, behavioural observation remains susceptible to observer interpretation. Double rating mitigated this but could not eliminate this limitation. The researcher's practitioner background risked expectation bias, addressed through reflexive documentation and external validation.

Integration complexity.
Synthesising heterogeneous data posed interpretive challenges, particularly when findings diverged. However, these complexities mirror real-world practice, where psychosocial and physiological responses seldom align perfectly. Rather than weakness, such complexity was embraced as epistemic richness.

Interdisciplinary navigation.

Working across biosciences, psychology, and social care required negotiating differing epistemologies and communication styles. At times this slowed progress but ultimately enriched interpretation, echoing Klein's (1990) view that interdisciplinarity thrives on productive tension.

3.12 Conclusion

To summarise, the philosophical rationale, design, implementation, and evaluation of the mixed-methods approach adopted for this study was grounded in pragmatism and the biopsychosocial model. The design integrated qualitative co-production with quantitative physiological testing to capture the multifaceted nature of wellbeing in advanced dementia.

Phase 1 generated stakeholder-informed qualitative insights and resulted in the development of the NCSOM observational tool. Phase 2 applied quantitative measurement to test physiological and behavioural outcomes. Phase 3 returned to participants for collaborative interpretation, completing a full cycle of inquiry and validation.

Through careful integration of qualitative meaning and quantitative evidence, the research aims to demonstrate that Namaste Care elicits measurable physiological changes alongside observed emotional connection. The mixed-methods framework not only produced richer evidence base but also embodied the relational ethos of Namaste Care—valuing subjective experience and scientific rigour equally.

Future research can build on this model by scaling up participant numbers, refining biomarker protocols, and embedding the NCSOM within broader dementia-care evaluation systems. Ultimately, this mixed-methods approach offers a replicable template for examining complex psychosocial interventions that resist simple measurement, reinforcing the principle that both "magic" and measurement belong within compassionate science.

Chapter 4

Phase 1

Consultation with key stakeholders to inform and refine study design

4.1 Rationale

4.2 Methodological protocol

4.3 Results

4.4 Recommendations for Phase 2

4.5 Design of a Namaste Care Session Observational Measure Tool

Chapter 4 Phase 1- Consultation with key stakeholders

(NB. The structure for the methodology section is based on the UK Health Research Authority Research Protocol Development Tool.)

4.1 Rationale

Phase 1 was necessary to assist with clarifying what it was the study would seek to measure and what biological measures would be appropriate and acceptable. Active involvement of stakeholders in this way aims to strengthen the research, ensuring that it is relevant, understandable and meaningful for the people it is relevant to. (Health Research Authority.)

4.2 Methodological protocol

Phase 1 consultation took a qualitative approach to understand the observable indicators that professionals and families use to report improved wellbeing in someone living with advanced dementia who is unable to self-report. This involved a contextualist approach where I sought to make meaning from the participants' experience of living with dementia or of caring for someone living with dementia. Given that this is a novel area of study, I used inductive thematic analysis of the data generated from focus groups, individual interviews and online questionnaire feedback. A draft observational scale was devised based on the feedback from this consultation. This observational tool was then tested in Phase 2 of the study.

Also crucial to phase 1 enquiry is careful consultation with professionals and especially families, as well as people living with a life limiting condition, about how to approach the collection of physiological data such as heart rate monitoring, blood pressure and saliva sampling in the least intrusive, most sensitive and empowering way. One suggestion to explore, in the Namaste Care spirit of 'doing with' not 'doing to' would be that the Namaste Caregiver also provides the same physiological data, given that caregivers also report a sense of wellbeing at the end of a session.

RESEARCH QUESTIONS/AIM For Phase 1

1. To explore participant's understanding of quality of life and wellbeing.
2. To develop an observational tool which can be used by services to capture data on outcomes of a Namaste Care.

3. To gain opinions about the acceptability and practicality of a range of options to test the effectiveness of Namaste Care over the time-period of one session by measuring biological and physiological responses.

PHASE 1 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study methods in phase 1 were designed to gain opinions about what we can observe in someone that indicates positive wellbeing and to elicit views and guidance from participants about how to approach physiological data collection most appropriately.

- **Focus Groups**-The focus groups were led by myself as investigator, using a semi-structured question framework but with flexibility to explore issues raised by participants. The target was 6-8 people in each group. They each lasted for 90 minutes with a break and had support from a research assistant who is trained in listening support skills (Dr Barbara Edwards.) They were audio recorded.
- **Individual Interviews**- These were offered as an alternative if participants would prefer not to attend a focus group. They were conducted face to face in a venue to suit the participants by me using the same semi-structured questions as for the focus group and they were audio recorded.
- **Online questionnaire-** Another alternative option for participation was through a short anonymous online questionnaire **using the same questions as the focus groups and interviews** (see below) and giving space for people to expand on answers if they choose to.

Focus Group/ Individual Interview Topic Guide (approved by ethics committee)

Welcome and introductions (10 mins)

- *Thanks so much for coming along and giving up your valuable time.*
- *The purpose of today is to help me to approach my research in the most ethical and supportive way for participants. My research will be looking at an activity called Namaste Care, and I will be exploring how effective it is at helping people with advanced dementia and potentially other life limiting conditions such as Parkinson's Disease. I'd like your input to help me understand the best way to go about this.*
- *As facilitator for the focus group, I want to reassure you that I have professional experience of working with people living with advanced dementia.*

- *The session will be recorded and your input to the research will be anonymised.*
- *Your participation is voluntary and there are no consequences in not taking part or answering specific questions. Please only discuss those things you feel comfortable sharing.*
- *Terms of confidentiality need to be agreed. We will take the approach of a confidential discussion ("what is shared in the room, stays in the room") and anonymity guaranteed.*

Ground rules

- *Agree ground rules for the group e.g. respect for other people's views and allowing space to talk.*
- *I will be trying to ensure that all voices are heard and that any different perspectives, e.g. where participants disagree with each other, are explored and understood.*
- *For the focus group, we have Barbara Edwards who is here to provide listening and emotional support. If any topics discussed trigger difficult feelings, Barbara is happy to speak with you privately if you want to take a break at any time.*
- *The findings from the focus group will be shared with you via a newsletter and please know that your time and hard work is highly valued.*

Introductions: *Please let's go around the room, introduce yourself and briefly explain your experience of dementia or other life limiting condition.*

……

Q1. QoL and Wellbeing meaning?

In research, the terms quality of life or wellbeing are often used. We might seek to measure whether a particular activity improves a person's wellbeing for example. I'd like to discuss what aspects of wellbeing you think are important.

So, I'd be interested to hear what wellbeing and good quality of life mean to you?

Prompts: Physical, social, emotional, perception, standards and expectations?

<SUMMARISE MAIN POINTS MADE TO CLARIFY UNDERSTANDING BEFORE MOVING ON>

……

Give an explanation of what Namaste Care is.

Bearing in mind someone with advanced dementia will find it difficult to express how they feel about an activity such as Namaste Care, we tend to rely on observations by caregivers.

Q2 What would you see in someone living with advanced dementia that would lead you to believe that an activity had improved their QoL/wellbeing? (10 mins)

Prompts if needed relating to:

Vocalisations/ body language/ posture/ cognition/ behaviour/ eye contact/ skin colour/eating and drinking/ facial expression

Would this be different from yourself?

What would you hope someone would observe in you to indicate positive wellbeing?

……

I would like to develop a scoring system that carers could use to record how a person has responded to a Namaste Care session.

Q3 Can you think of what I need to think about when I design the scoring form? (10 mins)

What would make completing the form easier? Or more difficult?

What would put you off completing the form?

Would you prefer a paper or digital format?

Prompts: time, layout, usability, scoring?

<SUMMARISE THIS SECTION BEFORE MOVING ON. SHORT 5 MIN COMFORT BREAK>

…….

The aim of my study is to empower people with advanced dementia to tell us themselves how they feel about a Namaste Care session by using physical data they can provide. This is in line with the approach in the Dementia Statements (Alzheimer's Society) about supporting people with dementia to participate in research.

Q4. How would you know whether someone with advanced dementia was willing (or unwilling) to take part in my study? (10 mins)

Who should we involve in the decision?

Prompts: Pre-existing knowledge of their opinion on research, proxy consent, non-verbal assent, would carers feel a need to please by saying yes?

Q5. What are your thoughts about asking someone living with advanced dementia who does not have capacity to consent, to give a saliva sample at the beginning and end of a Namaste Care session? (10 mins)

Explain that this would entail a soft swab in the mouth.

How have people you may know with advanced dementia responded to having a covid swab?

…….

A central philosophy in Namaste Care is 'doing with' not 'doing to.'

Q6. Thinking about this philosophy, would it feel more acceptable if the Namaste caregiver was also giving a saliva sample at the same time? (5 mins)

Use of technology to measure physical responses will also be looked at in this study.

Q7. How acceptable would it be for the person with dementia to wear a smart watch to capture other information (e.g. heart rate, movement) during a Namaste Care session? (5 mins)

Prompt if needed: minimising level of intrusiveness?

<SUMMARISE THIS SECTION BEFORE MOVING ON TO CLOSE THE GROUP/INTERVIEW>

CLOSING (5 mins)

- Ask for one final short observation from the group about what it has been like to discuss this topic.
- Thank everyone for their time.
- Ensure means to claim travel expenses are given out, as well as a small thank you gift and the aftercare sheet.
- Explain how the results of the consultation will be communicated with participant

With guidance from:

A bite size guide to running focus groups for patient and public engagement (england.nhs.uk)

The Focus Groups and interviews were transcribed, and participants were de-identified by being given a code. Together with the information from the online questionnaire, a thematic analysis was carried out to organise the data, summarise into an observational tool to be tested and to inform the ethical approach to phase 2 of the study.

The data was stored on a password protected laptop and any paper-based information was stored in a locked cabinet.

STUDY SETTING

Settings were chosen to ensure privacy, minimise disruptions and make accessing the study as easy as possible.

- The focus groups took place at the most accessible place for the participants of each group, for example the focus group for staff and volunteers at St Cuthbert's Hospice would take place in their Education Suite. The focus group with staff and volunteers from St Joseph's Hospice Hackney took place in their training room. The focus Group with staff and volunteers of Beamish Museum dementia service took place in their Resource Centre.
- Individual interviews took place at the family home. This was discussed and agreed in an initial visit where consent was agreed.
- In all settings, covid-19 safe precautions were taken- social distancing, optional face masks, hand sanitiser available, individual rather than shared access refreshments.

SAMPLE AND RECRUITMENT

Eligibility Criteria

Participants for phase 1 consultation were adults with the appropriate experience to comment on the study questions.

Inclusion criteria

- Males and females
- 18 plus
- Experience of caring for someone with advanced dementia of other life limiting condition either professionally, as a volunteer or within the family
- Or someone living with a life limiting condition with capacity to consent
- Focus Groups took place in Durham, England and in Hackney, London
- Individual interviews took place within the North-East region
- Online questionnaire will be accessible regardless of location

Exclusion criteria

- Under 18
- No experience of caring for someone with a life limiting condition

- Anyone who feels the discussion may cause them distress or exacerbate a pre-existing mental health condition.

Participant Sampling

Sampling aimed to provide a group of participants with differing roles and experience- professionals (NHS and voluntary sector,) carers, volunteers, individuals with a life limiting condition. This was to ensure a wider representation of views.

Size of sample target

2 x Focus groups of 6-8 participants = 76here76.. 20- 30 participants

Individual interviews- 10

Online questionnaire participants- 20-30

Target total- 50-60 participants

Sampling technique

Through established key contacts within the various organisations who are acting as study partners, participants were recruited through purposive sampling of known professionals, volunteers and family carers involved in the care of people living with advanced dementia (or other life limiting condition.) In the case of people who are themselves living with dementia, contact will be made through a research partner organisation that this person trusts and can be supported by.

Recruitment

An information sheet for participants was provided which can be shared by key contacts in the research partner organisations. Guided by the research partner organisations, an information session or email forwarded by the research partner organisation was useful to generate interest in participating.

Sample identification.

Identification of potential participants involved the following:

- Participants were identified by key contacts in research partner organisations, based on their knowledge of their colleagues and of any families that they support that they think would like to be involved in research.

- An introductory letter and information pack was made available to participants, and any potential participants will be contacted and an appointment made by the researcher to discuss the study if they consent to their contact details being forwarded by the key contact.
- A privacy notice was provided and discussed to ensure potential participants understand how their data will be processed and stored.
- There was no access to disease registers or clinical notes used by the researcher.
- Focus Group participants were provided with refreshments and travel expenses, paid through Durham University from the research budget allocated to this study.

Consent

The process of gaining informed consent will involve:

- discussion between the potential participant or his/her legally acceptable representative and the researcher, about the nature and objectives of the study and possible risks associated with their participation.
- the presentation of participant information (information sheet, privacy notice, consent form) which will have been approved by the REC, local regulatory requirements and will meet legal requirements.
- the opportunity for potential participants to ask questions.
- assessment of capacity. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:
    - understand the purpose and nature of the research.
    - understand what the research involves, its benefits (or lack of benefits), risks and burdens.
    - understand the alternatives to taking part.
    - be able to retain the information long enough to make an effective decision.
    - be able to make a free choice.
    - be capable of making this decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity.)
    - Where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected.

*It was anticipated that at the consultation stage, all invited participants would have mental capacity to give informed consent.

ETHICAL AND REGULATORY CONSIDERATIONS

Ethical approval for this phase of work (IRAS application 310353) was gained from Camberwell and St Giles Research Ethics Committee, following their review of the application, all study paperwork and interview at Committee.

4.3 Results of Phase 1 Consultation

Overview of Data and Analytic Approach

Phase 1 generated a substantial qualitative dataset derived from three focus groups, three individual interviews, and an online questionnaire completed by a wide range of stakeholders. In total, 53 participants contributed to this phase of the study, representing people living with dementia, family carers, health and social care professionals, volunteers, and allied health professionals. This breadth of participation enabled the capture of diverse experiential and professional perspectives on wellbeing, quality of life, and the observable effects of Namaste Care.

Given the volume of data generated and the pragmatic aim of informing the subsequent quantitative phase, a qualitative descriptive approach was adopted. This approach prioritised clarity, transparency, and faithfulness to participants' language, rather than deep theoretical abstraction. Transcripts and written responses were read repeatedly to achieve familiarity, and frequently occurring words, phrases, and descriptors were highlighted. These were clustered into codes representing shared concepts, which were then grouped to form broader thematic categories. Frequency of terms and consistency across participant groups were used to support the salience of identified themes.

The results are presented as a synthesised account of the combined datasets, structured around key areas relevant to the study aims: understandings of wellbeing and quality of life, observable indicators of wellbeing in people unable to self-report, and views on the acceptability and feasibility of physiological measurement within Namaste Care sessions.

A more detailed summary of phase 1 results including quotes and tables can be found in Appendix A2.

Participant Characteristics and Modes of Contribution

Participants engaged through multiple formats, allowing both collective sense-making and individual reflection. Focus groups were conducted with staff, volunteers, and carers at Beamish Museum Health and Wellbeing Team, St Joseph's Hospice (Hackney), and St Cuthbert's Hospice (Durham), generating rich discussion grounded in practical experience. Individual interviews were undertaken with family carers and one person living with dementia, allowing more personal and detailed accounts. The online questionnaire extended participation geographically and enabled input from professionals and carers unable to attend group sessions.

Across all formats, participants demonstrated a high level of engagement with the study aims. Many reported that the process of reflecting on wellbeing and observation itself was novel and thought-provoking, suggesting that these concepts are often implicit in care practice but rarely articulated explicitly.

Understandings of Wellbeing and Quality of Life

When asked what wellbeing and good quality of life meant to them, participants initially found the distinction difficult to articulate. However, as discussion developed, a clear pattern emerged: wellbeing and quality of life were viewed as related but distinct constructs.

Quality of life was commonly described as externally assessed and linked to measurable or observable circumstances such as physical health, living conditions, and financial security. In contrast, wellbeing was described as more internal, subjective, and experiential, encompassing emotional, psychological, and spiritual dimensions. Several participants expressed discomfort with the term "quality of life" due to its association with health economics and external judgement, particularly in relation to people living with advanced dementia.

Participants emphasised that wellbeing could be present even in the context of significant illness or disability, whereas quality of life measures risked overlooking these nuanced experiences. Importantly, many noted that the components they associated with wellbeing—such as feeling calm, valued, connected, and comforted—were universal human needs, not specific to dementia. This observation reinforced the relevance of measuring wellbeing rather than attempting to assess quality of life in populations unable to self-report.

Using the *five most frequent* descriptors for wellbeing used identified by participants, a simple definition of wellbeing for the purposes of this study could be suggested as:

Wellbeing is a state of feeling relaxed, content, happy and comfortable, with the opportunity to engage in meaningful activities.

Observable Indicators of Wellbeing in Advanced Dementia

A central focus of Phase 1 was to identify **observable indicators** that carers and professionals use to infer wellbeing in people living with advanced dementia. Participants consistently reported that although individuals may be unable to articulate their experiences verbally, changes in wellbeing are frequently recognised through behaviour, expression, and bodily cues.

Commonly cited indicators included:

- **Facial expression**, particularly softening of features, smiling, or reduced tension
- **Eye contact or visual engagement**, including sustained gaze or tracking the caregiver
- **Body posture**, such as relaxation of shoulders, unclenching of hands, or leaning towards the caregiver
- **Vocalisation**, including humming, sighing, or contented sounds
- **Responsiveness**, such as initiating interaction or responding to touch or voice

Participants highlighted that these indicators were often subtle and relational, emerging within the context of one-to-one attention rather than as isolated behaviours. Several carers noted that the absence of distress behaviours (e.g., agitation, repetitive movements, vocal distress) was itself a meaningful indicator of improved wellbeing.

Importantly, participants emphasised the dynamic nature of these indicators. Wellbeing was not viewed as a static state but as something that could fluctuate within a session. This supported the decision to design an observational measure capable of capturing change between the beginning and end of a Namaste Care session.

Calm, Relaxation, and Emotional Regulation

Across all participant groups, the most consistently reported outcome of Namaste Care was a sense of calm and relaxation. Participants described observable reductions in agitation, restlessness, and anxiety during and following sessions. These changes were often inferred through slowed movements, quieter vocalisations, and visibly relaxed posture.

Some professionals reported observing reductions in symptoms such as tremors or hallucination-related behaviours by the end of sessions, although they noted that these changes were not captured by existing documentation tools. This gap directly informed later refinements to the observational measure, ensuring space to record changes that fall outside traditional behavioural categories but are nonetheless clinically meaningful.

Participants also linked calmness with improved emotional regulation, suggesting that Namaste Care may support a shift from heightened arousal to a more settled state. While these observations were experiential rather than physiological, they later informed the selection of biological and physiological measures in Phase 2.

Connection, Relationship, and Feeling Valued

Another dominant theme was the importance of connection and relational presence. Participants repeatedly emphasised that wellbeing was closely tied to feeling seen, attended to, and emotionally held by another person. Observable signs of connection included leaning in, seeking eye contact, mirroring expressions, and initiating interaction.

Family carers, in particular, highlighted the emotional significance of seeing their relative respond positively to another person. Several noted that Namaste Care offered something distinct from routine care interactions, providing uninterrupted attention and a sense of being "special" or prioritised.

Participants also noted that the caregiver's attunement played a crucial role in shaping observable outcomes. The caregiver's tone of voice, pace, and sensitivity were seen as integral to eliciting calm and engagement, reinforcing the relational nature of the intervention.

Acceptability of Physiological and Biological Measurement

Participants were invited to comment on the acceptability and feasibility of collecting physiological and biological data during Namaste Care sessions. While there was general support for the idea of measuring effectiveness, strong views emerged regarding **how** this should be done.

Saliva sampling was widely viewed with caution. Participants raised concerns about confusion, distress, choking risk, and dehydration, particularly for people with advanced dementia. These concerns were

grounded in practical experience and highlighted potential unintended consequences of seemingly simple procedures.

In contrast, urine sampling was viewed as more acceptable and less intrusive, provided it could be integrated sensitively into existing care routines. Participants emphasised the importance of dignity, consent, and flexibility, reinforcing the principle of "doing with" rather than "doing to."

Heart rate monitoring was generally viewed positively, particularly if devices were familiar, unobtrusive, and comfortable. Several participants suggested that including caregivers in physiological data collection could reduce power imbalance and normalise the process.

Implications for Phase 2 Design

Collectively, the Phase 1 results provided clear guidance for the next phase of the study. Participants supported the development of an observational measure grounded in relational and behavioural indicators, capable of capturing change within a session. They also emphasised that any physiological measures must be acceptable, minimally intrusive, and ethically sensitive.

The findings directly informed:

- the structure and content of the Namaste Care Session Outcome Measure,
- the exclusion of saliva sampling,
- the inclusion of heart rate and urine-based biomarkers, and
- the emphasis on pre- and post-session comparison.

Phase 1 therefore fulfilled its aim of grounding measurement design in lived and professional experience, ensuring that Phase 2 proceeded with methodological, ethical, and relational legitimacy.

4.4 Summary of recommendations and redesign for phase 2

The results from phase 1 therefore provide specific direction which informs the approach to phase 2. Recruitment of participants for phase 2 will be via:

1. Join Dementia Research
2. St Cuthbert's Hospice
3. University networks

The key to appropriate recruitment of phase 2 participants will be thorough discussions with people interested in being recruited to the study and their families to consider individual needs and to screen for those who may find any of the element's distressing. This will be very individual, so a procedure will be written in to the phase 2 study protocol to reflect this.

The approach of using saliva sampling needed to be modified in response to the concerns raised during the consultation. Having checked with the manufacturers of Lollisponge™ to find out if it has been tested for safety in the case of people living with advanced dementia, and finding out that it had not, a rethink on biomarker collection was needed.
A decision was therefore taken in consultation with the study supervisory team as well as NHS professionals from Tees, Esk and Wear Valley NHS Trust and Cumbria, Northumberland, Tyne and Wear NHS Trust, to move to the use of urine sampling in phase 2 to collect biomarkers, and that this procedure would be developed in the most **participant friendly and sensitive way** in the methodology for phase 2.

4.5 Design of an observational measure for a Namaste Care session based on the feedback from phase 1 about indicators of wellbeing.

Using the specific observable indicators of wellbeing which people had described, an observational measure was devised ready for testing. A section was also added to enable the caregiver to record details of the session, resources used and notable responses. This section was based on measures designed by St Joseph's Hospice, Hackney and St Cuthbert's Hospice, Durham.

The draft measure was reviewed by Emma Biglands, an Occupational Therapist for Tees, Esk and Wear Valley NHS Trust (TEWV) who has also led a project to embed Namaste care into 2 organic wards in one of their hospitals and into some pilot care homes. She provided advice regarding the usability of the measure for care home staff, suggesting the use of colour coding for clarity and the form was amended to reflect her suggestions.

The resulting measure in draft form was designed as follows:

Namaste Care Session Outcome Measure *(Version 1)*

Recipient name or code		**Date and time:**

Before Namaste Care

INDICATOR ✓	**Score 1**	**Score 2**	**Score 3**	**Score 4**	**Score 5**
Facial expression	Distressed	Frowning	Impassive	Relaxed features	Smiles
Body tension	Muscles tightly contracted	Tense posture	Passive posture	Relaxed posture	Muscles relaxed, at ease
Eye Contact	Avoiding eye contact	Fleeting eye contact	Some eye contact	Sustained eye contact	'Sparkle' in the eyes
Breathing	Laboured or distressed breathing	Rapid, shallow breath	Normal breathing rate	Slow, relaxed breathing	Slow and deep breathing
Behaviour	Severely agitated	Unsettled	Passive	Settled	Peaceful and content
Engagement	Actively avoiding the activity	Disinterested in the activity	Observing the activity	Interested in the activity	Actively reaching out/engaging
Pain	Severe pain	Moderate pain	Mild pain	Minimal, localised pain	No signs of pain
Mood	Depressed or anxious	Low mood	Mood not obvious	Positive mood	Happy
Skin colour/texture	Grey or white pallor/ dry skin	Pale/ dry skin	Normal skin tone for the person	Colour in the cheeks	Good colour and hydrated skin
Communication	No attempts to communicate	Minimal non-verbal communication	Communicating non- verbally	Active gestures and movement	Attempts to vocalise or speak
Score *Total the number of ticks per column*	*1 x …….* =	*2 x …….* =	*3 x …….* =	*4 x …….* =	*5 x …….* =
TOTAL : Add column totals =					

Namaste Care interventions used:

☐	**Clean and moisturise face**	☐	**Hand massage**	☐	**Foot massage**
☐	**Comfort object**	☐	**Drink offered**	☐	**Food offered**
☐	**Fragrance used**	☐	**Hair brushing**	☐	**Reminiscence**
☐	**Reading**	☐	**Music**	☐	**Seasonal objects**

After Namaste Care

Indicator	A		B	
Facial expression	Frowning, tense or impassive		Relaxed features, smiles	
Body tension	Tense posture		Relaxed posture	
Eye Contact	Absence of or fleeting eye contact		Sustained eye contact	
Breathing	Rapid, shallow breath		Slow and deep	
Behaviour	Agitated, unsettled		Settled, content	
Engagement	Disinterested in activity		Interested in activity	
Pain	Signs of pain		No signs of pain	
Mood	Down, anxious or withdrawn, pale		Happy, colour in cheeks	
Communication	No attempts to communicate		Attempts to communicate	
Score *Please total the number of ticks in each column*		**A**		**B**

Session notes

Environment: Where did the session take place? How was the environment modified to create a calming space?
Products/items used:
Memorable moments/responses:
Anything to avoid in future sessions?

Feedback given to carer? **Any comments from carer?**

Form completed by …….. **Date completed:**

The measure was then tested by Cumbria Northumberland Tyne and Wear NHS Trust (CNTW) with 20 patients on a dementia inpatient ward. General feedback on the form was given by Bev Richardson (Clinical Support Assistant) and Julie Young (Advanced Nurse Practitioner and Research and Development Lead for Older Adult Community Pathway.) They felt that it reflected the changes seen during the session and the scoring was easy to understand. They found it rewarding to see the change expressed clearly from the start to end of session of the Namaste Care session.

Difficulties they identified were regarding eye contact if the person receiving the Namaste Care is blind or if their eyes were closed due to being relaxed. This then affected the score, and they found it awkward to measure. In the engagement section they felt the use of 'others' better reflected group Namaste Care and was less applicable in 1 to 1 sessions. They suggested changing 'interested in other's' to 'interested in caregiver.' Further feedback was that the 'before' and 'after' section should be the same for direct comparison of scoring.

They have observed that symptoms such as hallucinations and tremors reduce by the end of a Namaste Care session but there was no way to record this important change. They suggested adding a section to reflect this. In the communication section, there was a query about 'active gestures/movement' as an indicator. They felt this didn't fit and suggested' initiating communication' fitted better.

The outcome measure was updated to reflect these suggested changes and CNTW and TEWV ward staff continued testing. Inter-rater reliability for the measure was tested in phase 2 of the study and is reported in the phase 2 results.

Updated version of the NCSOM which was used in phase 2:

Durham University

NIHR | Applied Research Collaboration North East and North Cumbria

Namaste Care Session Outcome Measure *(Version 2)*

Recipient name or code		Date and time:

Before Namaste Care

Please tick one box per line which best describes the person ***before*** *the session* ✓

Reduced wellbeing ……  ***……Improved wellbeing***

INDICATOR	Score 1	Score 2	Score 3	Score 4	Score 5
Facial expression	Distressed, grimacing.	Frowning, sad or frightened	Impassive, emotionless	Relaxed features	Smiles, sparkly eyes
Body tension	Muscles clenched, rigid	Tense or slumped body posture	Passive, some muscle tone but not tense	Relaxed posture	Muscles relaxed, at ease
Breathing	Laboured or distressed	Rapid, shallow breath	Normal breathing rate	Slow and steady	Slow, deep, and relaxed
Behaviour	Severely agitated	Unsettled, fidgeting	Passive, inexpressive	Settled	Peaceful and content
Engagement	Actively avoiding caregiver	Disinterested in caregiver	Observing caregiver	Interested in caregiver	Actively reaching out to caregiver
Pain	Severe pain, grimacing, groaning	Moderate pain, some moaning	Mild pain	Minimal, localised pain	No signs of pain
Mood	Depressed, sad, or anxious	Apathy, low mood, or mild stress	Mood not obvious	Positive mood, motivated	Happy
Communication	No attempts to communicate	Minimal non-verbal communication	Responding non-verbally	Initiating non-verbal communication	Attempts to vocalise, speak, laugh or sing
Symptoms eg. hallucinations, tremors	Very severe	Severe	Moderate	Mild	Absence of Symptoms
Score *Total the number of ticks per column and multiply by score value*	*1 x …….* =	*2 x …….* =	*3 x …….* =	*4 x …….* =	*5 x …….* =
TOTAL: Add column totals to give score for before the session = (Range between 9 and 45)					

During/after Namaste Care

Please tick one box per line which best describes the person ***during*** *or* ***by the end of the session*** ✓

Reduced wellbeing ……  ***……Improved wellbeing***

INDICATOR	Score 1	Score 2	Score 3	Score 4	Score 5
Facial expression	Distressed, grimacing.	Frowning, sad or frightened	Impassive, emotionless	Relaxed features	Smiles, sparkly eyes
Body tension	Muscles clenched, rigid	Tense or slumped body posture	Passive, some muscle tone but not tense	Relaxed posture	Muscles relaxed, at ease
Breathing	Laboured or distressed	Rapid, shallow breath	Normal breathing rate	Slow and steady	Slow, deep, and relaxed
Behaviour	Severely agitated	Unsettled, fidgeting	Passive, inexpressive	Settled	Peaceful and content
Engagement	Actively avoiding caregiver	Disinterested in caregiver	Observing caregiver	Interested in caregiver	Actively reaching out to caregiver
Pain	Severe pain, grimacing, groaning	Moderate pain, some moaning	Mild pain	Minimal, localised pain	No signs of pain
Mood	Depressed, sad, or anxious	Apathy, low mood, or mild stress	Mood not obvious	Positive mood, motivated	Happy
Communication	No attempts to communicate	Minimal non-verbal communication	Responding non-verbally	Initiating non-verbal communication	Attempts to vocalise, speak, laugh or sing
Symptoms eg. hallucinations, tremors	Very severe	Severe	Moderate	Mild	Absence of Symptoms
Score *Total the number of ticks per column and multiply by score value*	*1 x …….* *=*	*2 x …….* *=*	*3 x …….* *=*	*4 x …….* *=*	*5 x …….* *=*
TOTAL: Add column totals to give score for before the session = **(Range between 9 and 45)**					

Durham University

NIHR | Applied Research Collaboration North East and North Cumbria

Session notes

Namaste Care interventions used:

☐	**Clean and moisturise face**	☐	**Hand massage**	☐	**Foot massage**
☐	**Comfort object**	☐	**Drink offered**	☐	**Food offered**
☐	**Fragrance used**	☐	**Hair brushing**	☐	**Reminiscence**
☐	**Reading**	☐	**Music**	☐	**Seasonal objects**

Environment: *Where did the session take place? How was the environment modified to create a calming space?*
Products/items used:
Memorable moments/responses:
Anything to avoid in future sessions?
Feedback given to carer? **Any comments from carer?**

Form completed by ……. **Date completed …….**

4.6 Summary reflexive notes to conclude Phase 1

I was aware with this phase of the study that I was operating in my 'comfort zone.' Talking to participants in focus groups and interviews felt far more natural for gathering opinions than the online questionnaire format, but generally this participatory way of approaching a subject, especially this subject, felt very appropriate and resulted in enough feedback to feel confident about a consensus.

I found the wellbeing discussion especially interesting and there was general agreement about the core elements of wellbeing. It was also thought provoking for participants to realise that what they identified as important to wellbeing was true of everyone, not just those living with a dementia. Although there are existing definitions, it felt important for this study to empower participants to arrive at their own definition.

I was struck by several issues during phase 1 of the study. Participants seemed to really value the opportunity to talk and make meaning out of their experience. Additional themes were brought into discussions by participants which were not directly being asked about but which were clearly important to them. One of these themes was the poor communication by health professionals to a person living with dementia about the realities of their diagnosis. Another theme was the apparent strain on family carers and their need for better professional and peer support. I was aware of feeling empathy and emotional impact from hearing the stories of family struggle to care for their loved ones. I also could hear the moral injury being described by dementia care professionals whose caseloads were stretched beyond their capacity to provide a good service. These issues would certainly bear further study to improve the experience of people living with dementia but are beyond the scope of this study.

In terms of the rejection of the idea that saliva samples could be collected to study biomarkers, I was initially surprised at the wariness of this method. On the surface, it would have appeared to be a very simple method of bodily fluid collection. However, what the participants identified as cautions around safety and around causing confusion were entirely valid. On exploring other studies which have attempted this method with people living with dementia, (e.g. Bourne et al, 2019) they found it difficult to get the amount of saliva required to test due to people living with dementia tending to be dehydrated. This therefore reinforces the important of patient and public involvement and co-design in research to arrive at the most appropriate methods of data collection. It has made me feel more confident that I am representing the views of the people this study will affect directly.

The switch to collecting urine samples required a rethink of logistics, health and safety and equipment for sample collection but would result in more fluid to test and was not a difficult modification in study design.

In approaching phase 2, I was confident about my skills in communication to explain the study to participants and in building positive trusting relationships with the people I will visit to deliver Namaste Care. This part of the process is very familiar to me. The consequent processing of samples in the laboratory and conducting ELISA assays are very unfamiliar procedures, which although I have practiced, are still my main concern in phase 2. To ensure the samples are processed correctly and to alleviate this concern to some extent, being allocated an Msc student to assist went a long way to allaying my worries.

Chapter 5

PHASE 2

Collection of biological, physiological and observational data during a Namaste Care session

5.1 Rationale

5.2 Methodological protocol

5.3 Results

5.4 Conclusion- reflexive notes

Chapter 5: Phase 2

5.1 Rationale

Testing both physiological measures alongside biological and observational methods will aim to provide a broader way to evaluate Namaste Care than with observation alone.

Does Namaste Care induce a relaxation response?

Of interest to this study is the interplay of the sympathetic/parasympathetic nervous system in response to an offered intervention. The sympathetic nervous system will be aroused in response to a stressful or threatening stimulus, such as an unwanted interaction or activity. Alongside the various stress hormones secreted in response to a stressful event, the heart rate will be elevated and the breathing rate increases. Whereas the activation of the parasympathetic nervous system restores the body to a calm, relaxed state when the person feels safe and at ease. In this situation, stress hormone secretion would reduce, the heart rate would slow, and the breathing would also become slower and deeper. These observational markers will be captured using the **observational measure** to be tested and via **resting heart rate measurements** at the beginning and end of the Namaste Care session.

Relevant urinary biomarker

Cortisol- can we observe a reduction in cortisol levels (indicating reduced stress) in response to a Namaste Care session?

Cortisol is a glucocorticoid that is produced by the adrenal glands as part of the hypothalamic-pituitary-adrenal (HPA) axis which is primed to respond to stress and help maintain homeostasis within the body. Cortisol affects the autonomic nervous system, as well as the heart and vasculature. Disease, aging and chronic stress can disrupt this finely balanced mechanism, leading to disruption of multiple physiological systems within the body. Cortisol levels are observed in blood serum, saliva, sweat and urine tests to operate as a circadian rhythm, with peaks usually in the morning. A stressful event will initially trigger the sympathetic adrenal medullary system, which releases catecholamines such as adrenaline and noradrenaline. This in turn activates the HPS axis; the hypothalamus and anterior pituitary release corticotropin-releasing hormone (CRH) and adrenocorticotrophic hormone (ACTH.) The zona fasciculata in the adrenal cortex responds to

these hormones with the production of glucocorticoids, principally cortisol, being released into the bloodstream.

Dysregulation of the HPA axis and increased cortisol levels have been linked to the progression of neurodegenerative diseases such as dementia. This finding matches the reports from people living with dementia who experience high levels of anxiety. Increased cortisol is also implicated in negatively affecting the experience of chronic pain. Pain is a key feature of advanced dementia, due to immobility and muscle contractures. Anecdotally, Namaste Care has been reported as reducing the person's experience of pain, and this may be due to a stress lowering effect.

Cortisol is naturally expressed in a diurnal circadian rhythm, that is controlled by the suprachiasmatic nucleus via a pulsatile system of hormone release. Typically, cortisol levels are low as we fall asleep and then begin to rise at 2-3am. The levels peak at around 8.30am (cortisol awakening response) and then continue falling during the day, reaching a low level around midnight.

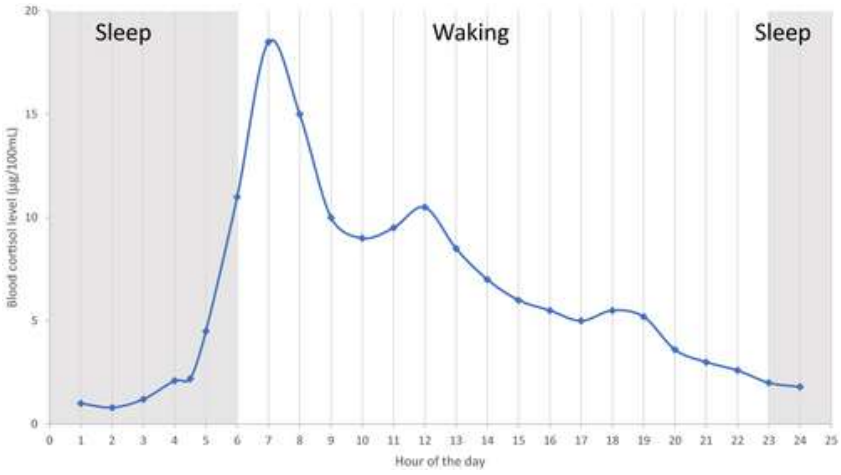


Figure 2 The cortisol diurnal circadian rhythm (Lovallo and Thomas, 2012)

This will mean that a baseline measure of cortisol will need to be established for each participant without a Namaste Care session, but at the same time as a session will begin and end. The results of the session samples can then be adjusted against the baseline measure.

Use of cortisol is a well-established means of examining the body's response to stress and the implications of varying cortisol levels (James et al, 2023.) For example, Kiess et al were able to demonstrate using salivary cortisol testing that cortisol levels are age dependent, increasing with age. However, studies using measuring cortisol levels in bodily fluids tend to be smaller scale due to the logistics and specialist nature of testing required.

Does Namaste Care produce positive mood changes?

Facial Temperature changes

Exploring non-invasive methods of measuring emotional and physical responses in vulnerable individuals, especially those unable to give consent, or those who are at the end of life, is an emerging area of study. In a study published in 2014, Engert et al argue that their results using thermal infrared imaging are a useful method to *estimate* activity of the sympathetic nervous system. This suggests a certain lack of precision, but an ability to track changes and trends.

Including this newly developing technology will allow the images to be compared to the other wellbeing indicators and may lead to the wider use of the technology as a less intrusive measure of mood and wellbeing for future studies. Finding a means to measure a person's subjective emotional experience without the need for self-report would be invaluable, and is a technology also being explored by companies such as PainChek for the measurement of pain.

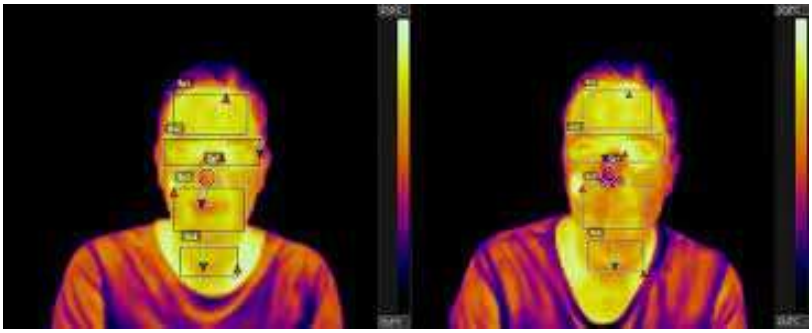


Figure 4 Example of facial temperature changes captured by thermal imaging

The proposition being tested is that emotions (psychological states in response to stimuli) can affect skin temperature, most notably on the face. Studies have found that an increase in nose tip temperature seems

to be associated with positive valence (pleasant) mental states. Conversely, a drop in nose tip temperature can indicate increased stress (Villacastin, 2024.) These types of applications of thermal technology are being tested for a variety of purposes in psychology and medical studies. For example, Moline et al, 2018 looked at temperature changes on the forehead and nose to indicate when someone tells a lie. Another study used thermal imaging to measure responses to a group activity for people living with Parkinson's Disease (Jiang et al, 2022.)

Relevant urinary biomarkers

Dopamine- Can we observe an increase in dopamine levels (increased sense of pleasure/reward) in response to a Namaste Care session?

Dopamine is a neurotransmitter and is most notably involved in generating a sense of pleasure and reward. It also plays a role in mood, attention, heart rate processing of pain and sleep. Dopamine is produced in two stages at the base of the brain. The amino acid, tyrosine is converted to L-dopa, then through enzyme action into dopamine.

Dopamine production has been shown to reduce in response to chronic stress (Bloomfield, 2019) and so measuring dopamine in session 1 and 4 will provide an interesting insight into whether there is any longer-term impact of regular Namaste Care sessions.

Oxytocin- would we observe an increase in oxytocin in response to a Namaste Care session?

Given the strong relational element of Namaste Care, the hypothalamic nonapeptide Oxytocin was reviewed as a candidate biomarker. Oxytocin is linked to increased wellbeing, social bonding, and anti-stress effects. It also appears to reduce sensitivity to pain. Salivary oxytocin is yet again proved to be unreliable (Martins et al, 2020) but the pooling of oxytocin in urine over the timeframe of a Namaste Care session would be possible to measure with 'before' and 'after' urine samples, given careful handling and cooling of the sample to avoid degradation before processing with an enzyme immunoassay (ELISA) kit (Reyes et al, 2014.)

Due to the delicate nature of this large unstable molecule, the sensitivity required to detect oxytocin will be explored by Dr Jon McPhetre, Durham University, to develop a methodology for analysis using mass spectrometry, and will therefore not be within the scope of this study.

Other urinary biomarkers considered:

Serotonin

The involvement of the neurotransmitter and hormone, serotonin, in mood regulation would have made it an interesting biomarker to look at, however resource constraints for the purchasing of ELISA kits meant that the number of urinary biomarkers had to be limited to two.

Endorphins

Given the anecdotal reports of Namaste Care helping to reduce the experience of pain, looking at levels of endorphins before and after a Namaste Care sessions would have been very interesting. As, above, resource constraints meant that this biomarker was reluctantly omitted but would be a worthy area of study for future research.

5.2 Methodological protocol

Aim:

To remove perceived positive bias towards the Namaste Care intervention, a series of biological, physiological, and behavioural measures was tested so that the person living with dementia could provide the feedback directly. The approach is driven by a desire to give people living with advanced dementia a non-verbal 'voice' and to explore ways to provide objective evidence relating to the intervention.

Measures to be tested were chosen to reflect the concept of wellbeing identified in phase one, focussing on emotional and physical wellbeing (absence of stress, feelings of reward and pleasure, activation of the parasympathetic nervous system indicating a relaxed state.) The refined observational tool could also be tested and qualitative information in the form of participant feedback could be recorded.

Study Protocol and Ethical Framework

STUDY DESIGN AND BACKGROUND TO METHODS OF DATA COLLECTION AND DATA ANALYIS

This study phase design is based on the findings of the phase 1 consultation outcomes. Considering concerns and advice given by consultation participants, plans were modified to acknowledge safety concerns about the suggested means of saliva collection for people living with advanced dementia and to include the Namaste Caregiver and main carer as participants, given the feedback that they also feel a benefit from Namaste Care sessions. Plans were further amended to accommodate the optimal means to detect the target biomarkers following a review of the literature.

Guiding principles:

- Minimising participant and carer burden in participating in the study.
- Minimal or non-invasive procedures for participants
- Sample collection as naturalistic as possible and ideally to fit in with normal routine.

Selection of the target biomarkers in urine

The aim of urine sample collection is to evaluate reduction of, or improvement in wellbeing over the timeframe of one Namaste Care session. Areas of interest could have included evaluating stress levels, pain levels and mood.

Salivary cortisol was originally considered as a measure of stress levels, however the consultation process carried out in phase one revealed mixed views and safety concerns related to the use of saliva sampling in people living with advanced dementia. Cortisol present in urine was therefore be tested instead, due to minimal burden to participants and being a familiar procedure for many people.

Additionally, testing for any changes in Dopamine levels (a chemical involved in the experience of pleasure/reward) could contribute to the overall picture of how a Namaste Care session impacts wellbeing.

Logistical considerations and resource budget:

Given a limited timeframe and resource budget, it was decided to test 2 urinary biomarkers for this study to achieve a realistic outcome. Cortisol and dopamine were therefore tested as the target biomarkers for ELISA testing.

Facial imaging

Participants were given the choice of whether to have this element of data collection carried out. Due to not having access to the analysis software used in the Parkinson's study, the temperature measurement was taken for nose tip temperature, and an analysis by eye was carried out for any variations in temperature distribution across the area around the nose.

Table of measures used:

Participant category	Able to consent?	Means of data collection	Who can collect the data to pass on to the researcher?
Healthy individuals	Yes	Oximeter Urine samples Facial imaging Verbal feedback	Participant/ Namaste Caregiver
People with mild to moderate dementia	Yes	Oximeter Urine samples Facial imaging Pilot observational measure Verbal feedback	Participant with help from carer/ Namaste Caregiver
The Namaste Caregiver	Yes	Oximeter Urine samples Facial imaging	Namaste Caregiver/researcher
People with advanced dementia	No	Case studies	Main carer/ Namaste caregiver

Table 6 Summary of measures to be used by group

STUDY SETTINGS

The Namaste Care sessions took place in the participants' home within County Durham. Lone working procedures for the Namaste Caregiver were in place.

SAMPLE AND RECRUITMENT

Eligibility Criteria

Inclusion criteria

- 18 years or older
- People living with dementia in the Durham and Chester-le-Street area **OR** healthy volunteers **OR** healthy Namaste Caregivers

- Willing to engage in 4 Namaste Care sessions delivered once weekly.
- Willing to provide urine samples on 3 occasions, wear a smartwatch for sessions on 2 occasions and have facial imaging performed on 2 occasions.

Exclusion criteria

- Anyone who feels that taking part in the study may cause them distress or exacerbate a pre-existing mental health condition.

Participant Sampling

To gain a full picture about responses to Namaste Care, including the additional beneficiaries identified, research participants will be sought in 3 main groupings:

1. Healthy individuals (control)
2. People living with dementia
3. The Namaste Caregiver

The Namaste Caregiver has been included as they also report feeling an improvement in their wellbeing by the end of a session. Given the current difficulties with health and social care recruitment, any intervention which improves staff morale is of interest.

Size of study sample

***The target recruitment number was 30**

- 10 Healthy Individuals
- 10 people living with dementia
- 10 Namaste Caregivers

Participant Sampling technique

A sample size calculation conducted using G*Power software (v3.1.9.7) indicated that a sample of **24 participants** assessed pre- and post- intervention would provide 85% power to detect a difference in urinary cortisol (effect size) of r=0.64 with two tails at the p=0.05 significance level. An effect size of r=0.64* was chosen because this magnitude of difference was observed in a similar previous study that measured urinary

cortisol pre- and post- massage therapy in adults with hypertension (mean urinary cortisol pre-intervention=125, mean urinary cortisol post-intervention=109, Wilcoxon-signed ranks test=3.56, $p<0.05$) (Hernandez-Reif et al., 2000).

Participants who drop out will not be replaced, therefore a target sample size of 30 participants (per group) was chosen to allow for attrition during follow-up whilst retaining adequate power.

*Effect size calculated using the formula $r = z/\sqrt{N}$ (where z=Wilcoxon signed ranks i.e., 3.56 and n=30)

Recruitment

Recruitment of potential participants was via:

1. **The 'Join Dementia Research' register (https://www.joindementiaresearch.nihr.ac.uk/)**

Join Dementia Research (JDR) was used as a recruitment tool. This is an online self-registration service that enables volunteers with memory problems or dementia, carers of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research.

The purpose of JDR is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers' preferred method of contact, to further discuss potential inclusion.

JDR is funded by Department of Health and Social Care working in partnership with the charities Alzheimer Scotland, Alzheimer's Research UK and Alzheimer's Society and is Health Research Authority (HRA) endorsed.

The online service and all associated documentation, methods of contacting volunteers and handling of data, were reviewed by a specially convened HRA committee which included experts in research ethics, data protection and information governance. Formal endorsement was issued by the HRA in a letter dated 7 June 2023.

The Admiral Nurse service at St Cuthbert's Hospice, Durham

A dementia specialist nurse led community service, which includes a Namaste Care service, has an established relationship with those referred to the service and is well placed to identify those they thought would potentially like to join this study.

Word of mouth and university networks

Involvement in three 'Older People into Science' events organised by the Psychology Department of Durham University and held in a community venue in Durham during Autumn 2023 resulted in the recruitment of some of the healthy individuals who were interested in taking part.

Sample identification.

Identification of potential participants will involve the following:

- Participants in the target geographical area can be matched via the criteria detailed on the Join Dementia Research Register. Participants will be contacted by the register and can self-select if they are interested in taking part.
- An introductory letter, participant information and privacy notice will be made available to participants and any potential participants will be contacted and an appointment made by the researcher to discuss the study.
- A privacy notice will be provided and discussed to ensure potential participants understand how their data will be processed and stored.
- There will be no access to disease registers or clinical notes by the researcher.
- Namaste Caregivers will have already been recruited and agreed to being participants before being matched to the person with dementia that they will visit. This is to ensure that the person living with dementia is not being asked to do anything that their Namaste Caregiver is not also doing. This was identified as an important principle in the consultation phase and supports the Namaste Care principle of 'doing with' not 'doing to.'

Consent

The issue of consent in relation to people with advanced dementia who may not be able to give informed consent was discussed thoroughly in the phase 1 consultation. Participants in the consultation felt that **proxy consent** was acceptable, based on a representation of the person with dementia's views and wishes regarding taking part in research.

The process of gaining informed consent involved:

- discussion between the potential participant or his/her legally acceptable representative and the researcher, about the nature and objectives of the study and possible risks associated with their participation.
- the presentation of participant information (information sheet, privacy notice, consent form) which will have been approved by the Research Ethics Committee.
- the opportunity for potential participants to ask questions.
- assessment of capacity by the key contact given their knowledge of the individual. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:
    - understand the purpose and nature of the research.
    - understand what the research involves, its benefits (or lack of benefits), risks and burdens.
    - understand the alternatives to taking part.
    - be able to retain the information long enough to make an effective decision.
    - be able to make a free choice.
    - be capable of making this decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
    - where participants can consent for themselves but are particularly susceptible to coercion, their interests will be protected by making shared decisions including the person and their family.
    - If a participant loses capacity to consent during the study, the researcher will suspend the collection of samples for that participant and liaise with the family to ensure the person is supported and to discuss whether it is appropriate to continue with the study in their best interests. (Signs that the person is losing capacity to continue with the interview may include inability to concentrate, becoming distracted, struggling to understand or answer questions appropriately, any signs that the person is feeling pressure or embarrassment such as stammering, flushed face and sweating.) The Lead Researcher and all Namaste Caregivers commit to remaining watchful and sensitive to any signs of fluctuating capacity and to place the welfare of the participant as central to the process.

- Where participants **<u>do not</u> have capacity to consent**, a consultee process was carried out. The main caregiver then gave proxy consent if appropriate. Proxy consent decisions were discussed carefully with the family and considered:

    1. The participant's previous views and wishes about participating in research.
    2. Their current health and social needs.
    3. The needs of the main carer to ensure the research does not add any carer stress.

Non-verbal signs of assent from the person living with dementia at all interactions will also guide any contact.

- All participants signed a consent form (i.e. provide written informed consent) prior to taking part in the study. Where participants were unable to consent, their main carer signed by way of proxy consent giving.
- The partner organisation was aware of any physical or communication access needs that the individual required due to the nature of the participants contact with that service (as a staff member, patient, or family member.) The partner organisation advised the researcher accordingly.
- Access needs were discussed with the participant (and their family where necessary) when the researcher makes initial contact so that appropriate arrangements can be made to enable to participant to take part in the research. This may include physical access requirements or communication support such as augmentative alternative communication aids. In the case of non-English speaking participants, a translator for verbal and written information could be arranged by Durham University.

Data protection and patient confidentiality

The study will comply with the requirements of the GDPR 2018 and Data Protection Act 2018 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

To protect personal information, consideration was given to how it was collected, kept secure, and maintained. This involved:

- The creation of coded, depersonalised data where the participant's identifying information is replaced by an unrelated sequence of characters.
- Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.
- Limiting access to the minimum number of individuals necessary for quality control, audit, and analysis.
- The confidentiality of data will be preserved when the data is transmitted to sponsors by ensuring only depersonalised data is shared.
- The data will be stored for 5 years.
- The data custodian is Professor Paul Chazot, Biosciences, Durham University .

Phase 2 Data Collection Methodology

Basic demographics were noted anonymously for each participant (age, gender, type of dementia.) Much more detailed information regarding medications being taken and co-morbidities would be relevant to a more in-depth study into the effects of Namaste Care. For this study, given the aim of testing measures, it was felt to be necessary to collect medical history information.

Heart Rate measurement method

Resting heart rate data for 6 participants living with dementia and 8 participants without dementia was collected. Resting heart rate was not collected for caregivers due to the logistics of the session.

Due to ease of data collection and minimal effort for the participant, the original plan to measure heart rate using a FitBit was amended, and a finger pulse oximeter was used to measure in beats per minute. At the beginning of each Namaste Care session, once the participant had settled, the oximeter was placed on the participants index finger, with their arm resting below heart level. Once a stable heart rate was established the value was recorded. This was repeated at the end of the session for comparison and the result recorded.

Measuring heart rate variability was also considered, but given the short duration of the intervention, it would be unlikely to significantly affect heart rate variability given that it is a measure of general health and wellbeing, and not short-term variation.

Facial Imaging/Nose tip temperature method

-4 out of 6 participants living with dementia consented to the facial imaging method

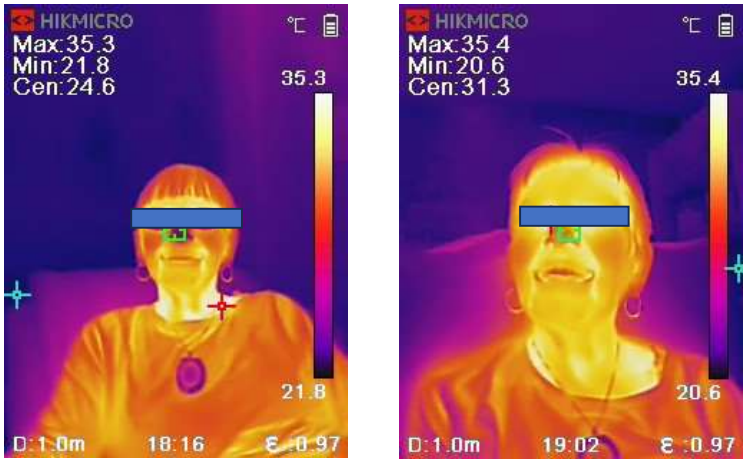
-5 out of 8 participants without dementia consented to the thermal imaging method.

-Thermal imaging was not collected for caregivers due to logistics of the session.

Nose tip temperature was taken using a HIKMICRO thermal imaging device with a thermal sensitivity of 40mK and a resolution of 160 x 120 px.

The temperature readings were taken at the start and end of the Namaste Care session when a thermal image was captured. The handheld camera was pointed at the participants face at approximately 1 metre.

A thermogram was captured as shown in figure 5.



Start of session **End of session**

Figure 5 Thermographic image showing nose tip as area of focus for temperature reading

Urine Sample Collection, processing and storage method

Equipment

Cardboard disposable urine collection cups for women

Cardboard disposable urine bottles for men

50ml Falcon centrifuge tubes

Cool box containing ice packs

P1000 pipette

15ml Falcon tubes

Baseline measure

Once the day and time of sessions was agreed with the participant, a baseline set of 2 urine samples was arranged. These urine samples were collected at the times that would be the start time and end time of the Namaste Care session but were taken the week before sessions started. This was to allow for adjustment of the cortisol results against baseline to reflect the circadian rhythm of cortisol.

Further urine samples were collected at the **start and end of session 1 and 4.** This was to compare whether the response to the session changes once it is familiar.

Procedure for urine sample collection:

Participants were asked to wash their hands and were given the following instructions:

Start of session

- Take the **red labelled specimen container** and remove the lid ready.
- Using the cardboard disposable urine collection cup (women) or directly into the red bottle and funnel (men), collect a urine sample.
- Transfer the urine collected into the red labelled specimen container.
- Screw the lid of the container shut.
- Wash your hands thoroughly.
- Place the red labelled specimen container containing the urine in a plastic bag and place in the cool box.
- Record the time the urine sample was collected on the sheet in the cool box.

End of session

The instructions were repeated for the end of the session, but the participant was asked to transfer the urine into the green topped specimen container. The Namaste Caregiver and/or family carer checked that the correct colour coded container was selected.

At the end of the session, the samples were transported to the lab by the researcher. The samples were then centrifuged at 1000 rpm for 20 minutes to separate the supernatant from the cellular material. A P1000 pipette was used to take off 10 ml of the supernatant and transfer to a labelled 15 ml Falcon tube. To avoid repeated freeze/thaw cycles 2ml of each of the samples was aliquoted into 15ml Falcon tubes.

Sample stabilisation:

Ellie Saunders conducted tests to determine if the addition of an antioxidant would maintain analyte stability.

She reports:

"A ten-fold stock solution of antioxidant was made using 10 mM ethylenediaminetetraacetic acid (EDTA) and 40 mM sodium metabisulphite ($Na_2S_2O_5$) and stored in a 1 L borosilicate glass bottle at 4ºC. 30 μL of antioxidant stock solution was added to 300 μL urine in Eppendorf tubes belonging two control samples, resulting in two 330 μL antioxidant-containing samples which were assayed alongside two neat 330 μL samples using a human DA enzyme-linked immunosorbent assay (ELISA) kit. DA concentration in urine was then determined with and without an EDTA/$Na_2S_2O_5$ antioxidant and analysed using a paired t-test, which revealed higher DA concentrations in samples containing the antioxidant, suggesting its role in maintaining analyte stability and enhancing biomarker detectability. The EDTA/$Na_2S_2O_5$ antioxidant was then added to all existing and newly collected samples prior to freezing in a ratio of 1:10 of antioxidant to urine."
The samples were then stored at -20 C (short term human urine storage guidance.)

Namaste Care Session procedure

Consideration was given as to whether it was possible to provide a standardised Namaste Care session to ensure consistency of approach, as individual variations may skew results. This was a problematic area, given that the nature of the Namaste Care approach is personalised to people's interests, preferences and sensory profile. It was decided to attempt to maintain a substantial degree of similarity for the purposes of this study, allowing for small variations in, for example, choice of drink and snack, poem or reading used and choice of massage wax.

Equipment used

- Songbird massage waxes x 3 (Balance, Relaxation or Mountain Forest)
- Kindle containing a range of music
- Towels and pillows
- Poetry books (Pam Ayers, Nature poems)
- Blanket
- Drinks and snacks chosen by participant

Namaste Care Standardised Session Procedure for this study

When	Activity	By whom	Approx timings
Prior to session	A urine sample is obtained in the container marked 'Before' in red, half an hour before the Namaste Care session begins.	Participant (and family carer if assistance is needed)	5 mins
Preparing for the session	Namaste Caregiver checks with the participant and /or carer about how the recipient is and whether there is anything they need to know before the session starts.	Carer and Namaste Caregiver	5 mins
	The room to be used is prepared- change of lighting, chosen music playing, favourite smell in the room.	Namaste Caregiver	5 mins
During the session	Greeting the recipient in their chosen way and establishing a connection. Gaining eye contact and interest. Checking for verbal consent or non-verbal assent to continue.	Namaste Caregiver	5 mins
	Resting heart rate is taken using the pulse oximeter		
	A facial scan photograph on week 1 and week 4 if consent given.	Namaste Caregiver	1 min
	Taking time to ensure the recipient is comfortable, using cushions and pillows if needed to support limbs. Tuck the person in lightly with a blanket.	Namaste Caregiver	5 mins
	Encouraging the recipient to take a drink and have a favourite snack.	Namaste Caregiver	5 mins
	Engaging the recipient in the chosen session activity (eg. reminiscence, chatting.)	Namaste Caregiver	10 mins
	Encourage recipient to take more to drink	Namaste Caregiver	5 mins
	Offer hand, foot and/or scalp massage	Namaste Caregiver	15 mins
	Short reading	Namaste Caregiver	5 mins
	Resting heart rate measure taken	Namaste Caregiver	1 mins
	A facial scan photograph on week 1 and week 4.	Namaste Caregiver	1 min
	Bringing the session to a close and saying goodbye	Namaste caregiver	5 min
After the session	The session outcome form is completed, and the Namaste Caregiver feeds back to family carer.	Namaste Caregiver	5 mins

	Next visit is arranged.		
	Within 5 minutes of the session ending, a further urine sample is obtained in the 'After' green labelled container.	Participant (and family carer if assistance is needed)	5 mins
	Urine samples are transported to the lab by researcher	Researcher	

Table 7 Standardised procedure for study Namaste Care sessions

The 4 Namaste Caregivers were asked to work to this procedure as closely as possible.

Data Analysis

Method for the measurement of urinary biomarker concentrations

Cortisol

ELISA kit used: Human COR ELISA by MyBioSource.

This is a double antibody sandwich ELISA where the Cortisol binds to the pre-coated surface (capture antibody) and any unwanted antibody remains unbound and is washed out. Incubation then takes place using a secondary detector antibody, followed by incubation with an enzyme-conjugated antibody, before a substrate is used to develop the colour for plate reading.

Dopamine

ELISA kit used: Human DA ELISA by MyBiosource.

This 2-site sandwich ELISA employs a pre-coated surface using a HRP-labelled enzyme and TMB substrate that the Dopamine binds to. Any unbound antigen is washed out. Incubation then takes place with an enzyme conjugated antibody and a substrate is used to develop the colour for plate reading.

The *full methodology* for the Elisa Testing can be found in **APPENDIX A3.**

Statistical analysis of the data collected will be carried out using GraphPad PRISM software.

5.3 Phase 2 Results

The results are organised by overall data and analysis by group, followed by an example presentation of the results for an individual with accompanying researcher notes.

- 5.3.1 Observational Measure pilot testing of revised measure
  - a. Reliability of the measure
  - b. Results of participants' Namaste Care sessions 1 and 4 outcome measures
- 5.3.2 Resting Heart Rate
- 5.3.3 Urinary Cortisol
- 5.3.4 Urinary Dopamine
- 5.3.5 Facial Temperature
- 5.3.6 Example of overall results presented for an individual participant
- 5.3.7 Case studies- see notes *
- 5.3.8 Participant feedback

N	**=20**
People with a diagnosis of dementia	=8
Healthy individuals	=8
Namaste caregivers	=4

Table 8 Participants numbers

***Notes:**

Two of the people living with dementia were not appropriate for obtaining biological samples due to their advanced condition and unwillingness of care home staff to assist with sample collection. The experience of these two participants was written up as case study examples of a narrative form of evidence.

Despite having trained 14 university students and staff as Namaste Caregivers, only 2 from that group chose to assist with the study and 1 person proved to be unreliable in terms of attending planned sessions. A decision was therefore taken for me to act as researcher/Namaste Caregiver for the remainder of the participants. The benefit of this was consistency of approach, but it meant that opportunities for data collection from Namaste Caregivers was limited, and recruitment numbers were lower than planned.

Observational Measure Pilot testing or revised measure

a. Reliability of the measure

The Namaste Care Session Outcome Measure was tested on wards and in the community in Tees, Esk and Wear Valley NHS Foundation Trust (TEWV,) Cumbria, Northumberland, Tyne and Wear NHS Trust (CNTW,) Whipscross Hospital's new Namaste Care Service, St Cuthbert's Hospice Namaste Care groups, and during participant visits.

Feedback from Whipscross Hospital was that it was easy to use without the need for training.

Feedback from CNTW was that they were using the measure widely in their dementia service and that the version updated since phase 1 did not in their opinion require any further changes. Unexpected outcomes for the measure are that they are additionally using the measure to inform assessments and formulations. They are also using it as the basis for supervisory discussions and staff development in terms of observational skills.

Inter-rater reliability scoring was carried out by staff within TEWV and by researcher and a Namaste Caregiver during participants visits. The resulting scores were analysed as follows, to establish a % variance and therefore the level of reliability for the Version 2 of the score.

See overleaf:

NCSOM Inter-Rater scoring and reliability calculations												
	Rater 1	Rater 2	% Variance	Rater 1	Rater 2	% Variance	Mean	SD	%CV	Mean	SD	%CV
Date	Before	Before		After	After		Before	Before	Before	After	After	After
30.8.23	32	36	11.10%	47	49	4.10%						
Measure amended due to feedback from phase 1												
4.9.23	35	30	16.60%	43	37	14%	32.5	3.5	10.9	40.0	3.0	7.5
13.9.23	30	31	3.20%	41	43	4.80%	30.5	0.7	2.3	42.0	1.0	2.4
25.1.24	36	34	5.90%	43	41	4.90%	35.0	1.4	4.0	42.0	1.0	2.4
1.2.24	35	37	5.40%	44	43	2.30%	36.0	1.4	3.9	43.5	0.5	1.1
13.2.24	31	29	6.90%	42	40	5.00%	30.0	1.4	4.7	41.0	1.0	2.4
12.3.24*	26	39	33.80%	31	40	22.50%	32.5	9.2	28.3	35.5	4.5	12.7
12.3.24*	26	37	29.70%	27	29	6.90%	31.5	7.8	24.7	28.0	1.0	3.6
12.3.24*	29	43	32.50%	33	43	23.20%	36.0	9.9	27.5	38.0	5.0	13.2
13.03.24*	24	41	41.50%	31	42	26.20%	32.5	12.0	37.0	36.5	5.5	15.1
22.3.24*	33	45	26.60%	35	45	22.20%	39.0	8.5	21.8	40.0	5.0	12.5
09.05.24*	25	43	41.80%	35	45	22.20%	34.0	12.7	37.4	40.0	5.0	12.5
09.05.24*	23	38	39.50%	31	43	27.90%	30.5	10.6	34.8	37.0	6.0	16.2
Average			23.62%			15%						

Table 9 NCSOM Inter rater scoring and reliability calculations

Overall variance = 19.4%

Inter-rater reliability (IRR) = 80.6% percentage agreement between raters >75% considered reliable (https://www.statology.org/inter-rater-reliability/)

Note: *Denotes scores recorded in a clinical ward setting. Higher variance in inter-rater scoring within a clinical setting as compared to a community setting.

Co-efficient of variance (SD = standard deviation)

Green= less than 15% variance

Yellow= between 15 and 25% variance

Red= more than 25% variance

The inter-rater reliability scores show an 80.6% agreement, which as a score above 75% therefore reflects reliability. A stronger score would be produced from a greater number of testing episodes, and it is evident that there was less agreement within a clinical setting on the before score but general higher level of agreement at the end of the session. This was discussed with a representative from the NHS Trust which provided the information and will be considered as part of the discussion section.

b. Results of participants' Namaste Care outcome measures

In terms of results of the outcome measures completed by the Namaste Caregiver based on observations of study participants at the beginning and end of the session, the results can be expressed as follows.

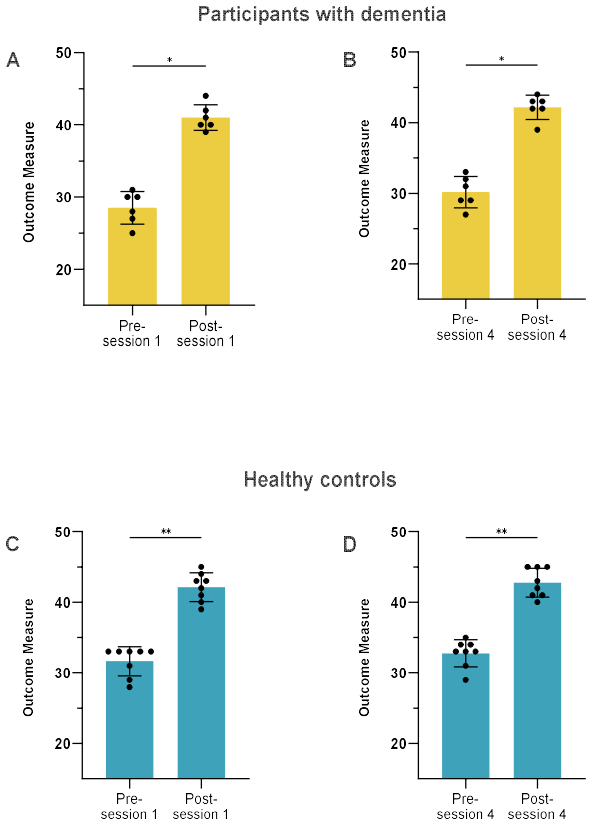


Figure 5 Pre *and post session Namaste Care Outcome Measures scores for people living with dementia, healthy controls were analysed with Wilcoxon matched pairs signed rank test demonstrating a significance in results for people living with dementia and a greater significance in the healthy controls.* *Significance * P<0.05 **p<0.01 ***p<0.001*

Analysis of the NCSOM scores were significant in showing consistent improvements in wellbeing by the end of a Namaste Care session for all participants. It is noteworthy that the starting wellbeing measure score was higher in session 4 (graphs B and D,) as compared with session 1 scores (graphs A and C.) This may point to a longer-term benefit of the sessions, or the positive anticipation of participants for the session.

Also of interest is the stronger significance of the increase in wellbeing scores for the healthy control group, when compared to those living with dementia. This may be due to the filter of dementia symptoms affecting wellbeing in the dementia patient group, this showing a slightly dampened response to the session.

Resting heart rate (HR)

Obtaining the heart rate result proved simple and highly feasible means of data collection, producing the following results.

Average HR, representing beats per minute:

Start of session 1	End of session 1	Start of session 4	End of session 4
72.9	62.5	70.7	62

Table 10 Summary of resting heart rate averages

Resting heart rate dropped significantly from the start to the end of the session. On one occasion a participant's heart rate remined the same, a contributing factor being that he was on edge about being on time to attend an appointment after the session. Another participants' heart rate increased at the end of the session; however, this followed a significant disruption to the session. These two results are therefore explainable as differing from the main trend of significant decrease in heart rate. It must also be noted that the heart rate increase due to a disruption has therefore affected the average for end of session 4.

All participants where heart rate was measured= 14 people. (Due to logistics, the caregiver heart rate was not measured.)

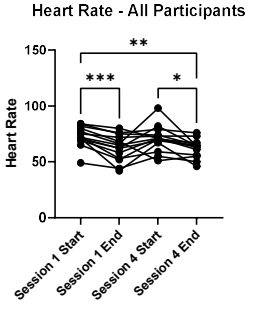


*Figure 6 A summary of all participants' resting heart rate results at the start and end of session 1 and session 4. Analysis using one-way Anova showed significance across all groups. Significance * P<0.05 **p<0.01 ***p<0.001*

Heart rate dropped overall from the beginning to the end of the session when the result for people living with dementia and the healthy control group was calculated together. That drop in beats per minute was most significant in session 1, compared to session 4, and was also significant from session 1 to session 4.

The measurement of the heart rate proved the most straightforward and quick measure to use in terms of logistics, fitting into the start and end of the session unobtrusively.

Looking at the results according to the 2 different groups measured leads to a difference in significance being identified, as follows:

Analysis By Group

6 x Participants living with a dementia. Each line denotes 1 participant tracked across 4 measurement points.

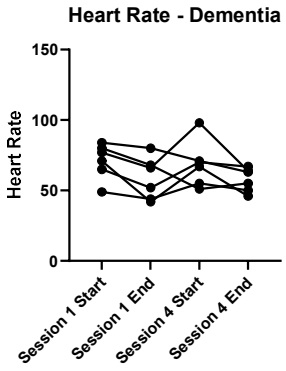


Figure 7 Resting heart rate results for the beginning and end of sessions 1 and 4 for people living with dementia. An analysis using one-way Anova showed no significance.

Despite an overall fall in heart rate across session 1 and session 2, this result was not significant for the participants living with dementia. This could be due to the elevated baseline cortisol levels in this group shown in the baseline testing of cortisol (see results for urinary cortisol.) This ability to compare against the results of other measures demonstrates the power of triangulation of results to assist in a fuller understanding of mechanisms involved.

8 x Healthy control participants. Each line denotes 1 participant tracked across 4 measurement points.

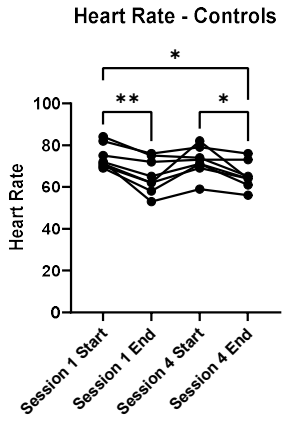


*Figure 8 Resting heart rate results taken at the beginning and end of session 1 and 4 for healthy participants/controls. Analysis using one-way Anova showed a significant reduction in heart rate by the end of the session, especially in session 1. Significance * P<0.05 **p<0.01 ***p<0.001*

Heart rate dropped overall from the beginning to the end of the session for healthy control participants. That reduction in beats per minute was most significant in session 1, compared to session 4, and was also significant from session 1 to session 4.

The higher number of healthy participants than people living with dementia does give the healthy control group greater power in calculations.

This pattern of significance is confirmed in a series of paired T-tests as follows, where * denotes significance as follows:

Confirming significance using T Test analysis of heart rate results

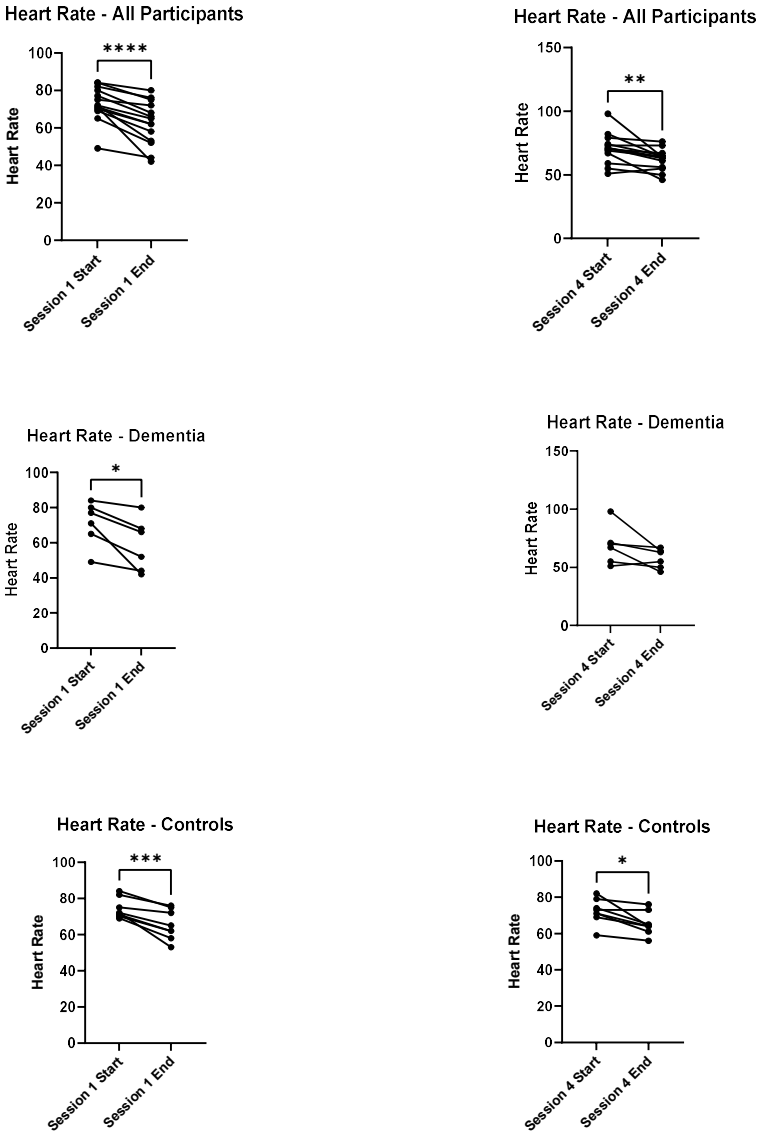


*Figure 9 Heart rate analysis using paired T-test to confirm strongly significant results. Significance * P<0.05 **p<0.01 ***p<0.001*

Results of urine sample testing

General comments on feasibility

Collection of urine samples in a community setting and transporting them promptly to the laboratory for processing proved time intensive and the availability of one researcher for this task limited the number of potential participants for the study. The laboratory process was a specialist procedure which would have been more suited to a multi-disciplinary team where specialist tasks could have been allocated according to expertise. One participant living with dementia showed signs of increased stress (performance anxiety) at being asked to produce a urine sample, which would both affect the result and proved to be an ethical challenge that needed to be worked through with his family carer. Providing sufficient volume of urine was not an issue for any participants.

Urinary Cortisol Results

Giving the participants choice on time of day for the session to take place, as you would for any Namaste Care session, meant that direct comparison between participants was less meaningful than if session time had been more tightly controllable, given the circadian rhythm of cortisol.

The most striking result from the cortisol sampling was the **baseline measure results**. These showed a significantly higher level of cortisol in the urine of people living with dementia, when compared to the healthy control participants and the Namaste Caregivers.

Baseline cortisol levels separated by group:

PWD =people with dementia / HC= healthy control / CG= Namaste caregiver

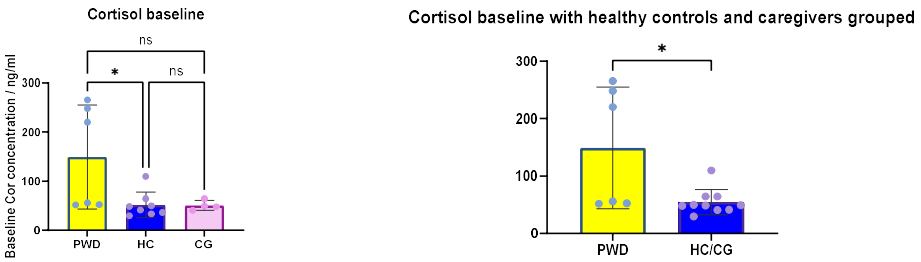


*Figure 10 Baseline cortisol levels (no Namaste Care session) showing people living with dementia (PWD) having significantly higher baseline levels than those without dementia (HC and CG.) One-way Anova with Tukey's multiple comparisons test applied. Significance * P<0.05 **p<0.01 ***p<0.001*

Representing cortisol levels according to the time-of-day samples were collected showed the following:

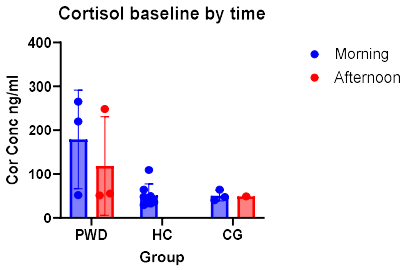


Figure 11 Cortisol levels depending on time of day collected showing a higher reading for people living with dementia in the samples taken in the morning which matches the expected circadian rhythm of cortisol.

Again, expressing the results by time of day demonstrates the higher levels of cortisol of participants living with dementia both in the morning and afternoon sessions, compared to the healthy control and caregiver groups. None of the healthy control participants chose to have afternoon sessions, hence the absence of a red bar in the figure above. Of note is the fact that the cortisol levels were lower in the afternoon for people living with dementia, but this difference was less marked in the caregiver samples.

Although this is a small sample, the results do correspond to the reports of people living with dementia telling us that they feel anxious all the time and have low stress tolerance. Studies have identified stress as a causative factor in developing dementia (eg. Vellapandian, 2023, Canet et al, 2019) and therefore this result adds weight to the idea that stress reduction as a therapeutic target could be a mechanism both for the prevention and the treatment of dementia.

Looking at the overall results for urinary cortisol presented overleaf, there is a general trend towards lower cortisol levels by the end of a Namaste Care session, however the results do not show significance as compared to the heart rate results, and no correlation was found between the heart rate and cortisol results.

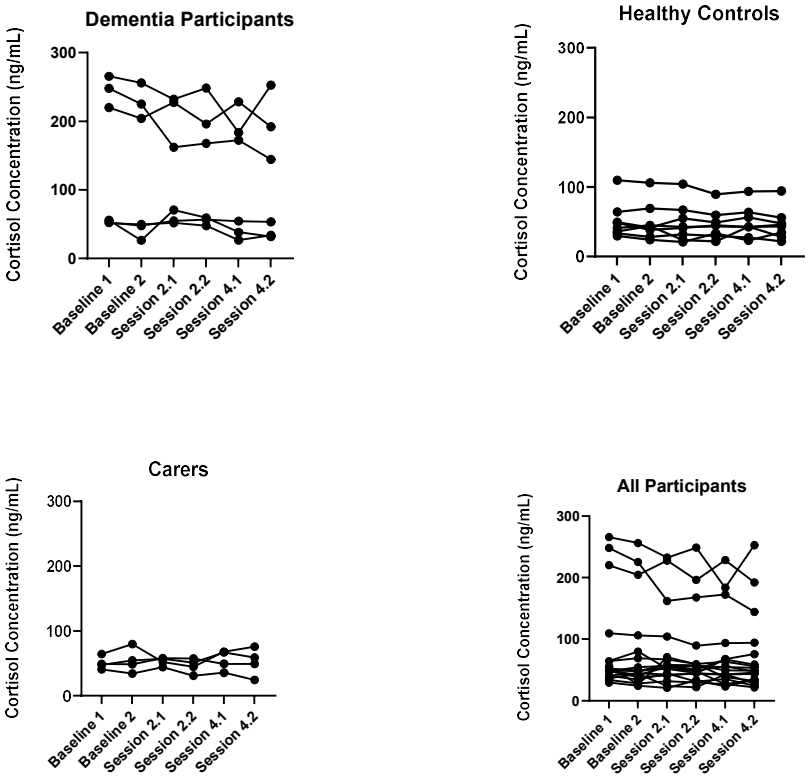
Clear exceptions to the trend of lowered cortisol lie particularly among the participants living with dementia, some of whose cortisol level can be clearly seen increase from the beginning to end of 1 and session 4. The results demonstrate the difficulty in analysing as a group, where meaning is not clear. Reporting by individual participant alongside the other measures taken is demonstrated as an alternative to result presentation in section 5.6.1 below.

Namaste Caregiver results may have been skewed by the researcher as caregiver urine samples showing increased stress due to trying to co-ordinate data collection in sessions. This may not have been the same result in a standard Namaste Care session.

Overall results for the urinary cortisol sampling were as follows:

Urinary Cortisol results

Each line denotes 1 participant tracked across 6 measurement points



Measurement points:

Baseline 1: Same day of the week and time as the planned start of the Namaste Care session but no session.

Baseline 2: Same day of the week and time as the ending of the Namaste Care session but no session.

Session 2.1: First session start time

Session 2.2: First session end time

Session 4.1: Fourth and final session start time

Session 4.2: Fourth and final session end time

NB Carers= Namaste caregivers, not family carers

Figure 12 Series of analysis for urinary cortisol. Results were analysed with groups separated and then all participants. All timepoints were analysed by Friedman Test, with multiple comparisons corrected using Dunns. No significance found.

Urinary Dopamine

Comparing baseline dopamine levels by group did not show any significant differences between the participant groups as compared to the cortisol baseline results.

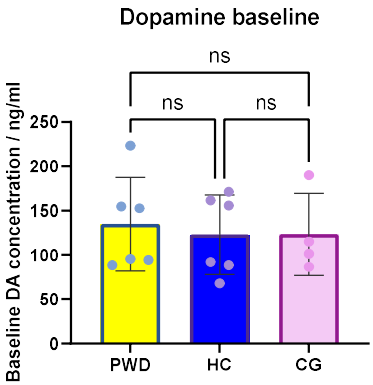


Figure 13 Dopamine urinary concentration at baseline (week prior to Namaste Care sessions) compared by group. No significant differences found using one-way Anova and Forsythe Brown Test

The results for urinary dopamine presented overleaf only show one significant trend, and that is a generally higher level of dopamine and the start of session 4. This may be due to a positive anticipation for the session, following the participant experience of previous sessions. The level of dopamine measured however shows no clear trend of increasing or decreasing across the session, with results being very individual in nature.

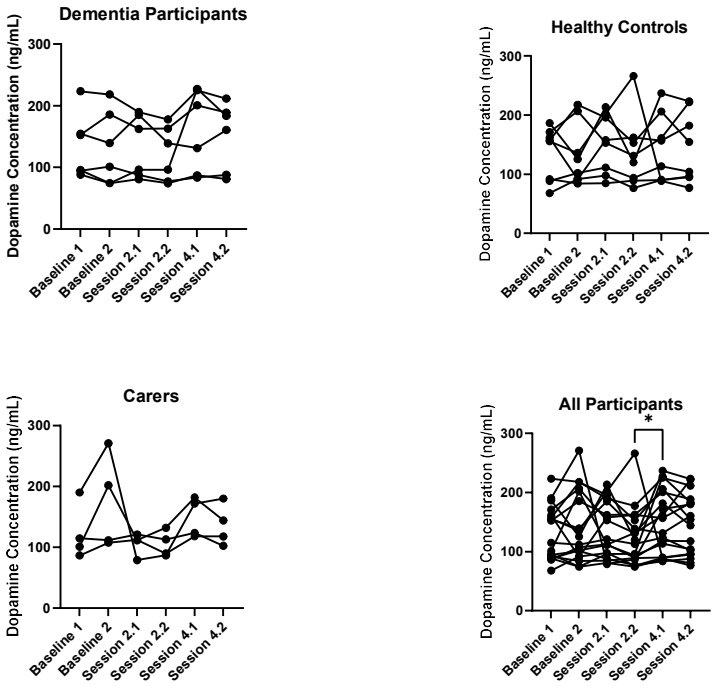
The dopaminergic system has been found to be severely impaired in people with Alzheimer's Disease and other dementias, meaning that dopamine as a measure of wellbeing and feelings of pleasure may not be a useful and reliable biomarker.

It is also possible that the results for session 4 in particular were affected by the participant knowing that this was their last session, as they all expressed sadness that sessions were coming to an end.

Overall results for the urinary cortisol sampling were as follows:

Urinary Dopamine results

Each line denotes 1 participant tracked across 6 measurement points



Measurement points:

Baseline 1: Same day of the week and time as the planned start of the Namaste Care session but no session.

Baseline 2: Same day of the week and time as the ending of the Namaste Care session but no session.

Session 2.1: First session start time

Session 2.2: First session end time

Session 4.1: Fourth and final session start time

Session 4.2: Fourth and final session end time

NB Carers= Namaste caregivers, not family carers

*Figure14 Results were analysed with groups separated and then all participants. All timepoints were analysed by Friedman Test, with multiple comparisons corrected using Dunn's. Significance * P<0.05 **p<0.01 ***p<0.001*

Facial Temperature Imaging

Analysis of nose tip temperatures recorded at the beginning and end of session in those participants who agreed to this measure. Not all participants agreed to this measure and caregivers were not scanned for nose tip temperature.

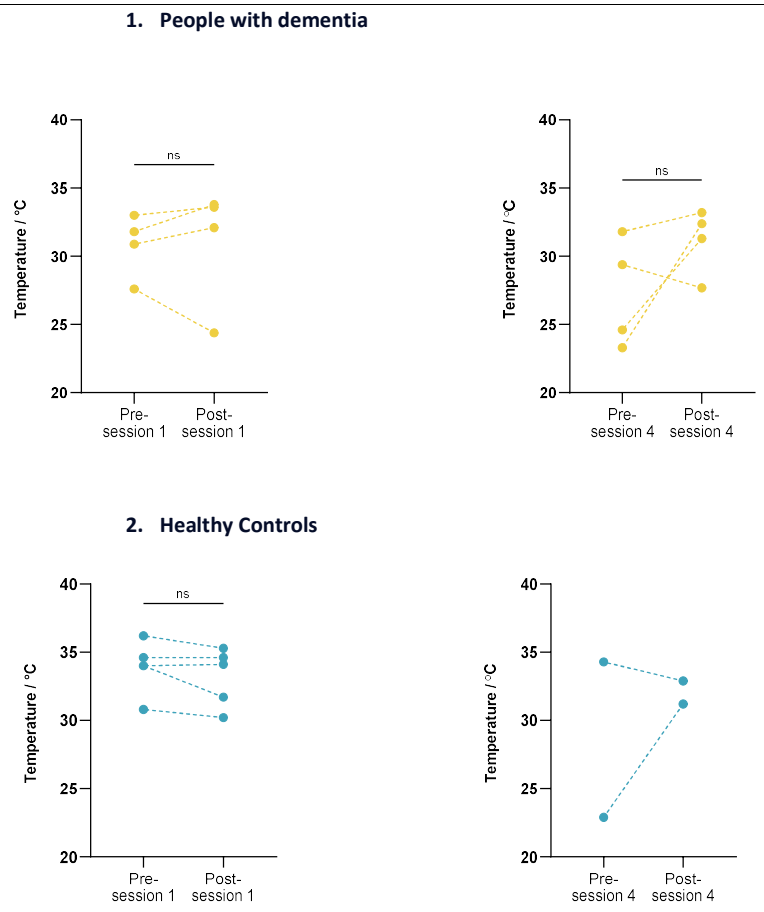


Figure 15 Nose tip temperatures analysed by Wilcoxon Test. No significance found.

Trends identified in the data were that people living with dementia tended to experience an increase in temperature from beginning to the end of the session, whereas the healthy controls generally experienced a drop in temperature.

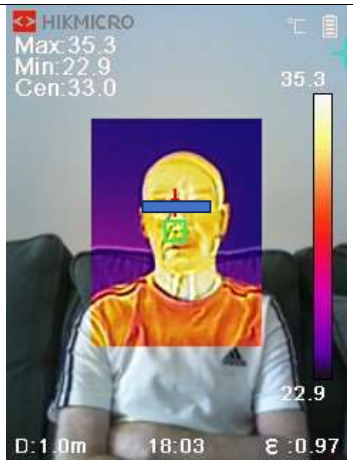
Example results of an individual participant

Expressing the results for one individual participant, alongside session notes.

Green Indicates a positive result indicating the participant was more relaxed. The Pink highlights that his dopamine levels did not increase.

Table 11 Collated results for participant A1

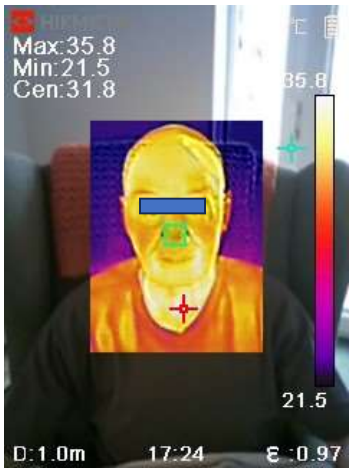
Participant ID	**Age**	**Gender**	**Diagnosis**	
A1	74	Male	Alzheimer's Disease	
Heart rate (BPM)	**Start session 2 10.50am**	**End session 2 12 noon**	**Start session 4 10.20am**	**End session 4 11.10am**
	77	↓ 66	98	↓ 64
Facial Temp. *C	**Start session 2**	**End session 2**	**Start session 4**	**End session 4**
	33	33.6	31.8	33.2
Cortisol (ng/ml) % change from baseline measure actual cortisol	**Start session 2**	**End session 2**	**Start session 4**	**End session 4**
	-12.442562	-2.9118762	-30.805374	-1.3519425
Dopamine (ng/ml) % change from baseline actual dopamine	**Start session 2**	**End session 2**	**Start session 4**	**End session 4**
	-15.110715	-18.609393	0.6686157	-3.1471768
Session 2 Thermal images:				



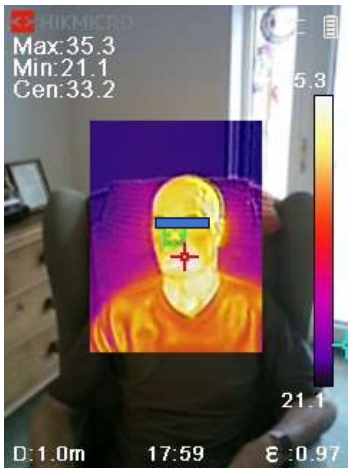
Before

After

Session 4 thermal images



Before



After

Notes

NB. This participant was not able to give urine samples at session 1, so the samples were taken for session 2 and session 4.

This participant chose to have very little verbal interaction, as his verbal communication was severely affected by his dementia, and he struggled to convey what he wanted to say.

His wife thought that he needed help to relax, and that he would enjoy massage. In this case, the participants wife very much acted as enabler for the sessions to take place.

The session started with my preparation of the room whilst he and his wife went to get the urine sample. The participant returned to the room to sit in a high-backed chair, and I would make him comfortable with his feet on a foot stool, a pillow behind his head, a blanket over him and his hands on another pillow. I then took his heart rate measurement and thermal image. I noted it was often difficult to hold the thermal imaging camera steady.

He liked the flavour of ginger, and so I offered him a cool cordial or ginger and lemongrass to drink given that it was the summer. He liked chocolate but declined my offer of a chocolate to eat by shaking his head and patting his stomach.

The participant requested the session to be mainly related to massage. We started with a hand massage, then a foot massage. I also massaged his lower leg, as he and his wife reported that he sometimes had painful spasms in his calf muscles. He said that this did ease the pain. I ended the massage with a scalp massage which he reported was his favourite part and often sent him to sleep.

I chose funny poems by Pam Ayers to read after the massage, usually raising a smile.

Having found out the background of this individual, I reflected on the fact that he liked to keep busy and so for him, doing an activity rather than simply receiving care may have been more rewarding for him. As it was, his dopamine levels did not increase during the session. In this case, the session seemed to act more as a form of stress relief, or relaxation activity and this is reflected in the heart rate and cortisol data. It is notable that compared to baseline, this participant was much more relaxed even at the anticipation of the session starting by session 4, perhaps indicating that trust and an expectation of relaxation had been established.

Across both sessions, there was an increase in nose tip temperature, potentially indicating positive emotion. In terms of explanation for the lack of increase in dopamine, having found out personal history and preferences of this participant, it was apparent that what he found rewarding and pleasurable was being active and achieving tasks, which was not an element in the standard sessions offered, but would have been included had the session not been standardised for the purposes of research. He therefore clearly experienced relaxation from the session, but less sense of reward.

Case studies

In both cases the participant was referred to the study by a hospice-based Admiral Nurse. One of the participants was also registered with Join Dementia Research. Both case study participants had advanced dementia, but for differing reasons, it was judged to be not in their interests to provide physical data and samples, therefore writing up the Namaste Care sessions as case studies was agreed to be the most appropriate means to gather information. Proxy consent for both participants was given by their next of kin, having provided the participant information to them to consider and having discussed their needs carefully. Some details have been altered to protect the participant's identity.

Case Study 1

Joan is 85 and lives in a small residential care home on the outskirts of Durham city. She has lived in this area all her life and worked in a local laundrette for many years, being well known to the locals. She loved socialising and regularly went with her husband to the working men's club. She loved bingo, dancing and gossiping with her friends. She had always taken a pride in her appearance, liking her hair done and wearing nice clothes. Joan's husband died 10 years ago, and she has been 'a bit lost' ever since. She was diagnosed with Alzheimer's Disease in 2019. Joan's only daughter lives in Aberdeen, and she has no surviving friends and family who would visit her.

On contacting the residential care home to arrange the first visit, I was informed that they would not allow Joan to be part of the study as she could not consent. I explained that proxy consent was acceptable in this case, but the manager would not agree. She however suggested that I could visit 2 people in the home who were at the end of their life but who could consent, giving me their names. With various negotiations around this, it was agreed I could visit Joan to offer her Namaste Care sessions and write up the outcome, but that the staff would not help Joan to give urine samples, heart rate or any of the other measures. I was not clear if they felt strongly about the consent issue, whether they thought it was not in her interests, or if they did not want to take on an extra task for staff.

At my first visit, I was met by staff who commented sarcastically that I must like a challenge. They told me that Joan could be verbally and physically aggressive and that I should 'watch myself.' This had been mentioned in the referral from the Admiral Nurse, but she had seen no signs of this behaviour during her visits. As I signed in, I could see that a lot of the

residents were in the lounge listening to a singer. However, I was directed to Joan's room as "she would have created a right commotion" if she'd been in the lounge.

When I arrived at Joan's room, the door was open, and she was sitting looking out of the door. There was no TV, radio or music playing, and Joan was sitting in a puddle of spilled coffee which was over the table next to her, and on the floor around her feet, soaking the bed socks she was wearing. Her coffee mug was empty, so I do not know if she had managed to drink any. From the sense I had gained of Joan from her daughter, I greeted her in a lively, upbeat way, telling her who I was and asking if I could spend some time with her. She readily agreed with a beaming smile. I cleaned up the spilled coffee and changed her bed socks for her.

Joan was chatty and interested in me, sitting herself more upright in her chair, uncrossing her arms and reaching out to hold my hand. She decided on 50's music to listen to and chose a chocolate biscuit to eat along with the carton of orange juice I had taken her to drink. Joan has had frequent urine infections, and I was aware she needed encouragement to drink. Joan was unable to hold the carton herself, although she seemed determined to keep trying. She accepted me helping her to hold it steady so she could have a drink from the straw. She smacked her lips and gave a satisfied 'ahhhh' when she'd had a good drink of the juice. We laughed and joked together, and she said it was good to have a friend. I asked if she'd like me to brush her hair, and she said "yes, put me straight, will you."

I offered Joan a hand massage and she said, "aw, you're a nice girl." She was quieter during the hand massage, watching intently what I was doing and sighing every now and then. She appeared to relax, her breathing slowing and some colour coming to her cheeks.

As I was preparing to leave, I asked if I could visit again, and she was very keen to say yes. She asked me to put the TV on for her, "to keep her company." There was no evidence of aggressive or agitated behaviour during my visit.

The following week when I visited, Joan was much more subdued. Again, she had spilled her drink, this time all over her trousers and seat. I called for staff to change her and clean up the spill. They seemed irritated at being asked to do this but did it in sullen silence. Joan seemed aware of this this and made sarcastic comments about them being workshy and not knowing what a good day's work was. She pushed them away when they were finished and turned her head away with disgust.

It was more difficult to engage Joan on this visit. When I offered her a choice of music, she asked for "something gentle," so I played her some very relaxing music. She did not want a

hand massage and was more abrupt when we were talking. The tea trolley arrived, and Joan's coffee was put in a cup with a spout this time. The staff put it on the table next to her and left. She did not initiate picking up the cup, but when prompted she attempted to have a drink. She could not handle getting the spout to her mouth or tipping the cup up enough to get a drink. She accepted me helping her again and took a biscuit from me but did not eat it. She did say it was nice to have a visitor, but that she was "out of fettle today." On leaving, I arranged to visit the following week.

I reported back to the Admiral Nurse about the issues Joan was having with drinking and the attitude of staff, so that she could offer support.

For the following few weeks, I was ill with a flu virus and unable to visit, and then when I rang to arrange to visit, I was told that Joan was also unwell, and it was not appropriate to visit.

As the end of phase 2 of the study was fast approaching, I managed to visit Joan one more time. She had lost weight and was a lot less responsive, looking pale and drawn. She was passive in receiving a hand massage and when I read to her, although she did make eye contact occasionally and attempted a smile. She shook her head when I offered her a biscuit, but she took a couple of chocolate buttons and some sips of juice. There was no sign of staff around to check on her during my visit. She appeared much frailer and more vulnerable, with a sense of 'giving up.'

I reported back to the hospice that I would be unable to continue visiting and they said they would try to get a staff member to pick up the visits for her, as she didn't have anyone else to visit.

Case Study 1- Reflexive notes

I was aware of feeling a great deal of frustration with the care home staff throughout my initial interactions and visits. The Care Home Manager had said that Joan was "in the wrong place" and that "we don't *do* dementia here" in my first conversation with her. I wondered if this was due to Joans 'difficult behaviour' and whether this attitude may have been different with someone living with dementia who was less 'trouble.' My concerns around the kind of care she was getting from staff grew when I saw her each time in puddles of liquid and with apparently very little attention from staff. The interactions between her and staff that I did see were tense on both sides.

Due to the warning that I'd received about Joan's behaviour, I approached the first visit with some feelings of nervousness, which proved to be unfounded. Joan was hungry for company and some physical support with her eating and drinking. I enjoyed spending time with her, especially during the first visit when we had lots of fun and banter.

I had feelings of guilt about Joan throughout and between my contact with her. Due to her lack of visitors, I felt I wanted to do more. This tension often arose when Namaste Care volunteers saw the situation the person they were visiting was in and led them to worry about them and their family carers between visits. It is the double edge of making a positive relationship but having to maintain appropriate boundaries and not attempt to 'rescue.' We often talked about this theme in volunteer supervision.

There is also an impact on the Namaste caregiver when they begin to see a deterioration in the person's condition, and I was also aware of this impact with Joan. The juxtaposition of researcher as Namaste caregiver felt extremely stark in this short series of visits. The feedback that I received from the referrer was that my visits were 'better than nothing' but they certainly felt like a drop in the ocean of Joan's needs. As she approached the end of her life, it did not feel like she was being honoured, respected or valued by the care home staff and that I had given only brief glimpses of those things.

The fact that I had to miss some visits due to illness also reminds me of a theme identified by volunteers at the hospice, in that their weekly visits had acted as a kind of monitoring of how the person with dementia was. They also acted as a barometer of carer stress levels, enabling feedback to the Admiral Nurse if issues were apparent or changes noted. There was a 'safety net' that families felt was in place in this situation with ongoing weekly visits. Due to the short period of time my visits happened over, and the gap due to illness, this monitoring function was never established and so a deterioration in Joan's symptoms was not picked up and reported back to the Admiral Nurse.

In summary, getting to know Joan brought moments of joy, but also feelings of frustration and sorrow at what I saw of her life. I was left with a strong impression that we need to do better in care services. Everyone deserves to spend their last years and months with comfort, happiness and peace.

Case study 2

Gill is a 67-year-old lady living with fronto-temporal dementia. She had recently moved into a large care home after her husband began to struggle to meet her physical needs at home, with the progression of her symptoms. Her husband visits her daily but is proactive in wanting Gill to have as much stimulation as possible and he was very supportive of her having Namaste Care visits. Given the extremely advanced nature of her symptoms, the fact that she was doubly incontinent and that obtaining urine samples would have potentially been an additional burden to her, it was agreed that I would spend some Namaste Care time with Gill and write up my observations as a case study. Her husband strongly advocated for her to be a part of the research, as she had expressed a wish to take part in dementia research when she had been diagnosed, and he wanted to respect her wishes. He believed that she would want to make a difference in whatever way she could, and he had no doubt she would have consented to take part.

Gill had worked as a nursery assistant and loved being busy. She enjoyed sewing and knitting and was known for the beautiful baby clothes she made. Her favourite music was country and western, and songs from musicals. While I visited Gill, her husband took the opportunity to go for a walk and read the paper.

When I initially visited and introduced myself, Gill watched me intently for a while before switching her attention to look out of the window. There was a bird feeder outside her window, and she appeared fascinated. I soon came to understand that Gill's attention came and went like this, and that moments of connection between us were punctuated with periods where she appeared lost in her own world.

I helped Gill to take frequent sips of juice and read to her. I noticed that she was very interested in touching things, and so I offered her the balls of wool I had taken, which she appeared to enjoy exploring. I played music from her favourite musical, Calamity Jane, and she seemed relaxed and content. She relaxed further during a hand massage, appearing to become sleepy with her eyes closing. She tried to speak on occasions, but it was unclear what she was trying to say. I reflected this back to her, saying that I understood she had things she wanted to say. She looked sad and nodded at that, reaching out to hold my hand. I did receive a clear 'yes' when I asked if I could visit again and a smile.

I visited Gill on 2 further occasions. Due to changes in her medication, she was sleepier during these visits, and she looked incredibly sad. Again, I read to her and played music. She found it harder to accept the sips of drinks I offered to her, but the care home staff

reported that generally she was eating and drinking well. Although it was thought that Gill was approaching the end of her life, she appeared hydrated and well nourished, and so it was unclear how long she had left to live.
Her husband fed back that he had enjoyed someone taking a close interest in Gill and having someone to talk to, given that they had not children that he could share the experience with. Last I heard, which was four months after I ended my visits, Gill was still alive and still watching her birds.

Case study 2- reflexive notes

The utter devotion of Gill's husband was both heart-warming and heart wrenching to witness. He was extremely active in her care and in advocating for her. He would talk to her about holidays and funny moments with friends, and she would look at him with a look that can only be described as love. At times, when I showed up and her husband went out for a walk, I felt like I was intruding on their time for my own reason's and had real mixed feelings about being there. However, her husband was keen for her to have a variety of visitors, and he valued my visits, as well as those of the Admiral Nurse.

I felt a deep sadness when I was with Gill, possibly because of empathy for her apparent sadness. I also wonder if it was partly due to her younger age. As a team during my time at the hospice, we often found working with people who were living with dementia at a younger age much harder. The feelings of loss seemed amplified. Loss of those years of retirement and all the plans that people had made. A sense of a life cut shorter than it could have been. These things impact the Namaste caregiver, although clearly not as profoundly as the person themselves and their family.

I was struck by the difference in the staff attitude in this care home as compared to the staff described in case study 1. The staff here seemed calmer, more compassionate and there was a more informal feel to arrival which put me at ease as a visitor. When we think about environment during Namaste Care, a key part of the environment that people are living in whilst in care is the one created by staff. It is not just about the physical environment, or the sensory environment, but there is a layer to the space which is filled by the attitude and approach of caregivers which is felt very keenly, for good or ill.

Gill also brought into focus for me the uniquely individual approach each person I have ever spent time with has taken towards living and die with the condition. Some, like Gill are quietly sad and wistful about it. Some, like Joan, rage against the disease until it wears them out. Whatever ways they choose to live with dementia,

it is a great privilege to be alongside them for part of that journey, but also one which I now realise takes an emotional toll on the caregiver.

Participant feedback comments

The feedback gained from participants and family carers about the Namaste Care sessions was entirely positive. Comments were noted at the end of every session and are summarised below by participant code.

NB. Namaste Caregiver comments were not recorded.

Participant	Comments
A1	Wife- I can see such a difference in how **relaxed** he is by the end of the session. We are so grateful for your visits.
A2	It is so lovely to have **someone to talk to.** I feel so **relaxed** by the end. You have a nice way about you, **gentle and calm**. I wish you could keep coming.
A3	Wife- He wouldn't have tried this I don't think unless it was research. But now he's tried it, he will **accept this type of care in future**. You have helped him to **relax**, which is hard for him as he is stressed a lot of the time. It's really lovely what you do, and I have enjoyed being in the room too.
A4	I enjoyed it very much. I feel spoilt. It's very **soothing and nice**.
A5	I want to help with research to make things better. I feel like **I can talk to you** and **you understand**. I look forward to the sessions. I like the hand massage, but the **head massage is the most relaxing**. It's all very **relaxing.** I wish it didn't have to end.
A6	I wasn't sure about this but I'm glad I tried it. It's lovely. I've never had a massage before. My hands feel so lovely afterwards. I feel I get on with you. You are **easy to talk to.**
A7	It's nice to have a visitor. You put me at ease. The music is **relaxing.**
A8	Husband- I like that she has someone other than me **visiting.** She loves to be **pampered.**
B1	This is time for me to **chill.** Really **lovely.**
B2	That's **nice**, that. It makes me **sleepy** and **relaxed**.
B3	It's very **calming.** I like the **head massage** the best.

B4	I wasn't sure what to expect, but it's been **fun.** I do struggle to **relax** and this has helped.
B5	I have **looked forward to the visits** and will be sad when they end. It's all very **lovely**. It makes me **feel special.**
B6	The music is nice, it's undemanding, it just washes over you. It's so relaxing, really beautiful. What's not to like? I think it works because you are a good listener, **you understand** and are tuned in.
B7	I definitely **slept better** at night after the session. The caregiver is so **lovely and kind**. She's a **good listener** too. I feel cared for. I have attention and reassurance. It **calms me down**.
B8	It's very **calming and relaxing**. The combination of everything, the music, the massage, helps you **switch off and enjoy**. It's **so peaceful.** The scalp massage is the **most relaxing.** I now **use the ideas** when I visit my mam in her care home.

Table 12 Summary of participant verbal feedback

The common themes highlighted by the feedback therefore are the **relational and calming** nature of the intervention, which was repeated by most participants.

Conclusion

Reflexive notes for phase 2

I was acutely aware of the juxtaposition of the familiarity of the home visits to deliver Namaste Care and the discomfort of applying a research lens to the sessions. When the central aim of a Namaste Care session is relational, the addition of data collection into the relationship felt intrusive. I experienced a deep questioning of 'who is this research for?' and a feeling of resentment that the intervention was having to 'prove itself.' That being said, the study participants did not show or express any signs that the data collection was a burden, other than the one participant who became anxious about providing a urine sample, and the reluctance of some participants to have the facial scan.

The various forms of data collection in sessions felt clumsy initially but became more efficient over time with practice. The heart rate measure was the quickest and least intrusive of the measures in practical terms and gave the clearest and most consistent results.

The standout result for me was the cortisol baseline measure. People living with dementia have been telling us that they feel stressed and anxious all the time. Again, I experienced irritation that this self-report is not powerful enough without having to demonstrate it with scientific testing. My hope however is that this result sends a very clear message about the forms of care that will benefit people living with dementia and may inform treatment development.

My discomfort was most pronounced within the laboratory although I realised that using an ELISA kit is essentially like following a recipe. I could have arranged for the samples to be sent off to a laboratory for analysis if my resource budget had allowed, however with me processing the samples (with close guidance) I felt I could track the sample journey closely and have a holistic view of the data.

I was aware of mixed feelings as this phase ended. I was relieved that the samples had been processed but sad that relationships with participants were ending. Their involvement in phase 3 is incredibly important to me personally and to the strength of the study.

Chapter 6

PHASE 3

Results Sharing, Co-Interpretation and Knowledge Mobilisation

Phase 3 – Results Sharing, Co-Interpretation and Knowledge Mobilisation

6.1 Rationale for Participatory Results Sharing

The need for ongoing dialogue and a drive to give those affected by dementia a voice continues as a strong thread throughout this study. Many study participants are invested in finding out the results of the research they have given their time to (Participant in Research Experience Survey (PRES) 2019-20.) The Health Research Authority provides guidance on this (HRA, 2023) and promotes a participant right to feedback from the study they were involved in as good practice.

Phase 3 was therefore designed not simply as a dissemination exercise, but as a co-interpretative process grounded in participatory and rights-based approaches to dementia research. Involving stakeholders in interpreting findings aligns with contemporary ethical guidance on research with people living with dementia, which emphasises inclusion, voice and epistemic justice (Alzheimer's Society, 2022; Bartlett & O'Connor, 2010). Traditional biomedical research often privileges quantitative findings interpreted solely by researchers; however, in psychosocial dementia research, lived experience and practitioner insight are critical to contextualising outcomes (Tanner, 2012; Kontos et al., 2017).

The participatory orientation of Phase 3 reflects principles outlined in the World Health Organization Global Action Plan on the Public Health Response to Dementia (2017–2025), which advocates for meaningful involvement of people living with dementia and carers in research and service development. It also aligns with UK policy commitments articulated by Alzheimer's Society through the Dementia Statements, particularly the right to be involved in research concerning care.

Phase 3 therefore operationalised co-production principles (Beresford, 2016; NIHR INVOLVE, 2021), recognising that interpretation of findings about "wellbeing" in advanced dementia cannot rest solely on statistical significance. Instead, meaning making required dialogue between researchers, practitioners, volunteers, carers, and where possible, people living with dementia.

6.2 Method: Structure of the Results Sharing Event

A knowledge mobilisation event was therefore organised and held on 13th June 2024 in the Teaching and Learning Centre, Durham University. Stakeholders attending included study participants and their families, health colleagues from Tees, Esk and Wear Valley Foundation Trust, colleagues from Cumbria, Northumberland, Tyne and Wear NHS Trust, Namaste Care volunteers, representatives from Dementia UK, Beamish Museum Health and Wellbeing Service Manager, Oriental Museum Dementia Art Group, a

representative from my funders, NIHR ARC NENC, the dementia team from St Cuthbert's Hospice, students and academics. 54 people attended to hear a presentation of the study results and to engage in round table discussions.

The format deliberately integrated quantitative presentation with facilitated discussion, allowing stakeholders to reflect on whether the findings resonated with their experiential understanding of Namaste Care.

Data presented included:

- Reductions in resting heart rate across sessions.
- Changes in urinary cortisol levels.
- Dopamine analysis findings.
- Thermal imaging data (nose tip temperature variation).
- NCSOM behavioural outcome scores.

Visual representations of physiological change were juxtaposed with anonymised narrative case examples. This dual presentation echoed calls within mixed-methods literature for integration at the interpretation stage rather than merely at data collection (Creswell & Plano Clark, 2018).

6.3 Results

Stakeholder Interpretation of Physiological Measures

Resting Heart Rate

Stakeholders responded particularly strongly to the resting heart rate data. The finding that resting heart rate demonstrated consistent, measurable change was perceived as both clinically meaningful and practically accessible. Volunteers commented that the heart rate data "validated what we see," suggesting that the physiological data functioned as confirmatory evidence for long-held experiential knowledge that Namaste Care has a calming effect.

From a biopsychosocial perspective (Engel, 1977), heart rate reduction may reflect parasympathetic nervous system activation, associated with relaxation and safety. The Polyvagal Theory (Porges, 2011) provides a useful explanatory framework here, proposing that social engagement and relational safety cues regulate

autonomic function. The structured sensory environment of Namaste Care — warm blankets, gentle touch, familiar music — may signal safety and co-regulation, leading to measurable autonomic shifts.

Stakeholders interpreted this not as "proof" of magic moments, but as evidence that relational care produces embodied physiological change. This interpretation supports work by Kontos and Naglie (2009), who argue that personhood in advanced dementia remains embodied and relational, even when cognitive expression is limited.

Importantly, participants emphasised that resting heart rate was appealing because of its feasibility. Unlike urinary biomarkers or thermal imaging, resting heart rate monitoring is low-cost and scalable. This has implications for implementation in resource-constrained care settings

Cortisol and Stress Biomarkers

The cortisol findings generated more nuanced discussion. While some reductions were observed, results were not universally significant across all sessions. Stakeholders reflected on the complexity of interpreting stress biomarkers in advanced dementia populations, noting that baseline stress levels may be influenced by multiple contextual factors including pain, dehydration, infection, environmental noise, and carer strain.

The hypothalamic–pituitary–adrenal (HPA) axis dysregulation commonly observed in dementia (Ouanes & Popp, 2019) complicates straightforward interpretation of cortisol as a stress proxy. Participants engaged critically with the idea that "less cortisol equals better wellbeing," acknowledging that wellbeing in advanced dementia is multidimensional and cannot be reduced to a single biological indicator.

This discussion reinforced the importance of integrating biological measures with behavioural and contextual interpretation, rather than privileging biomarkers as definitive.

Thermal Imaging and Nose Tip Temperature

Thermal imaging findings prompted interest but also caution. Although shifts in nose tip temperature have been associated with emotional arousal and stress responses (Ioannou et al., 2014), stakeholders noted that such technology may not be easily transferable into routine care environments.

Participants were intrigued by the idea that emotional states could be visualised through non-invasive imaging yet emphasised that the presence of unfamiliar equipment might itself influence participant

experience. This reflexive discussion highlighted the tension between research innovation and ecological validity.

Interpretation of the Namaste Care Session Outcome Measure (NCSOM)

The newly developed NCSOM was widely perceived as acceptable and meaningful. Volunteers described it as "capturing what matters," particularly in relation to observable shifts in engagement, relaxation, symptom expression, and responsiveness.

Stakeholders noted that unlike broader quality of life scales such as QUALID (Weiner et al., 2000), the NCSOM was session-specific and sensitive to immediate change. This aligns with recommendations in dementia measurement research that outcome tools must be proportionate to intervention "dose" and context (Logsdon et al., 2002).

There was strong agreement that the NCSOM avoided the deficit-focused framing that some proxy measures unintentionally reinforce. Instead of asking what was absent, it documented what was present during the session. This strengths-based framing resonates with Kitwood's person-centred care model (Kitwood, 1997), which emphasises preserving personhood through positive relational interaction.

Emotional and Relational Responses to the Findings

A notable feature of Phase 3 was the emotional tone of the event. Several participants expressed relief that the study had demonstrated measurable change. For practitioners who had previously encountered scepticism regarding the "evidence base" of Namaste Care, the findings carried symbolic weight.

This reflects broader tensions in health and social care between experiential knowledge and hierarchies of evidence (Greenhalgh et al., 2014). Psychosocial interventions frequently struggle to achieve recognition within evidence frameworks prioritising randomised controlled trials. The study's mixed-methods design was therefore perceived as bridging professional epistemologies.

However, some participants voiced concern that over-medicalisation of Namaste Care might risk undermining its relational ethos. This critical reflection was valuable: it affirmed that measurement should serve practice, not distort it.

Implications for Interdisciplinary Practice

The results-sharing process illuminated the inherently interdisciplinary nature of Namaste Care evaluation. Biological sciences, psychology, sociology, palliative care, and volunteer-led community practice intersected within a single intervention framework.

This aligns with calls from National Institute for Health and Care Excellence for integrated, non-pharmacological dementia care pathways. It also reflects arguments from Atkinson (2013) regarding the importance of spatial and relational dimensions in therapeutic environments.

Participants from clinical backgrounds highlighted the potential for heart rate monitoring to strengthen conversations with medical colleagues who prioritise physiological data. Meanwhile, hospice staff emphasised that the relational narrative remained central.

Knowledge Mobilisation and Collaboration

The event catalysed further collaboration. Regional dementia networks expressed interest in piloting the NCSOM. Academic partners discussed opportunities for multi-site replication, potentially contributing to larger-scale trials.

Given that this current study is a small-scale study, exploring the feasibility of a variety of measures, it will not produce the kind of evidence required to clearly validate the efficacy of Namaste Care. However, a large, multi-partner Horizon Europe study, led by a team at University College Cork will aim to provide this kind of evidence with a planned 5-year Namaste Care project. A randomised control trial is being planned to compare Namaste Care against standard dementia care.

Having heard me speaking about this study at the Namaste Care Conference in September 2023, the research team at University College Cork asked to meet with me on 18/7/24 to discuss potential measures they could use. They viewed my study as ‘proof of concept’ on which they can base their approach. Their project will be care-home based, so will have the benefit of using longitudinal measures such as QUALID, but they are also interested in the observational measure tool that was developed out of phase 1 of this study and were very keen to discuss the details and practicalities of the biological and physiological measures used. This demonstrates the translational impact of the study beyond its immediate setting.

Another ongoing collaboration is with Cumbria, Northumberland, Tyne and Wear NHS Trust (CNTW.) Following their attendance at the results sharing event, the Namaste Care team requested an online call to discuss training and good practice. They also requested that I deliver the presentation of results to a wider staff team including senior managers and consultants, as they are still experiencing some resistance from this

level of staff about Namaste Care implementation. In their experience, the Namaste Care intervention has been nurse led and lacks the policy backing of it becoming standardised practice.

To draw the knowledge mobilisation event to a close, Felicity Shenton, the Public Involvement lead for NIHR ARC NENC gave a closing summary of her thoughts on the results that had been shared. Her main reflection was about the power of creating an inclusive event that was non-academic and generated dialogue about the results. She advocated for the importance of ensuring evidence is accessible to the audience it directly affects. She also reflected on the potential power that Namaste Care could have in becoming an integral part of standard dementia care, based on what she had heard from participants.

6.4 Conclusion and Reflexive Notes

Phase 3 required careful reflexivity. As a practitioner-researcher with prior commitment to Namaste Care, there was a risk of interpretive bias. Structured facilitation by someone other than the researcher and inclusion of critical perspectives from the phase 3 participants and other stakeholders mitigated this.

The co-interpretation process revealed that quantitative findings alone cannot define wellbeing. Rather, they must be situated within relational narratives and ethical commitments to dignity, comfort and human connection. The personal impact of presenting the study findings to the participants who had provided the data was a highly meaningful event. It also appeared to be extremely meaningful to those who attended the results sharing event and consultation. People living with dementia and their families who attended told me that it made them feel like they were helping others, given that there was no cure on the horizon for them. This meaning making felt like a very human response to what is essentially a terminal diagnosis.

Phase 3 demonstrated that participatory results-sharing is not a peripheral activity but an essential methodological component of biopsychosocial research.

The process confirmed that:

- Resting heart rate is a feasible, scalable indicator of physiological change.
- Biomarkers provide complementary but complex insight.
- The NCSOM is acceptable and meaningful in practice.
- Quantitative evidence can coexist with relational care values.

By returning findings to those who contributed to them, the study upheld principles of justice and reciprocity, reinforcing that research in advanced dementia must remain accountable to lived experience as well as scientific rigour.

7 DISCUSSION

7.1 Wellbeing in people living with dementia.

6.2 Development of an effective Namaste Care session outcome measure (NCSOM)

6.3 Resting heart rate as a measure of wellbeing during a Namaste Care session

6.4 Use of biomarkers in urine as a measure

6.5 Thermal imaging/nose tip temperature as a potential measure

6.6 A comparison of measures

6.7 Observations and reflexive practice

6.8 Identification of themes that may uncover the key mechanisms of Namaste Care

6.9 Nature of inter-disciplinarity

6.10 Study strengths and limitations

6 Discussion

The study has been broad ranging and admittedly could have focussed on any one of the many elements covered in much more depth. However, as a feasibility study, this exploration of potential measures has highlighted some interesting areas which require discussion and has resulted in some potential advice for future research with people living with advanced dementia.

6.1 Wellbeing in people living with dementia.

Underpinning phase one of this study was a consideration of the concepts of quality of life and wellbeing, to decide what the study would aim to measure within a Namaste Care session. Participants generally agreed that these two concepts were not the same. The opinion was that quality of life of ourselves, or others, was based on a judgement, the implication being that we were comparing it to some personal standard or societal standard which remains unvoiced but is integral to our perception of quality of life. In professional practice, this approach was often to be heard from family carers who judged their loved one to have a poor quality of life, when observing the person as a visitor seemed to show someone who was content and well cared for. This trend of family concern was echoed by the Alzheimer's Society 2013 research which showed that only 41% of relatives thought that loved one living with dementia had a good quality of life. In exploring this with families, it most often related to the fact that they were comparing their loved one's life now, to what it used to be before their dementia.

Definitions and discussions of quality of life (QoL) and wellbeing (WHOQOL measure, Britannica, Cambridge Dictionary) tend to agree that the concepts are ambiguous and subjective. Looking at two often used definitions, we can detect similar themes as identified by study participants in phase 1. The World Health Organisation, for example, defines QoL:

"…as an individual's ***perception*** of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."

In contrast, wellbeing can simply be defined as:

"the state of ***feeling*** healthy and happy."(Cambridge dictionary.)

These definitions emphasise a distinction between Quality of Life's perception (cognition) and wellbeing's feeling (affect.) Given that dementia severely impacts cognition, especially in its later stages, focussing on whether the study should attempt to assess quality of life or wellbeing was an important starting point in the consultation discussion, and resulted in a recommendation by participants to measure wellbeing. The

reasoning given was that wellbeing can be observed in someone, whereas it was impossible to know a person's perception of their experience when they were unable to self-report.

Whilst the two definitions of wellbeing and quality of life quoted above would tend to support the opinions given by study participants in phase one, there are other definitions which are not as clear cut. For example, the Department of Health (2014) describes wellbeing as "an individual's experience of their life; and a comparison with social norms and values." This definition suggests more of a perception of how we compare to others in contrast to what the study results suggest, as this definition is more overlapping with the ideas participants had about quality of life.

Exploring further, in an article entitled 'Wellbeing is more than happiness and life satisfaction: a multidimensional analysis of 21 countries,' Ruggeri et al describe wellbeing as:

"…the combination of feeling good and functioning well; the experience of positive emotions such as happiness and contentment as well as the development of one's potential, having some control over one's life, having a sense of purpose, and experiencing positive relationships." (Ruggeri et al, 2020.)

Although elements of this definition are very similar to the study definition arrived at from combining participants views, some elements such as 'functioning well' and 'development of one's potential' may feel less appropriate and sensitive for people living with dementia. It must be acknowledged that the study participants were indeed thinking about wellbeing through a dementia lens, and this may have influenced the elements that they viewed as indicative of wellbeing.

Strohmeir and Camic, 2017, explore how to conceptualise, measure and recognise wellbeing based on interviews they conducted with people living with *mild to moderate* dementia, and argue that:

"Wellbeing in the dementias is a fluctuating subjective state and involves a sense of agency, engagement, happiness, feeling well, confidence and optimism."

This definition echoes many of the themes identified as important in phase one, and includes some of the key elements of emotion and connection which were included in this study's definition of wellbeing:

Wellbeing is a state of feeling relaxed, content, happy and comfortable, with the opportunity to engage in meaningful activities.

Interestingly, Strohmeir and Camics' definition starts with a 'sense of agency' as key, (also included in the Ruggeri definition) and this theme was also identified in phase one as 'choice, independence and autonomy,' but it was not in the most frequently used descriptors. It may be that this sense of autonomy was more important to the people in Strohmeir and Camic's study as they were people in the early stages of the

disease, anticipating their future. In phase one of this study by comparison, most participants were family carers, professional and volunteers with only a low number of people living with dementia. This will provide a different viewpoint on what is most important. They were also being asked to think about the advanced stages of dementia, in contrast to the Strohmeir study. Study participants may well have been advocating for what they wanted for the person with dementia, which was first and foremost to be content, comfortable and happy. One study participant living with mild dementia who took part in an individual interview did say that his future terrified him due to the loss of control over his life he would most likely experience. He voiced "how will people know what I need?"

This calls into question whether a focus on the elements of wellbeing is also different depending on the stage of dementia. It is clear from the descriptions of the progression of dementia summarised in chapter 2, that the needs of people change as dementia progresses, however study participants in phase 1 felt that there were core elements which applied to everyone, regardless of a diagnosis. Returning to the frequency of wellbeing descriptors used, choice was the sixth most frequent descriptor word used about wellbeing. Reflecting on important elements of Namaste Care, such as offering choice of music, choice of massage wax scents and so on, then this suggests that the study definition of wellbeing could be adapted to incorporate this important concept, as follows:

Wellbeing is a state of feeling relaxed, content, happy and comfortable, with the opportunity to engage in meaningful activities and make our own choices.

In a key piece of Namaste Care research (Stacpoole et al 2017,) the paper acknowledges that wellbeing is difficult to measure in people who do not communicate easily. I would argue that what they mean is people who are not able to verbalise easily, as people living with dementia clearly communicate non-verbally in the same way that all humans do. That non-verbal communication arguably becomes more important as they lose their verbal communication. Stacpoole et al took the approach of looking at measures of *ill-being* as a proxy way to conversely measure wellbeing, such as looking for reductions in agitation. In choosing to measure cortisol, this study essentially in part took this proxy option in looking at stress levels and assuming a drop in stress would indicate wellbeing.

A few more points to pull out from Stacpoole's study, include the mention of the wellbeing of professional carers and the idea that 'Namaste is a feeling.'

Thinking about the wellbeing of carers was an important area I had wanted to explore in this study but ended up not having enough caregiver volunteers to collect data from. In Stacpoole's study, the professional carers talked about finding Namaste Care rewarding to deliver, as they saw the positive effects on care home residents, thus giving a feeling of achievement. Staff talked about 'feeling good' and happy with their work. This is an area that future Namaste Care research could focus on, both the wellbeing of the Namaste Caregiver and the wellbeing of the family carers. From professional practice in the community, it does appear that the benefits of Namaste Care have a ripple effect outwards from the person living with dementia at the centre, to then reduce the stress of the people around that person when they see their loved one more content.

In Stacpoole, (2017,) family and staff talked frequently about the sense of calm that Namaste Care evokes. Summarised by the phrase, 'Namaste is a feeling,' many examples are given of care home residents being less tearful, more social, less agitated and the whole care home environment benefiting the calm atmosphere. Again, that idea that wellbeing involves feeling relaxed and happy is therefore conveyed by this paper, supporting this study's definition.

Given the lack of agreement on the detail of a wellbeing definition, it would therefore be advisable for each piece of research to clearly define what they mean by either wellbeing or quality of life in the context of their study and ideally to conduct consultation on the meaning of these terms with stakeholders as part of the research design stage, to ensure it meets the needs of the beneficiaries of the research.

6.2 Development of an effective Namaste Care session outcome measure (NCSOM)

The development of an observational measure which could capture the wellbeing outcomes

across one single Namaste Care session became more significant than anticipated through the course of the study. The scores recorded for the study participants showed a significant increase from the start of the session to the end of the session, indicating that observers believed that they were witnessing improvements in wellbeing of the Namaste Care recipient by the end of the session.

The use of the dementia specific score, QUALID, in long term residential care settings is well established, and some Namaste Care studies conducted in these settings (e.g. El Alili et al, 2020) have used QUALID measures effectively to track improvements in a residents' wellbeing. In care settings, as previously explained, Namaste Care can potentially be delivered daily and the QUALID score can be completed based on longitudinal

observations. This means of measuring the effectiveness of Namaste Care was not however applicable to community-based projects where Namaste Care was delivered in people's own home and only once weekly. This gap in evaluation was therefore a driver for the development of a Namaste Care Session Outcome measure as a product of phase one of this study.

However, collaborating with colleagues from Tees, Esk and Wear Valley NHS Trusts (TEWV) and Cumbria, Northumberland, Tyne and Wear NHS Trusts (CNTW) also uncovered their need for a one session measure. Both Trusts had introduced Namaste Care into their inpatient wards and given the more transient nature of their inpatient stays, could not effectively use QUALID to measure outcomes over time. They also required a tool which could capture outcomes across the time frame of one session, and they were integral to the development of the tool both in terms of content and usability testing. Colleagues introducing Namaste Care into the dementia services at Whipscross Hospital also made use of the measure, as well as numerous care homes following Namaste Care training that I regularly delivered on behalf of Namaste Care International.

Girard et al (2016) provide a useful structure within which to consider the effectiveness of the Namaste Care session outcome measure developed during this study in their primer on observational measurement. The ability to observe and interpret what we see is fundamental to the advancement of knowledge and understanding across many different disciplines. Ensuring validity and reliability, time effectiveness and minimising observer reactivity are all central to producing an effective measure.

Measurement instruments

Observers can make judgements about an area of interest, most commonly behaviour, and those judgements need to be standardised as accurately as possible. The measurement instruments within the NCSOM were established by study participants in phase 1 to reflect aspects of non-verbal communication, physiology and behaviour that they felt were important indicators of wellbeing. The 9 indicators chosen were given a scale measurement between 1 to 5 each, resulting in a single pre and post session score within the range of 9 to 45. The higher the score the higher the wellbeing rating, based on how each indicator was being expressed.

The resulting format was found to be easy to use in practice without the need for training in how to use the tool. The scoring section as a tick box format was very time efficient, and the final scores could be worked out later. The section of the form that allowed Namaste Caregivers to record details of the session took a little longer to complete, but all users felt that this was important for sharing information between workers and for establishing preferences for the individual receiving the Namaste Care.

The choice of colouring the columns and indicating a grading from reduced wellbeing to improved wellbeing could influence the observer, particularly as the observer completing the measure may well be the Namaste

Caregiver, and so they have an investment in in showing that their work was effective. This was debated with representatives from the partner NHS Trusts, but they felt that the colour coding gave clarity and guidance for non-medical professionals who may be completing the measure. To reduce Namaste Caregiver bias, it could be useful for a neutral observer not directly involved in the Namaste Care session to complete and before and after score. However, on discussing this with pilot users of the measure, they felt that the Namaste Caregiver has a much better feel for the subtleties and small changes which can occur during a session.

Degree of inference

The amount observers are required to infer from what they observe will obviously affect the degree of subjectivity involved. Having attended a workshop delivered by Janneke Van Leeuwen, a visual artist and neuroscientist (thinkingeye.org) it was clear to see how people viewing the same piece of art or photograph see different things and create different meanings from what they saw.

Inferences in observational measures can be either *message-based* or *sign-based*. With a message-based inference, observers are asked to interpret the meaning behind behaviour and therefore there is a high degree potential variability on inference. With sign-based instruments, such as the NCSOM, small elements of behaviour or non-verbal communication that require the observer to merely record what they see without interpretation have a much lower degree of inference and are therefore considered more reliable.

Types of observers

Turning attention to the people likely to be doing the observing, there is an important consideration in terms of feasibility and objectivity. The NCSOM may be completed by dementia professionals, care home staff, volunteers or family carers. Girard et al point out that participant observers such as the Namaste Caregiver, whoever that may be, are preferable due to the insight they will gain from engaging in the session. It was therefore vital that the NCSOM be very accessible and self-evident in its' usage, rather than requiring specialist training to use. Feedback on using the NCSOM was gained from dementia specialists, volunteers, care home staff, university students and family carers. All found that they were able to use the measure without instruction.

Validity

Arguably the most important aspect of any measure is the extent to which it captures accurately that which it aims to measure, that the observations made are *valid*. As Green and Thorogood (2018) term it, "the *truth* of a measure." Validity is essentially at the heart of the credibility of any measure.

So, does the NCSOM measure what is aims to measure?

Wellbeing is a state of feeling relaxed, content, happy and comfortable, with the opportunity to engage in meaningful activities and make our own choices.

The NCSOM content is very specifically designed around the feedback from experts by experience (people living with dementia, dementia family carers or dementia professional and volunteers) about what it is possible to observe in someone to indicate their wellbeing. Indicators of whether someone was feeling relaxed included their facial expression, amount of body tension apparent, the nature of their breathing and their behaviour. Indicators of happiness and contentment were felt to be observable by noting the person's behaviour and mood and again by facial expression. The opportunity to engage in meaningful activities is captured in sections on engagement and communication. The tool also allows the person completing it to record on the last page what those activities were for future reference and to share what works for that person with others. That last page can also capture what choices were presented to the person and what they chose. For example, 'the Namaste Care recipient was offered a smell of lavender or mountain forest massage wax and showed more interest/response in the mountain forest.' By having 9 different indicators of wellbeing which were decided upon by experts, as well as having the option to record specific personalised details of a session, this provides a high degree of validity.

Important elements of validity also include *transparency* of the procedures used to arrive at the final product. By detailing the methods used in phase 1 of this study and reporting the participant feedback which was the basis for the construction of the NCSOM, the intention is to achieve transparency for the development process of the measure.

Inter-rater reliability is another element of validity which we can test and report on, indeed inter-observer reliability is a frequently used tool for demonstrating the validity of an observational measure. The degree of agreement or variance between two observers will provide a picture of how reliable the measure is across differing users. Scholars vary in opinion about the use of measures that adjust for random guessing but tend to agree that there is no ideal means to do this (Girard, 2016.)

For the NCSOM there was 80.6% agreement between raters over 12 separate sessions, which is above the 75% figure which is considered reliable. Continuing to test inter-reliability would obviously be beneficial.

Interestingly, scores recorded in a clinical ward setting were higher in variance in inter-rater scoring compared to when non-professional scorers completed it in a community setting. Exploring this finding with a clinical colleague from the NHS Trust involved led to her opinion that clinical staff were more tolerant of negative symptoms and that this showed in the baseline 'before session' score. However, despite this variance, all

people completing the measure agreed that the session had been beneficial for wellbeing, it was that there was slightly less of a shift from the start of the session to end in these clinical settings.

Triangulation with for example, the resting heart rate measurement results shows a high degree of agreement with the relaxation element of the NCSOM. The results for cortisol and dopamine, which could give some indication about mood were more mixed and do not correlate with the NCSOM scores overall.

Given the apparent reliability of the measure, the data arising from participant observations would validate the hypotheses that Namaste Care can induce a relaxation response and creates positive mood changes.

Applying the parameters outlined in the introduction for consideration of each individual measure, leads to an overall positive picture for the NCSOM.

The Namaste Care Session Outcome Measure:

Acceptability of method ✓ There was a gap in provision of a tool that could be specifically used to capture outcomes for a Namaste Care session, and so the measure has been widely welcomed as fulfilling that need.	**Ease of data collection** ✓ Feedback from pilot users is that it is quick and easy to complete. Care homes have reported creating a ducket within their Namaste Care room with blank copies to use.
Cost ✓ At present the NCSOM is a paper copy, so some printing costs are involved. It would be possible to devise an electronic version where the scoring is calculated automatically. I have seen templates such as these be developed for NHS online note keeping.	**Ability to scale up to larger studies** ✓ The NCSOM provides a consistent way to measure Namaste Care sessions, and a large Horizon Europe study has copies to consider its use for their project.

Table 13 Analysis of the NCSOM by study parameters

In general, the NCSOM has been well received and utilised in practice. The feedback from CNTW NHS Trust that they use the measure to inform assessments and formulation, and that they use it in supervision and staff development to discuss observational skills was an unexpected additional benefit. The NCSOM could be

further tested over a longer time-period and across varying settings, such as care homes, community services and hospitals, but the initial picture of usage would indicate it is seen as a valid and useful tool.

6.3 Resting heart rate as a measure of wellbeing during a Namaste Care session

The hypothesis that Namaste Care would induce a relaxation response and was expected to lead to a decrease in resting heart rate was validated by the results of the heart rate measurements taken before and at the end of a Namaste Care session. This significant result would indicate that Namaste Care brings about a parasympathetic nervous system activation and reduces the experience of stress.

A raised heart rate is an indicator of a stress response. The sympathetic nervous system, hypothalamic-pituitary-adrenal axis and the renin-angiotensin system react in response to perceived threat to release stress hormones and ready the body for action with a raised heart rate and blood pressure. (Zhang et al, 2016.) Monitoring blood pressure readings would therefore have been another option to measure any relaxation response induced by a Namaste Care session. However, to minimise participant burden, measuring resting heart rate via a pulse oximeter was a quick and low burden form of getting a picture of the physiological response to the session.

Measuring heart rate variability was also an option considered and would have been a good choice to monitor changes in autonomic variability. Heart rate variability (HRV) is a measure of the time interval between heart beats and is thought to be a measure of the health of the autonomic nervous system. A higher rate of variability thought to be healthier, as it demonstrates adaptability to stressors. It would have therefore been a useful measure to use if HRV could have been tracked across the timeframe of the session. However, the difficulty with fitting the smart watches, meant that resting heart rate was easier logistically. Consideration had to be given to how accurate and reliable the resting heart rate measure would be as an indicator of autonomic responses.

Hart (2013) looked at the association between a manual pulse rate, technology-based pulse measurements and heart rate variability (HRV) in the search for a user friendly and convenient option for chiropractic neurological assessment. Hart showed manual pulse rate results, and a Biopac heart rate scanner were strongly correlated in terms of resting heart rate readings. For ease of use, a pulse oximeter was used in this study to create minimal participant burden and to aid the researcher who was co-ordinating several measures at once. Pulse oximeters have been shown to be accurate when the person is a rest and the

accuracy decreases following vigorous exercise (Lyriboz et al, 1991.) Given that no exercise was included in the Namaste Care session, it was concluded that a pulse oximeter would provide a reliable result.

In using the resting heart rate as a measure of wellbeing in a Namaste Care session however, it could be argued that the content of the session would naturally affect the result. For the purposes of this study, session content was standardised as much as possible to provide a reasonable comparison and the content was deliberately calming and relaxing. However, in practice, Namaste Care sessions can vary in content, with some sessions being designed to be more active, stimulating and uplifting, which could well raise the heart rate in a positive way. This means that the readings themselves would always require explanation and context. This also reinforces the difficulty in measuring the results of a Namaste Care session using only biological based measures, which only make sense when cross referenced with narrative information and observation.

Again, applying the parameters outlined in the introduction for consideration of each individual measure, resting heart rate appears to be a useful measure.

Acceptability of method ✓ All participants accepted the resting heart rate measure and were interested in the clear change from beginning to the end of the session	**Ease of data collection** ✓ The pulse oximeter was easy to use, being left in place for 15 seconds to allow the heart rate to settle. It therefore took minimal amount of time, is small and easy to transport
Cost ✓ Pulse oximeters are low cost (averaging £10-20 each)	**Ability to scale up to larger studies** ✓ This means of data collection would be very easy to use in a larger scale study.

Table 14 Analysis of resting heart rate as a measure according to study parameters

6.4 Use of biomarkers in urine as a measure

In general, the collection of urine samples caused no problems for participants, apart from one participant living with dementia who found it stressful, which would have affected the results of his sample. Another person living with dementia was unable to provide a sample on one occasion and so their sample was taken at session 2 rather than session 1, again affecting the consistency of results. In general, the results showed clearer evidence that Namaste Care is effective in helping participants to relax but does not provide a clear pattern of evidence of an increase in pleasure, motivation and a sense of satisfaction.

6.4.1 Cortisol

The most significant finding arising from the cortisol samples, was the significantly higher baseline levels in people living with dementia. This validates the reports given by people living with dementia that they feel anxious and stressed most of the time. This would also reinforce the need for an intervention which could help to reduce those difficult feelings.

Although the overall trend in the data shows that cortisol levels decreased by the end of the session, the picture was mixed and did not achieve a significant result. Given the consistent and significant heart rate measure results which would indicate an increased relaxation response, and which corresponds to observable changes in participants reported by the outcome measure scores, this may then call into question the usefulness of cortisol as a measure.

Whilst the cortisol diurnal circadian rhythm has been well documented to show a peak after waking followed by a decline throughout the day, some variation can be caused by physical, environmental, psychological and social factors (Kovach, 2011.) Furthermore, changes to the usual pattern have been identified in various diseases, such as those living with fibromyalgia, depression and rheumatoid arthritis. Kovach et al, 2011, looked at the variation in the diurnal pattern for people living with dementia after noting a ‘dampened pattern’ in 69% of older adults with memory problems. They were able to show that 50% of participants had the expected negative slope profile of cortisol, however 38% of participants had a flat diurnal pattern, and 7% actually showed increased levels in the afternoon. The study concluded that dementia was having a dysregulating effect on the HPA axis, and that this was having an individual effect. Calculating group averages would therefore be misleading.

Given that chronic stress has been implicated as a risk factor in developing a dementia (Holleman, 2022, Ferrari, 2008) and that chronic stress can lead to dysregulation of the HPA-axis, there is an interesting

relationship between cortisol and cognitive performance, that would warrant further scientific exploration in terms of causation as well as symptom expression.

6.4.2 Dopamine

Again, a mixed result was obtained for the Dopamine sampling with no patterns of significance. The only clear trend was that there were higher starting levels of dopamine at the start of session 4. This could indicate the establishing of a trusting relationship and the anticipation of a pleasant experience, when focussing on dopamine as an indicator of reward and pleasure.

When reviewing the literature on dopamine however, it became clear that both chronic and acute stress can affect dopamine levels depending on context (Bloomfield et al 2019, Baik, 2020.) Bloomfield et al, 2019, noted the lack of understanding about the mechanisms of dopamine production in response to stress, but that dopamine production has been associated with stress and is a potential explanatory factor in gambling addiction for this reason. It is possible that therefore that a reduction in dopamine shown in the results indicates a reduction in stress. This would offer an alternative view on the significant increased dopamine levels shown in the results at the start of session 4. Interpreting why participants may have felt more stressed at the start of session 4 may be due to it being the last session, but it is impossible to interpret the results without explanatory feedback from participants. If Dopamine levels was acting more as an indicator of stress, we would expect to see a correlation between the cortisol and dopamine results, but having checked for this, no correlation was identified. This reinforces the need for narrative alongside the quantitative data to help interpretation of the meaning contained in the quantitative results.

When looking for potential biomarkers, Rehman and Masson (2001) note an impact as we age on the dopaminergic and noradrenergic systems, whereas the serotonergic and cholinergic systems are better maintained. This may indicate that Serotonin may have been a more reliable target biomarker to test. Furthermore, increasing evidence implicates impairment in the dopaminergic system with some forms of dementia, such as Alzheimer's Disease and Dementia with Lewy Bodies (Pan,2019, Nobili et al, 2017) leading to alterations in the pleasure and reward response. This would further reinforce the conclusion that it would not be a good measure of improved wellbeing during a Namaste Care session, as the results would be difficult to interpret.

Using the consistent criteria used to assess other measures, urinary cortisol and dopamine biomarkers would appear to be of less usefulness than some of the other measures tested.

Usefulness of urinary biomarkers as an outcome measure for Namaste Care:

Acceptability of method ✓ The method of sample collection was generally accepted and participants felt that they were accustomed to giving samples for their doctor. One person living with dementia found the process stressful, however. Due to the dysregulation in the noradrenergic and the dopaminergic systems in people living with dementia, a more reliable biomarker should be sought.	**Ease of data collection** ✗ Collecting urine samples added an additional burden for the Namaste Caregiver and the participant to manage and could arguably have detracted from the session. Transporting the urine samples was time sensitive and required specialist laboratory processing and storage.
Cost ✗ The ELISA kits are expensive, averaging £500 each. This would limit the number of samples which could be analysed on a limited research budget.	**Ability to scale up to larger studies** ✗ The cost of analysis and the logistics of collecting a larger number of samples would require a large team and a large resource budget.

Table 15 Analysis of urinary biomarkers as a measure according to study parameters

6.5 Thermal imaging/nose tip temperature as a potential measure

The use of thermal imaging to identify changes in emotional state and arousal is a novel and emerging area for the use of temperature measurement technology (Jian el al, 2022, Goulert et al, 2019.) Interpretation of the use of this measure is still in development, but nose tip temperature was chosen due to the suggestion that it is an accurate indicator of stress levels and emotion (Baskaran et al, 2022.) Negatively valanced emotions such as fear, stress and frustration have been associated with a drop in peripheral temperatures (Escobar et al, 2021) whereas a positively valanced state of emotion can be linked to an increase in nose tip temperatures (Salazar-Lopez et al, 2015.) There is ongoing debate however about this apparent clear delineation and further research is required to add to the evidence base for researchers to be able to apply this technology effectively.

Within this study, there was a clear difference in the results between people living with dementia, where the trend was for an increase in temperature by the end of the session, and the healthy controls, whose temperature tended to drop by the end of the session. One factor skewing the results could be that fewer healthy participants consented to the temperature imaging. Another issue to consider is that the participants with dementia were starting from a more negatively valanced starting point, as evidenced by the higher baseline cortisol readings. Moreover, heightened responsiveness to temperature has been identified in dementia patients (Fletcher et al, 2015.)

Thinking more deeply about the controllable parameters of a study, it was not possible to control the temperature of the environment. To provide a true picture of the response to the Namaste Care session, a consistent environment and a consistent ambient temperature for all participants would have provided a better and more reliable outcome. However, in practice, each session took place in a different venue, with varying temperatures which will have influenced the results. For example, one healthy control who lives in a very cold house and reports feeling cold a lot, took off her cardigan when it came to the hand massage and consequently her temperature reading dropped. This drop in temperature could not be assigned to a change in arousal or emotion, but rather environmental factors were more likely at play.

While it is hoped that thermal imaging technology offers researchers a non-invasive and portable option (Engert et al, 2014), which could be used in hospital, care home and hospice settings, with minimal burden to patients, this study would suggest a mixed response in terms of the acceptability of the measure. One participant felt that it looked like a speed gun and didn't like it being pointed at her. This would suggest the design of the technology needs to be sensitive and appropriate to increase the acceptability, possibly to resemble an ordinary camera or tablet device. Furthermore, a more thorough understanding of the physiological mechanisms that the temperature changes represent would help to increase confidence in the use of this technology.

Usefulness of thermal imaging as an outcome measure for Namaste Care:

Acceptability of method ✗	**Ease of data collection** ✓
Issues of acceptability by participants and also by the academic community for this emerging technology would suggest that further work needs to be done to validate	It took practice to be able to master the accuracy of capturing a stable picture and to locate the sensor at the person's nose tip. With practice, the data collection

the approach and to make the technology more normalised and accessible.	element of using the technology became quick and easy.
Cost ✓ The thermal imaging camera represented a one-off payment of £300. It requires calibration once yearly, but as an investment in kit that can be used repeatedly, it proved cost effective for use in research.	**Ability to scale up to larger studies** ✓ The use of the kit is repeatable and lends itself to larger scale studies, however with a larger team working on data collection, more thermal cameras may be required for working in the community.

Table 16 Analysis of facial temperature scanning as a measure according to study parameters.

6.6 A comparison of measures

Whereas most Namaste Care studies have focussed on collecting qualitative data on the effectiveness of the intervention, this study has attempted to seek ways to broaden the evidence base by employing both qualitative and quantitative methods to identify useful outcome measures for future studies.

The feasibility of combining subjective and objective data in relation to Namaste Care was tested by Froggatt et al, (2018.) They combined an analysis of care home activity records and sleep data, with interviews and questionnaires to demonstrate the usefulness of combined data to provide a fuller picture.

Being able to demonstrate a positive physiological response to a Namaste Care session, would validate the numerous reports by observers of an improvement in wellbeing. To this end, having tested out a range of measures, the two which stand out as complementary and providing reliable qualitative and quantitative information which is easily replicable are the Namaste Care Session Outcome Measure (NCSOM) and the resting heart rate measure.

Whilst the biomarkers in urine provided some interesting results it would require a biology specialist to process the samples, analyse and understand the results. This type of measure is therefore less accessible to a researcher not from that background.

Thermal imaging proved to be an easy-to-use tool but was less acceptable to participants and is still in development as a technology, so it is harder to recommend this as a measure at the present time without its' further development.

Coming from a social sciences background, I would argue that the information in the numerical data only makes sense with an accompanying narrative such as that provided in the example given for one participant only in the results section. Whether someone chose to have a chocolate or not, chose to remove a cardigan or fell asleep during their massage for example, will all provide insight into the person's individual responses. In a situation where it was impossible to exactly replicate the content of each Namaste Care session in a controlled environment, the factors influencing any responses should be recorded to aid understanding.

Also of interest, is the choice of ways to display the information gathered. The results section was organised by type of measure used, however a summary of all the measures together for each participant (see Appendix **A4**) led to a realisation about another factor to consider when looking at individual responses. As a qualified psychotherapist, with diagnostic training, I realised that some of the increases in cortisol in sessions could be explained by the type of personality people had. For example, at least 3 of the healthy control group whose cortisol levels increased by the end of a session, were highly anxious, people pleasing personalities, with a fear of getting things wrong. Knowing they were part of a research study may well have affected their results. This area of study offers promise for understanding what works for who and in what context. This realisation echoes the reflection made regarding participant A1 in the results about what he would find rewarding (and so potentially affecting dopamine production) given his personality. Hunt et al, 2023, also noted that personality types of people living with dementia, most notably that of neuroticism, negatively impacted their view of their quality of life.

On this theme of the format of data presentation, being able to show key demographics of participants such as age, sex and diagnosis as shown in Appendix A4 may further aid understanding and identify patterns.

In practice, Namaste Care practitioners trust what they observe in terms of responses to a session. In a care homes study conducted by Worcester University over 3 years the findings were captured in a film called 'Seeing is Believing' To provide further evidence for the intervention, perhaps capturing film of responses to a Namaste Care session would be a more powerful tool in conveying the effect of Namaste Care to a wider audience.

6.7 Observations and reflexive practice

6.7.1 Researcher as caregiver

The experience of delivering Namaste Care sessions for the purposes of research, as opposed to what I had previously been used to in spending Namaste Care with someone requires acknowledgement and reflection.

Whilst the normal focus of a Namaste Care session is entirely on engaging and meeting the needs of the person living with dementia, in this instance part of the focus was on ensuring that the required measures were taken. I was aware within myself of some anxiety about collecting the urine samples on time, getting the thermal imaging done and taking the heart rate measurement. This anxiety would not exist in a normal non-research-based session but is reflected in the small amount of data collected for Namaste Caregivers. It may have been more effective for the researcher to not be involved in the session and only to be present to collect data and make observations, however it must be acknowledged that the presence of an additional person in a session may have been intrusive to the relational and trusting element of the sessions.

I was also aware, that in an attempt towards some degree of consistency in Namaste Care session content for research purposes, this then moved away from the individual and person led nature of Namaste Care which is personalised according to each person's preferences. Whilst some choice was offered in the session (food, beverage, smell of massage medium, poems) in general the sessions were much more consistent than would normally be the case. As an experienced Namaste Care practitioner, that felt very restricting and alien.

Offering Namaste Care to people who did not have a dementia was a new experience. I found myself having more conversation with them and giving them more explanations about what I was doing compared to those living with dementia, as I had more need to justify the intervention. This has never felt necessary when spending time with someone living with dementia, who appear content to experience the sensory interventions offered in-the-moment. Reflecting on this need to explain things more to people without dementia, I am aware that this may have taken them into a more cognitive rather than purely experiential place and may have influenced their responses to some degree. It also introduced a difference between groups which is unlikely to entirely explain the difference in the results between the people with dementia and healthy controls but may have had some small effect.

One of the aims for the study was to look at whether there was evidence that the Namaste Care session also improved the wellbeing of the Namaste Caregiver, as I have experienced myself and as numerous practitioners have reported. To do this, more individuals willing to act as Namaste caregivers for the purposes of the study would have been necessary. In a situation of a larger team of Namaste Caregivers, there would

have been an opportunity to separate the role of researcher and Namaste Caregiver to avoid the tension this dual role introduced to the session for the researcher/caregiver.

The researcher practitioner is a developing role which can provide a bridge between academia and clinical practice (Daniels et al, 2021.) Co-production, partnerships and collaboration are buzzwords in the research world at present. However, from the experience of conducting this study, there is some way for academia to go to fully respect the clinical experience of practitioners and to support them adequately in understanding research methodology and practice.

The demand for evidence-based practice research to support improvements in service delivery has opened the door for research minded, curious practitioners like me, to use our practical knowledge and experience to inform research. McBeath et al, (2014) looked at the organisational contexts that supported research-minded practitioners, as being critical to facilitating that research. They noted that where academic research is seen by research-minded practitioners as discipline bound, detached, causally focused and authoritarian, a practice-based research approach was viewed as evidence based, real world, deep, experiential and understanding-focused. My experience during this study would echo this dichotomy and I would advocate for a greater coming together of academia and practice to complement one another and use one another's strengths. For the period of this study, I left my job in a hospice to focus entirely on the pursuit of academic enquiry and upon reflection, I believe something was lost in terms of the embeddedness within a practice team which could have supported the study more fully. This would have then required me to be located within a research supportive organisation such as the hospice, with an appropriate culture that valued the contribution research made to service improvement.

6.8.1 Importance of carer as enabler of the research

In the process of contacting the research participants, giving them information about the study, agreeing consent and arranging visits, it quickly became evident that the main carer of the people living with dementia (usually a spouse, but in one case a daughter) were the key enablers that allowed the research to happen. They acted as advocates, supporters, organisers and encouragers. In practice, whilst each participant with dementia had identified a willingness to take part in research either by being registered on Join Dementia Research or by making verbal wishes known, the carer essentially acted as necessary gatekeeper for that individual and a constant sense of monitoring the best interests of the person with dementia was very apparent. From an ethical standpoint, this gave me confidence that the carer would intervene if they believed the sessions were having a negative effect on their loved one, upholding the principles of beneficence and

best interest decision making which was the intention of the study. It was evident that the research would not have been able to proceed without the support of the carers, and that indeed, they appeared to derive a sense of meaning and purpose from the experience.

Whilst the purpose of the Namaste Care visits was to collect data relevant to the experience of a Namaste Care session, it became an opportunity for the carer to talk freely and they frequently told me of areas of difficulty which would benefit from further study. One area consistently mentioned was the lack of post-diagnostic support and the feeling of 'being left to it.' Another key area was about the lack of communication and clarity about the prognosis of the disease and lack of support to plan for future changes in need.

A further benefit of the carer's involvement was the feedback they were able to give about the improvements in wellbeing they reported that they observed in the person living with dementia by the end of the session. This insight led to one of the participants accepting a longer-term Namaste Care visit from the local hospice, where he had previously not wanted the service.

In a 2020 study by Dalkin et al, the role that a Namaste Care visit played in offering the main carer temporary respite from their caring responsibilities was identified, and this benefit did appear to be replicated in this study. All carers left the room once the session started, some took it as leisure time and others caught up with household tasks, but all reported the time to themselves as beneficial. They also reported a sense of knowing that their loved one was having a relaxing and pleasurable time with someone they trusted.

In summary, carer involvement was crucial to the success of each participant with dementia's involvement in this study and is a testament to the unseen, unpaid care being provided (costed by Carers UK and Sheffield University as being worth £162 billion a year to the economy.) This would indicate an important need to ensure the needs of the carers are also met in research design and that researchers feel confident to identify any signs of carer stress and signpost to appropriate services, given they are being given privileged access to families navigating the life-limiting condition that is dementia.

6.8 Identification of themes that may uncover the key mechanisms of Namaste Care

Returning to the hypotheses posed in the introduction, there is strong evidence that **Namaste Care induces a relaxation response.** Resting heart rate *decreased* as expected during Namaste Care. Cortisol levels as expected generally *decreased* during Namaste Care, although the evidence was not definitive or significant. There was an increase in outcome measure scores.

The idea that Namaste Care activates the parasympathetic nervous system by producing a calming and soothing intervention would appear to be the clear conclusion from this study.

The role of complementary therapies such as massage in contributing to relaxation is well established (e.g. Mortada, 2024; Weerapong, 2005.) Changes to the parasympathetic nervous system during massage were measured using heart rate, heart rate variability and blood pressure, and changes in cortisol levels were also noted, indicating a relaxation response (Weerapong, 2005.) Also noted was a reduction in anxiety and an improvement in mood, which elicited a relaxation response. This was very much mirrored in response to Namaste Care shown in the broad range of data collected for this study.

Massage in particular could be argued to be a very relaxing intervention. Nicolle Mitchells is a massage practitioner and trainer who specialises in massage for people living with dementia, developed from her experience of supporting her mother with dementia. Given that her mother was emotionally unpredictable, Mitchell (2025) describes massage as providing foundational moments which enhanced their relationship. Mitchell cites the work of Kilstoff and Chenoweth (1998,) which showed how massage can provide a safe space, opportunities for connection and improved relationships. Mitchell's accumulating experience of the effects of massage was confirmed by a study by Fung and Tsang, which demonstrated that massage reduced the tumultuous feelings people with dementia were feeling and improved communication. The innate nurturing instinct in all of us is also activated by massage, as Mitchell reports similar examples as we found in the hospice-based project of people living with a dementia giving us a hand massage in return. It would therefore appear that loving touch is a crucial element to the Namaste Care approach.

Given that Namaste Care includes an element of massage and use of smell and music therapy, does this mean that it should be classified as a complimentary therapy? My argument would be that these are just some of the elements of Namaste Care and based on years of experience in mental health care and social care, from experience, the key mechanism for Namaste Care is relational and is related to the quality of attention given to the individual, which quickly builds trust and appropriate intimacy. Only with these conditions in place, could a person living with dementia, whose anxiety levels are already elevated, allow themselves to relax and feel safe.

There were mixed results in showing that **Namaste Care produces positive mood changes.** Dopamine levels *increased* by session 4 but did not show a clear response from start to end of the session. Facial temperature *changes* in response to Namaste Care were evident and showed a difference between people living with dementia and healthy controls, but the data demonstrated the individual nature of responses. An *increase* in outcome measure scores would suggest positive mood changes. This may call into question the range of quantitative measures tested, rather than Namaste Care in itself, given the consistent feedback gained from

the practice of Namaste Care, where each session usually generates a smile, sometimes laughter and often a sparkle in the eyes. Measuring this 'magical' element is tricky.

Given the relational element of Namaste Care, oxytocin may have been a good target biomarker as an indicator of human bonding and feelings of affection. Due to the instability of the oxytocin molecule (Schaebs et al, 2021) and the difficulties in analysing oxytocin using ELISA immunoassays even for experts, the possibility of testing for oxytocin was explored by Dr Jon McPhetre (Durham University) using mass spectrometry. He was able to develop a suitable methodology, and testing of the existing samples may be possible in the future.

Further considering the effect of Namaste Care on mood, it is worth noting that Namaste Care interventions are founded on the principles developed by Naomi Feil (2021) in validation therapy. Her theory is that when we see a negative feeling in someone with dementia, we should acknowledge it and name it. Her belief is that unacknowledged feelings such as anger, sadness and fear, gain power when they are not acknowledged. Noticing and acknowledging the feeling appears to diffuse it and cause a shift in mood. This could prove to be another powerful element of the intervention that adds to the relationship between the recipient and caregiver.

It would therefore appear that the varied elements of Namaste Care weave together to create an intervention that is greater than the sum of its' parts. To take it apart and study the individual elements of Namaste Care to identify if there is one key element would then turn it into a different intervention. Namaste Care provides a personalised and integrated intervention which is complex to study and would appear not to respond well to reductionist enquiry.

6.9 Nature of inter-disciplinarity

Tait and Lyall (2007) note that the nature of inter-disciplinary research often demands more time, resources, effort and imagination than does a single discipline research and therefore has a higher risk of failure. It could be argued for this reason, that a doctoral research study with a limited budget and a single researcher would struggle with an inter-disciplinary approach. Tait and Lyall also point out however the potential rewards possible with an interdisciplinary approach, which is the advancing of a knowledge base and tackling complex social issues.

The theme of inter-disciplinarity has indeed been a difficult one throughout this study. I agonised over how one person could be an expert in all the areas I was attempting to study. How could I 'embody'

interdisciplinarity? My psychotherapy training was integrative in nature, drawing on varied therapeutic models and approaches. This way of thinking is therefore not alien to me. I was trained to consider the psychoanalytical theoretical models, the existential, phenomenological, behavioural and neuroscientific ways to understand mental health in an applied psychology approach. This approach would meet the definition of inter-disciplinarity proposed by Tait and Lyall:

"We define interdisciplinary research as occurring where the contributions of the various disciplines are integrated to provide holistic or systemic outcomes."

What I learned from the experience of undertaking a PhD was that the journey of this study was also a search for a 'home.' I was placed in the biosciences department due to the biological and laboratory elements of the research. However, without a background in the biological sciences, this proved to be a highly stressful element of the study. With a bachelor's degree in Sociology and a master's degree in Integrative Psychotherapy, the scientific elements of this study was a steep learning curve. I would have felt more comfortable being in the Sociology or the Anthropology Department, however the nature of a doctoral study is to stretch our ways of thinking, and this has certainly been the case.

Fortunately, I found a home by being accepted onto the Wolfson Institute's doctoral training programme, where inter-disciplinarity is a key theme and important support to work through my struggles was provided. It does make me wonder if locating inter-disciplinary studies within such institutes rather than a single department would support the process more effectively.

Awareness of methodological dualism has therefore been a constant presence. Attempting to generate objective, empirical data suitable for the needs of the medical profession, whilst also seeking to incorporate subjective experience and understanding has led to a broad study, which has not allowed room for a great deal of depth in any one area. The combined nature of the evidence generated however is more likely to meet the needs of a wider audience and is arguably more accessible.

The role of stakeholders in the study process has been crucial in keeping the focus of the research 'real world' based and contributing to the inter-disciplinarity of the research, given these stakeholders do not have allegiance to a discipline. Tait and Lyall note that research designed in collaboration with potential users results in stronger inter-disciplinarity and applicability. This gives confidence that the way that the Namaste Care Session Outcome Measure was developed leads to a stronger and more user-friendly product.

6.9 Study strengths and limitations

This study has been informed by an intimate and reflexive knowledge of the practice of Namaste Care by a very experienced practitioner. That perspective is arguably both a strength and a limitation. Viewing an intervention from within, with an intuitive knowledge of how it works in practice has guided what measures may be appropriate to test and how the ethics of the study should most appropriately be approached. However, arguably this has not resulted in an independent, neutral observer view which would have been possible from a researcher with no background in Namaste Care.

Mitigating this bias to some extent is the careful consultation which took place in phase 1 and the use of supervision to provide varying perspectives and to challenge the researcher viewpoint. Feedback has been that the contribution of participants in all phases, both in shaping the study design and then engaging in the testing of measures has given them some positive meaning and they have felt like they had contributed to something important.

The study has been able to show that Namaste Care produces a relaxation response and has provided an easy measure (heart rate and outcome measure) to capture this outcome. It has been less successful in finding a range of measures which demonstrate changes in mood, although the outcome measure also does record this.

The individual nature of the responses identified by the measures reinforces the need for Namaste Care to be tailored to the individual. In doing so, it validates the person-centred approach advocated by Tom Kitwood, (1997) and the more recent move to discussions about person-led and relational care. Often described as having 5 'petals' or needs, Kitwood's 'Flower of Need' includes the need for individuals to have comfort, identity, occupation, attachment and inclusion, with Namaste Care meeting all these needs. What is often missed in discussion about the Flower of Need, however, is that the 5 petals are held together in the centre by 'love.' There is an awkwardness about talking about love in professional care services, leading to this vital ingredient often being overlooked. The need for professional boundaries, and the numerous abuse scandals uncovered in social care has led to professional distancing and administrative 'back-covering' in my experience. I would argue that Namaste Care provides an opportunity for staff to express love appropriately and safely.

Strengths of the Study

A central strength of this doctoral study lies in its clear alignment between research aims, methodological design, and the complex realities of dementia care practice, as outlined in Chapter 3's discussion of

philosophical underpinnings, mixed-methods rationale, and integration quality. From the outset, the study did not seek to offer definitive proof of efficacy for Namaste Care, but rather to explore the *feasibility* of measuring its effects in people living with advanced dementia. This framing is methodologically appropriate, ethically sensitive, and well aligned with Medical Research Council (MRC) guidance on the development and evaluation of complex interventions. By resisting premature claims of efficacy, the study establishes a credible and necessary foundation for subsequent large-scale evaluation.

A further significant strength is the explicitly biopsychosocial orientation of the research. Dementia is increasingly recognised as a condition that cannot be adequately understood or addressed through biological reductionism alone. By integrating physiological measures (heart rate, biomarkers, thermal imaging) with behavioural observation and stakeholder-derived understandings of wellbeing, this study responds directly to long-standing critiques of both purely biomedical and purely qualitative approaches. The mixed-methods design, justified in Chapter 3 (Sections 3.3–3.8), enabled triangulation across data types and provided a more nuanced account of wellbeing than any single modality could have achieved. Importantly, this integration was not superficial. Qualitative findings and genuine consultation with stakeholders actively shaped measure selection, interpretation of quantitative results, and reflexive understanding of divergence across data strands.

The development of the Namaste Care Session Outcome Measure (NCSOM), described in detail in Chapter 4 and grounded in the validity and trustworthiness criteria set out in Chapter 3.10, represents a further key contribution. Unlike many existing tools, which are either insufficiently sensitive to moment-to-moment change or rely heavily on proxy judgements detached from immediate observation, the NCSOM was co-designed with stakeholders and grounded in real-world practice. This participatory process enhanced face validity, acceptability, and feasibility, particularly in community and care settings where research burden must be minimised. The study demonstrates that meaningful observational assessment is possible even in advanced dementia, challenging assumptions that such populations are inaccessible to systematic evaluation.

The inclusion of physiological measures constitutes another notable strength and reflects the study's commitment to quantitative validity and reliability as articulated in Chapter 3.10.1. Resting heart rate emerged as a particularly accessible and scalable indicator of relaxation response, offering a pragmatic bridge between experiential accounts of calm and clinically intelligible data. The study's demonstration that heart rate can be reliably captured in non-clinical environments, including participants' homes, strengthens the ecological validity of the findings. Although more experimental biological measures (e.g. urinary

biomarkers, thermal imaging) yielded mixed results, their inclusion is a strength in a feasibility context, as it provides valuable information about practicality, participant burden, and data quality that can inform future trials.

The researcher's dual role as practitioner and academic also constitutes a strength when critically and reflexively managed, in line with the reflexivity framework outlined in Chapter 3.9.5. Intimate, experiential knowledge of Namaste Care enabled ethical sensitivity, appropriate pacing of sessions, and realistic assessment of what could be measured without disrupting care. This insider perspective facilitated trust with participants and caregivers and supported recruitment in a population often excluded from research. Reflexive practice, supervision, and stakeholder consultation functioned as important safeguards against unexamined bias, allowing practitioner knowledge to inform rather than dominate the research process.

Finally, the study's emphasis on dissemination, collaboration, and real-world impact is a substantial strength. Phase 3 results-sharing events, engagement with NHS Trusts, and advisory input into the Horizon Europe In-Touch project demonstrate that the research has relevance beyond the academy. These collaborations suggest that the study has already influenced emerging research design and practice discussions, supporting its contribution as 'proof of concept' work within the wider evidence-building trajectory for Namaste Care.

Limitations of the Study

Despite these strengths, several limitations must be acknowledged. These do not undermine the study's contribution but rather delineate the boundaries within which its findings should be interpreted, consistent with the limitations of mixed-methods research discussed in Chapter 3.11.

The most significant limitation relates to sample size and generalisability. Recruitment of people living with advanced dementia presents well-documented ethical and practical challenges, including fluctuating capacity, frailty, and carer burden. As a result, participant numbers were necessarily small, limiting statistical power and precluding strong claims of generalisability. However, this constraint is consistent with the study's feasibility focus. The findings are best understood as indicative rather than confirmatory, offering direction for future hypothesis-driven research rather than definitive conclusions.

A second limitation concerns the heterogeneity of participants and settings. Namaste Care was delivered in varied environments, primarily community and home settings, which enhanced ecological validity but with limited experimental control. Environmental factors such as ambient temperature, background noise, and timing of sessions could not be fully standardised and may have influenced physiological measures. While

such variability reflects real-world conditions, it complicates interpretation of some biological data and may partially explain inconsistent findings across measures such as urinary biomarkers and thermal imaging.

Measurement challenges represent a further limitation, particularly when considered alongside the discussion of instrument reliability and feasibility in Chapter 3.10. Although the study succeeded in identifying resting heart rate as a promising indicator, other biological measures proved less robust. Urinary biomarkers were sensitive to timing, hydration status, and sample viability, while thermal imaging was affected by environmental conditions and participant movement. These findings highlight the difficulty of translating laboratory-based measures into applied care contexts. Importantly, however, identifying what *does not* work reliably in practice is a valuable outcome of feasibility research and prevents inefficient or burdensome measurement in future trials.

Observer bias and interpretive subjectivity also warrant consideration and were anticipated in the methodological design (Chapter 3.9 and 3.10). Behavioural observation, even when structured, involves interpretive judgement. The researcher's familiarity with Namaste Care may have shaped expectations regarding outcomes. This limitation was mitigated through reflexive journaling, supervision, double rating where possible, and triangulation with physiological data. Nonetheless, complete neutrality is neither achievable nor necessarily desirable in applied dementia research; rather, transparency and reflexive awareness are critical, and these were consistently prioritised.

The study was also limited in its capacity to examine relational mechanisms directly. While Namaste Care is widely understood to operate through connection, presence, and attunement, these dimensions remain difficult to operationalise. The inability to measure oxytocin or other relational biomarkers represents a missed opportunity to explore the biological correlates of relational care. Ethical, logistical, and financial constraints precluded this analysis, but future research may build on this insight using advances in minimally invasive measurement.

Interdisciplinary complexity constitutes another important limitation, echoing the challenges of interdisciplinary navigation identified in Chapter 3 and revisited in Section 6.9. Working across biosciences, psychology, and social care required continual negotiation of epistemological assumptions, terminology, and standards of evidence. At times, this slowed progress and limited depth within individual disciplinary domains. However, this tension reflects a broader challenge in dementia research, where no single discipline can adequately address the phenomenon. Rather than resolving these tensions, the study exposes them, contributing to ongoing debates about how interdisciplinary dementia research should be conducted and evaluated.

Finally, the study's scope was necessarily broad. In seeking to explore multiple potential measures within a single doctoral project, depth in any one area was constrained. This breadth, however, aligns with the exploratory aims of feasibility work and enabled comparative insight across measurement approaches. Future research can now proceed with greater confidence about where to invest resources and where methodological returns are likely to be limited.

Summary

Taken together, the strengths and limitations of this study reflect the realities of researching complex, relational interventions in populations with advanced dementia. The study's contribution lies not in definitive answers, but in methodological clarification, tool development, and the demonstration that meaningful, ethical measurement of wellbeing is possible even in late-stage dementia.

Suggestions for future areas of study

There would be great benefit in exploring further the reported effect that Namaste Care has in reducing the experience of pain, especially as pain is a key feature of advanced dementia and severely impacts on mood. In a larger scale study, achieving wellbeing testing at the start and end of a Namaste Care session for the caregiver would also be extremely worthwhile in the current climate of difficulties in staff recruitment in health and social care. It would also strengthen the argument for Namaste Care to be more widely available if benefits could also be demonstrated for family carers in seeing their loved one having improved wellbeing.

8. Study Conclusion

Is it possible to measure magic? What Buber, (2008) describes as an 'I-thou' moment; can it be tested? The intangible, relational, transpersonal sense that people experience during Namaste Care has proved resistant to a simple, reductionist approach, but this study has been able to pull at and test some of the threads which weave together to make the whole. As a holistic intervention, people who have experienced Namaste Care would say that is more than sum of its parts, and that the best way to measure its effectiveness is to experience it first-hand. The striking validation reinforcing the reports that people living with dementia feel anxious and stressed highlights the need for a calming and reassuring intervention. As well as suggesting ways that this could be measured, the study results suggest that Namaste Care is just such an intervention.

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Appendix

A1 St Joseph's Hospice Namaste Care Session Outcome Measure

A2 Detailed Phase 1 results

A3 Laboratory Methodology and Sample Processing

A4 A summary of Individual participants results and demographics

A5 Phase 3- notes from round table discussions

St Joseph's Hospice
Serving East London and the City

Namaste session notes

Namaste Care in East London

Community member	Initials + 5-digit code	Location type**

**Own home / Care home / Supported Living / Day care setting / Hospice ward/ Hospital ward **

Volunteer name	

Session details	Number	Date	Start time	Duration / mins

Who else was present? (family carer/ paid carer/ other)

A. How did the community member seem to you before the start of the session?

Select a number from 1 - 5 to rate the person's overall level of well-being & engagement:

✔ or type 'a' in box ☐ **1** (low) ☐ **2** (slightly low) ☐ **3** (ok) ☐ **4** (fairly good) ☐ **5** (very good)

Please explain why you have given this rating: *e.g. describe their facial expression; body posture; mood/ energy; level of eye contact; interest in communicating (verbally or non-verbally); or other?*

B. What did you do during the Namaste session?

Namaste care activities / interventions tried	✔ Type 'a'	Details - including products/ items used
Hands cleansed/ massaged		
Feet cleansed/ massaged		
Face cleansed/ cream applied		
Hair brushed/ combed/ stroked		
Comfort object		
Movement encouraged		
Snack offered		
Drink offered		
Fragrance/ scent used		
Seasonal object		
Memory box		
Reminiscence		
Music		
Reading		
Other		

Please describe the session, and any impact it seemed to have: e.g. details about activities; the community member's preferences; how did they respond; what was the impact of the session on them (or on the carer/volunteer); any carer involvement, quotes; etc.

C. How did the community member seem to you during / following the session?
Select a number from 1 - 5 to rate the person's overall level of well-being & engagement: *Type 'a' in box* ☐ **1** (low) ☐ **2** (slightly low) ☐ **3** (ok) ☐ **4** (fairly good) ☐ **5** (very good)
Please explain why you have given this rating - including any observed changes: *e.g. describe their facial expression; body posture; mood/ energy; level of eye contact; interest in communicating (verbally or non-verbally); or other?*

D. How do you feel the session went?	☹	😕	😐	🙂	😄

Date form completed		**Next session**	

Please return the completed session notes **as soon as possible** to the Namaste Care office by email to namaste@stjh.org.uk. THANK YOU for being a Namaste volunteer!

A2 Detailed results of phase 1 consultation

The results were analysed using a qualitative descriptive approach where patterns in the data and frequency of terms were used to create structure and meaning. This approach was due to the large amount of data generated to enable swift movement to phase 2. Transcripts were read for familiarity and then re-read to highlight recurring words and were clustered to develop codes (a grouping of similar concepts.)

Summary of participants:

Format of data collection	**Participants = 53**
Focus Groups x 3 Beamish Museum Health and Wellbeing Team St Joseph's Hospice, Hackney St Cuthbert's Hospice, Durham	**18 people in total** **3** care staff **9** volunteers **6** family carers (**5** of the staff and volunteers had dual role as family carer for someone living with dementia)
Individual interviews	**Total =3 people** **2** x family carers **1** x person living with dementia
Online Questionnaire *Circulated via:* Tees Esk and Wear Valley Trust staff Northern Regional Namaste Care Forum Namaste Care International Durham County Council Care Academy Oriental Museum Dementia Group, Durham John's Campaign TIDE Carers group	**Total completed = 29** Person living with dementia or other life limiting condition =2 Social care professional =2 Health professional =8 Family carer =9 Volunteer =3 Allied health professional =5

Table 17 Participant summary information

The results are presented here as a **synthesis of feedback** gained from the focus groups, individual interviews, and online questionnaires. The data from the focus groups and individual interviews was transcribed from audio recordings, and the data from Qualtrics was available within the project file.

Section 1 – Quality of Life and Wellbeing meaning

Q1 What does wellbeing and good quality of life mean to you?

When asked about what wellbeing and quality of life meant, participants at first found it difficult to express. Although one participant felt that they were the same thing, the majority felt that they were linked but different. The general opinion was that quality of life was more subjective and based on a judgement of life circumstances such as health and finances.

For example:

"I think you can have a good quality of life but not have that deep sense of wellbeing. Again, it depends how you're measuring quality of life. Sometimes it's financially, physically you can say a good quality of life but mentally, emotionally and spiritually, to me that's where the wellbeing comes in and if that element is missing, it's not complete."

"I have a problem with quality of life to be honest. To me it's very much an external view. I'm thinking of, you know, there's sort of the health economics kind of quality of years, quality of life years added. The kind of things NICE look at when they're approving you know and intervention. But that's somebody outside looking in and saying, 'we are measuring your quality of life.' I think for me the nub of what you're looking to get at is definitely the wellbeing side of it. I know it's not easy, obviously because how do you measure that? But I think if you say measuring quality of life, I don't necessarily think that is the road to go down."

"*I think quality of life is more about their needs, like feeding them the right food and things. I think wellbeing is more of a mental thing and an individual thing."*

"I think quality of life maybe has more defined factors involved. So, if you think about quality of life now, things like people's financial situation would come into it, wouldn't it? Whether their heating situation, social situation, those impact on you, but you can still be in that maybe difficult situation and have wellbeing."

Quality of life was described as how you or others perceive, think about or judge your life, whereas wellbeing was described in terms of how a person feels. Participants agreed that wellbeing is easier to observe in someone who cannot verbalise their opinion. Wellbeing responses will therefore be analysed thematically below.

An initial simple tally of the frequency of key wellbeing descriptor words or phrases was carried out.

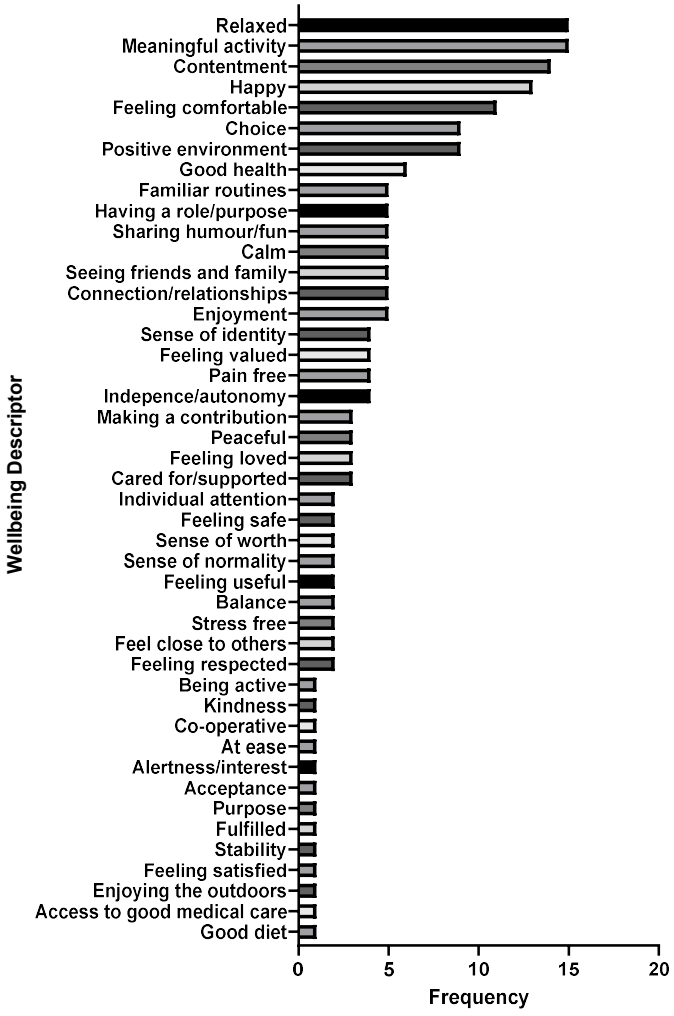

Figure 16 Shows the frequency of descriptor terms describing wellbeing.

Wellbeing descriptor terms

The descriptor words were then clustered by subject area with the frequency of use of the term summarised in figure 2 above. Organising the data on wellbeing thematically in this way suggested the following 5 themes of important elements to consider in this study.

Theme 1	**Theme 2**	**Theme 3**	**Theme 4**	**Theme 5**
Positive feelings	*Physical health*	*Connecting with others*	*A meaningful and purposeful life*	*Environment, space and surroundings*
***Relaxed** ***Contentment** ***Happy** Calm Enjoyment Feeling loved Peaceful Kindness Stress Free Feeling safe Acceptance of your situation Feeling satisfied	***Feeling comfortable** Good health Pain free At ease Being active Access to good medical care Good diet	Connection /relationships Sharing humour/fun Seeing friends and family Being cared for/supported Individual attention Feeling close to others Being co-operative Alertness/ interest/engagement	***Meaningful activity** Choice Familiar routines Having a role/purpose Independence/autonomy Feeling valued Sense of identity Making a contribution Feeling useful Sense of normality Sense of worth Feeling respected Feeling fulfilled Balance/stability	Positive environment/ place Enjoying the outdoors

Table 18 Thematic analysis of wellbeing descriptor terms

*Using the ***five most frequent*** descriptors for wellbeing (**highlighted**), a simple definition of wellbeing for the purposes of this study could be suggested as:

Wellbeing is a state of feeling relaxed, content, happy and comfortable, with the opportunity to engage in meaningful activities.

Notably, of the top 5 most frequently used descriptor terms, 3 came from the theme associated with positive feelings, suggesting that people give greater weight to the importance of emotional wellbeing. Also, reflecting frequency rating meant that 2 themes were not represented in the definition.

Q2 What would you see in someone living with advanced dementia that would lead you to believe that an activity had improved their quality of life/wellbeing?

Participants felt that there were a good number of mainly non-verbal clues that could be observed in someone living with dementia that indicated that an activity had improved their wellbeing. There was a general feeling that these clues were often more subtle in those with advanced dementia and reading them also depends on knowing the person. For example:

Focus Group 2- Respondent 2

"I think that's an issue for our newer volunteers, sometimes it is managing people's expectations because somebody isn't going to say 'thank you so much for coming, I've had a lovely time.' So, those kinds of indicators that we would just normally consider to be polite, our community members aren't able to do so. It's almost about managing expectations, so you can see that somebody is really enjoying the session, but it might be a lot less demonstrative or a lot less verbal, the feelings I think are probably still there but it's how they're demonstrated."

Again, the feedback on specific indicators was analysed and grouped into subject area clusters (category) and those categories provided sub sections to 4 overall domain areas.

Domain	**Category**	**Specific indicators of improvement in wellbeing**
Body Language	Facial expression	Smiles, raised eyebrows, absence of frown, relaxed features
	Amount of body tension	Relaxed shoulders and posture, unclenched hands
	Eye contact/expression	Some eye contact during the session, a 'sparkle' in the eyes, eyes 'light up'
	Breathing	Slow and deep

Behaviour	Absence of signs of unmet need	Lack of- aggression, agitation, restlessness, wandering or distress, no indications of pain
	Engagement	Co-operation, movement, more animated, interest in activity or in the person who is spending time with them, reaching out, settled
Mood	Happiness and enjoyment	Improved colour in cheeks, smiles/laughter, eating and drinking, showing warmth and affection
Communicative interactions	Verbalisations	Words/feedback, less shouting out, attempts to speak, repeating words spoken to them
	Positive vocalisations	Noises such as 'mm' and 'aha', humming and singing
	Non-verbal responses	Contented sighing, nodding, responsiveness to caregiver's words and actions

Table 19 Summary of thematic analysis of suggested indicators for wellbeing

In summary, any positive change in the person living with dementia during the Namaste Care session was felt to be an indicator of improved wellbeing. Noticing and interpreting that change was felt to be more effective when the observer had a relationship with the person and so understood the way they individually expressed themselves. For example, a family carer commented about how she knew her husband had enjoyed an activity:

"I could tell in his face. He looked more animated and interested. Sometimes he was so engrossed he didn't want to leave."

An online participant responded:

"It may also depend on personality/characteristics- how they responded previously to something positive."

Sub question: Would this be different from yourself?

Participants were taken by surprise by this question but on considering it, they felt that the same things would be observable in themselves.

Designing an observational tool for a Namaste Care session

Q3 Can you think of what I need to think about when I design the scoring form?

All those who responded to this question said that the form needs to simple, quick, jargon free and easy to fill in. Several participants commented that the form should not be completed during the session, as it would "spoil the atmosphere" (family carer) and that "Making notes on a tablet or laptop in the presence of the patient can seem a little cold and inattentive." (Online questionnaire respondent.)

There was a consensus that it would be useful to have tick box options which were quick to fill in, a simple scale of level of engagement/enjoyment, but that the form needed to have space for some comments and narrative, particularly to capture 'magic moments.' It was also felt to be useful to record any negative reactions to certain interventions for future reference. Another comment was that there should be space to record any changes of medication, poor sleep, illness or other change of circumstances to give some context or explanation if the person did not engage in a particular session. In terms of scaling or tick box options, it was felt it would be important to give examples of what to look for to ensure consistency of reporting.

In terms of format, no-one thought that the form should only be available digitally. Most people said both paper and digital formats would be useful depending on circumstances. Those working or volunteering in the community felt the paper option would be better.

St Joseph's Hospice, Hackney, who deliver Namaste Care into the community, have kindly provided a copy of their current scoring form, which was developed and refined by volunteers as an example of a session record to work with for the purposes of this study.

Section 2- Supporting decision-making.

Q4. How would you know whether someone with advanced dementia was willing (or unwilling) to take part in my study?

Discussions on this topic did not highlight any major concerns about gaining consent to participate in the study. For example:

"Well by knowing her, I know she would have wanted to. She would have wanted to help. When she was diagnosed with dementia it was mentioned about taking part in research and she said yes, but then we never heard any more about it." (Family carer for his wife.)

"It's no different from everything we do all the time. Everything we do is via consent. Hand massage is by consent. We know if somebody doesn't, they don't have to say stop doing that. We know." (Namaste volunteer, Focus Group 2.)

"Information from family regarding what their views would have been when had capacity. The person complying with intervention and not displaying any resistance or appearing in any way distressed." (Online respondent.)

In terms of cautions, one participant in Focus Group 1 expressed concerns that her mother was now quite paranoid about any involvement with professionals and that even though she would have previously consented, now that her symptoms have progressed, she felt it would not be appropriate for her to take part. This point highlighted the general view that a full discussion with the family carer would need to occur to consider previous opinions on research as well as reviewing the current needs of the person to ensure taking part would not cause any distress.

Another online respondent raised the concern that not wishing to take part in the study should not prevent access to Namaste Care.

"Implied consent for receiving Namaste is indicated by body language. The separate consent for being part of a research project will involve a combination of discussions with their representatives and the individual at times when they are at their best. It would be ethically questionable if Namaste is withheld from people who want the intervention but do not want to be part of a research study."

In summary, it was felt that a decision for a person living with dementia who was unable to consent could be based on the following:

1. Knowledge of the person's beliefs and preferences relating to participating in research.
2. Recruiting participants for phase 2 of the study who have previously registered with 'Join Dementia Research' indicates they have already expressed an interest in participating in research.
3. Recruitment to the study could also take place through an organisation or service which has a thorough knowledge of the person and their circumstances and a trusted relationship.
4. The appropriateness for each person will be very individual and will need careful discussion with the family to consider their current needs as well as previously expressed opinions.
5. The main family carer very often is already making decisions on their behalf with regard to health, care and finances.
6. It was regarded as perfectly acceptable for the main family carer/next of kin to give proxy consent, but it was felt that more than one person should be involved in the decision to ensure a balanced view.
7. Not wishing to take part in the research should not exclude a person from accessing Namaste Care if they wish to.
8. Assent from the person with dementia should be sought with each research-based intervention, (as it is anyway with Namaste Care) and with all elements of the Namaste Care session. If there are any signs of dissent, the research element of the intervention should cease.

Physical information gathering

Q5. What are your thoughts about asking someone living with advanced dementia who does not have capacity to consent, to give a saliva sample at the beginning and end of a Namaste Care session?

(Examples of a Lollisponge ™ saliva collection device was provided in the focus groups and individual interviews to try out. A picture of a Lollisponge™ device was displayed in the online questionnaire.)

All respondents apart from one thought that the idea of obtaining physiological evidence of the benefits of Namaste Care was important and understood the reasons it was being explored. There were very mixed views about the idea of obtaining a saliva sample from someone living with advanced dementia using a saliva sampling option of a 'Lollisponge.' Although the majority of those who responded were broadly in favour of the idea of collecting saliva samples in this way, there were also some people who expressed concerns.

Categorising the responses made, the following is a summary of the number and feel of responses.

Broadly supportive and positive about the idea	42 responses
Negative about the idea	14 responses
Unsure about the idea	4 responses

Table 20 Categorisation of responses about the use of saliva sampling

Views in favour included:

"I think there's things you could assess, like if somebody doesn't have any problems having their teeth cleaned, it would be a good indicator that they would be ok, will handle well, or spoons, things like that." (Focus Group respondent.)

"Well, that looks alright. It's nowhere near as invasive as a covid test and he kept having to have them whether he liked it or not. He would have been ok with that I think." (Family Carer, in interview.)

"I think this is a reasonable request. I have no strong views against it at all. In looking at question below I suspect collecting a saliva sample in manner detailed above would feel much less invasive and more comfortable than covid swab." (Online respondent.)

"I think if it is brief and not uncomfortable and it may benefit them or other people with dementia at some point I think this is fine if all in best interest decision making process are in agreement." (Online respondent)

"I wouldn't mind but some people would. I suppose it's case by case." (Online respondent)

"I think as long as everyone involved with caring for the person knows what is happening, family and others, and they are happy for them to be part of the research, as well as all legal/ethical issues have been conducted and approved then I can't see why a saliva sample cannot be taken. The way in which it is done would have to be done sensitively and compassionately." (*Online Respondent)*

"I think they would be able to indicate whether they felt this was invasive and would therefore either allow this or not. A person who did not want to allow this would close their mouth. If handled sensitivity this should not be disagreeable for them." (Online Respondent)

Those expressing concern commented for example:

"*I think I would worry about her biting it. I don't think she would understand what to do, if I gave that to my mam. She would like, be freaked. Yeah, it's cause it's very unfamiliar." (Focus Group participant.)*

"Good luck getting someone with dementia keeping a swab in there month for a minute, I think it would be stressful to the person with dementia." (Online respondent.)

"It has the potential to cause distress. I would not like such an invasive procedure at any time, but especially after being relaxed and comforted. It has the potential to compromise the Namaste experience and in turn adversely affect the integrity of the research itself." (Online respondent)

"Is it important? It seems a little intrusive. The Namaste carer is there to provide support and not appear as a medical wanting samples. I think most should be able to make a judgement about how the visit went without taking samples. In the next question I have answered "Straightforward" but that is not a personal answer only what I have been told. Plus, the ethical approach below. Is it really necessary?" (Online respondent.)

Issues of importance or concern which will need to be addressed in the next phase of the study are therefore:

- A check on the safety of the Lollisponge™ saliva collection option showed it has not been tested in this patient group.
- Potential to cause distress must be eliminated or minimised.
- The act of sampling affecting the outcome of the session must be considered.
- An Ethical Approach

Q6. Thinking about this philosophy, would it feel more acceptable if the Namaste caregiver was also giving a saliva sample at the same time to measure how they feel about a session?

In relation to the query about whether it would feel more appropriate to ask for a saliva sample from someone with dementia if the Namaste Caregiver also gave a sample, the online questionnaire responses were more weighted towards this idea not making a difference to how the respondent felt about the saliva sampling idea. However, in the focus groups and interviews, all participants felt that this would feel more equitable and acceptable.
All family carers who were interviewed said that they would themselves be willing to give a sample themselves, to measure whether they had experienced any benefit from the time spent with their loved one by the Namaste Caregiver.

Exploring other options

Q7. How acceptable would it be for the person with dementia to wear a smart watch to capture other information (e.g. heart rate, movement) during a Namaste Care session?

Commented [TL1]: Try to make this a little less specific to keep your options open. I've added a couple of suggestions.

There were no objections to the idea of a person living with dementia wearing a smartwatch, and some expressed a view that it was preferable to saliva sampling due to being non-invasive. A number of respondents pointed out that most people will be used to wearing a watch and that some people are accustomed to wearing a falls monitor. One respondent wondered if the person with advanced dementia may be reluctant to give up the smartwatch

and another wondered if some people might find it irritating. An indicative sample of comments include:

"Lots of people with dementia are used to wearing fall detectors so I would imagine this may not be too much of an issue." (Online respondent)

"Put it on at the beginning of the session and take it off at the end. She would have been fine with that, I'm sure." (Family carer interview)

"I think this is also fine. People with dementia may have other procedures etc as part of routine care/other conditions and these devices are unlikely to cause discomfort." (Online respondent)
"I think this would be acceptable if it provided an indication of the feelings of the person with dementia on how they felt." (Online respondent)
"This would be much more acceptable than a swab, but unlikely to be reliable as a primary source of information as different people will react differently to wearing a device. A third consent would be required to place a device on a person, and they may pick at it, or find it irritating." (Online respondent)

Final comments

Consultation participants have been supportive of the idea of looking at ways to evaluate Namaste Care and have been very valuable in highlighting ways that plans for the next phase of the research will need to be modified. These results can therefore inform recommendations to be incorporated into the study protocol for phase 2 of the research.

In the final comments section, comments from participants included:

"Good questions, thank you and good luck." (Online respondent.)

"Just that I think this is all very important. One of the things I wish I'd done differently is thinking about doing things with xxxx. I was so busy seeing to the care, I didn't think about activities, her need to be stimulated, you know, social time." (Family carer interview.)

"Interesting ethical issues and made me think about the value of the research and its contribution to the body of knowledge and research already conducted in Namaste Care

approach and activities. I wish you luck and look forward to seeing the outcomes of this innovative research. The question about the response of PLWD and swabs has been variable, some very willing some not so, so I found this question difficult to answer so selected 'some distress' as this is worst case scenario...it has depended on how the person is approached, language used and who was conducting the swab." (Online respondent)

"It is excellent to ask advice about these methods. It illustrates how the primacy of positivist epistemologies has led to inappropriate evidence-based practice. The inevitable subjectivity of observation and the opinions of experts by experience is not a confounding variable, it is an asset. The confounding variable is the integration of invasive objects." (Online respondent.)

"I think the medical profession leave you to your own devices and I think it would be very helpful if there could be a programme where the carers could meet and learn about this (Namaste Care.") (Focus group participant.)

"The questionnaire is straight forward and easy to complete. I can't answer the question regarding how a person living with dementia has responded to being covid swabbed as I've never experienced this. What I can say is that I feel covid swabs would in many cases have been a necessary procedure and even though none of us like doing them, as responsible humans we do it to protect ourselves and others. Swabbing someone with advanced dementia to measure data on their response to a namaste session is not necessary in my opinion. Even if it's a quick sweep of the mouth is quite invasive and would be detrimental to the whole namaste process; as the session is to promote calmness and enhance the person's wellbeing. A swab will always be a reminder of a clinical procedure no matter with who or how its performed." (Online respondent)

A3 Laboratory methodology for urine sample processing and analysis

"Samples collection and storage

All urine samples were collected by or in the presence of Nicola Kendall. Hygienic collection of human urine samples was ensured through use of collection kits containing gloves, specimen cups and specimen pots. Participant samples were collected into 50 mL Falcon® centrifuge tubes and transported to a laboratory in a cool box, where the tubes were centrifuged at 1000 RPM for 20 minutes using a centrifuge (Figure 2.1). A P1000 pipette was used to obtain the supernatant and then transfer it into labelled 15 mL Falcon® tubes, which referenced the group, the session the sample has been obtained from, and whether it was collected before or after the Namaste Care session. Approximately 10 mL of urine was obtained from each participant, which was aliquoted as 2 mL samples into 15 mL Falcon® tubes to avoid continuous freeze/thaw cycles. All samples were stored at -20°C as per guidelines for short-term storage of human urine.

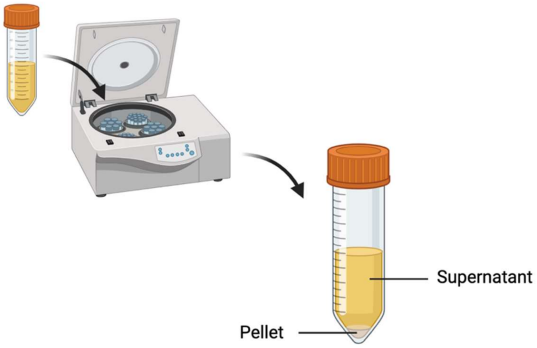

Figure 2.1 Separation of supernatant from pellet during centrifugation.

Sample stabilisation

Prior to freezing the samples, an antioxidant was added to maintain analyte stability. A ten-fold stock solution of antioxidant was made using 10 mM ethylenediaminetetraacetic acid (EDTA) and 40 mM sodium metabisulphite ($Na_2S_2O_5$) and stored in a 1 L borosilicate glass bottle at 4°C. 30 μL of antioxidant stock solution was added to 300 μL urine in Eppendorf tubes belonging two control samples, resulting in two 330 μL antioxidant-containing samples which were assayed alongside two neat 330 μL samples using a human DA enzyme-linked immunosorbent assay (ELISA) kit. DA concentration in urine was then determined with and without an EDTA/$Na_2S_2O_5$

antioxidant and analysed using a paired t-test, which revealed higher DA concentrations in samples containing the antioxidant, suggesting its role in maintaining analyte stability and enhancing biomarker detectability. The EDTA/$Na_2S_2O_5$ antioxidant was then added to all existing and newly collected samples prior to freezing in a ratio of 1:10 of antioxidant to urine.

Measuring biomarker concentration

Human DA two-site sandwich ELISA

A human DA ELISA kit from MyBioSource was used to quantitatively assess DA concentration in urine samples. Prior to beginning the assay, all samples were thawed on ice and materials acclimatised to room temperature; when not in immediate use, solutions were stored at 2-8°C. Once fully thawed, samples were aliquoted into labelled 3.0 mL Eppendorf tubes® for dilution marked with the participant group and session number. The kit utilised a two-site sandwich ELISA (Figure 2.2) to quantitate DA in samples, using an antibody specific for DA that had been pre-coated onto a 96 well microplate. The minimum detectable dose (MDD) for human DA was listed as up to 0.5 ng/L. Expected DA concentrations were predicted to fall between 30 and 300 ng/L (UCSF Health, 2023; Yi et al., 2012).

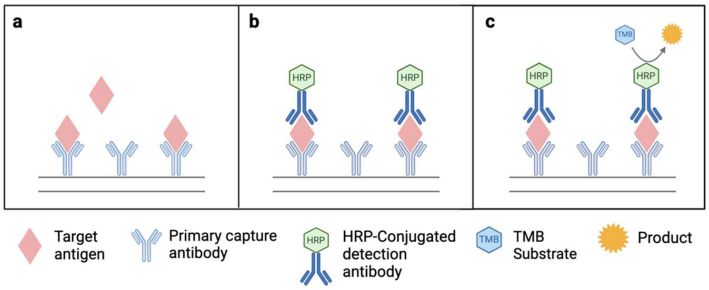

Figure 2.2 Principle behind a two-site sandwich ELISA using HRP-labelled enzyme and TMB substrate. (**a**) Target antigen binds to pre-coated primary capture antibody and unbound antigen washed out. (**b**) Incubation with enzyme-conjugated antibody. (**c**) Colour developed with substrate.

A serial dilution was prepared (Figure 2.3) by pipetting 150 μL of undiluted Standard solution into an Eppendorf® tube containing 150 μL of Standard Diluent and mixing thoroughly, then transferring 150 μL of this solution into another Eppendorf® tube containing 150 μL of Standard Diluent, again mixing thoroughly before the next transfer. This process was repeated three more times to produce six standard solutions that were added at 50 μL to the microplate. Sample Diluent was then added at 40 μL to each sample well, followed by 10 μL of urine in duplicate for a 1:5 dilution, leaving two blank wells without solution. The plate was covered and incubated at 37°C

for 45 minutes. All wells were then aspirated and washed according to the washing procedure outlined in Appendix 5.2. HRP-conjugated detection antibody was then added at 50 μL to each well except the blanks, and the microplate was once again covered and incubated at 37°C for 30 minutes. The aspiration/wash process was repeated five times and 50 μL of chromogen solution A and chromogen solution B were then pipetted into each well. The plate was mixed through gentle agitation and incubated at 37°C for 15 minutes, protected from light. Following incubation, 50 μL of Stop Solution was then added to each well, causing a colour change in the wells from blue to yellow. The optical density (OD) was read at 450 nm using a microplate reader within 15 minutes of completing the assay.

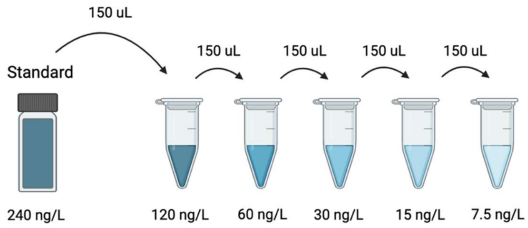

Figure 2.3 Dilution of human DA standard to produce a two-fold dilution series.

The average zero standard OD was subtracted from the absorbance values obtained from the serial dilution, which corresponded to specific DA concentrations. These data were plotted in Microsoft Excel to produce a standard curve for human DA concentration in ng/L (Figure 2.4).

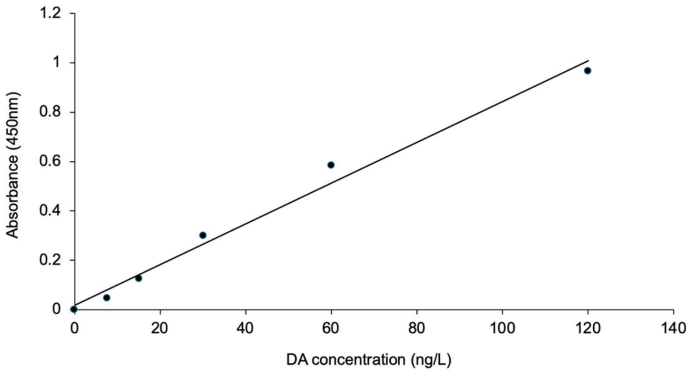

Figure 2.4 Standard curve for human DA concentration.

Duplicate absorbance readings were averaged, and the mean zero standard was subtracted from each value. Dilute DA concentrations were derived using the standard curve data in Excel, and then multiplied by the dilution factor to correct for dilution during the assay, generating actual DA concentrations in ng/L. For each participant, DA concentration was also presented as a percentage change from baseline DA concentrations.

Human COR double-antibody sandwich ELISA

A human COR ELISA kit from MyBioSource was used for quantitative detection of cortisol in urine samples. Prior to beginning the assay, all samples were thawed on ice and materials allowed to acclimatise to room temperature; when not in immediate use, solutions were stored at 2-8ºC. Once fully thawed, samples were aliquoted into labelled 3.0 mL Eppendorf tubes® marked with the participant group and session number. The kit employs a double antibody sandwich technique (Figure 2.5) to quantitate cortisol in samples, using an anti-Human cortisol monoclonal antibody pre-coated onto a 96 well microplate. The detection range was listed as 15.6 ng/mL to 1000 ng/mL, with an MDD of up to 5 ng/mL. Predicted urinary cortisol concentration for a healthy adult falls at ~ 40 ng/mL (Huizen, 2019).

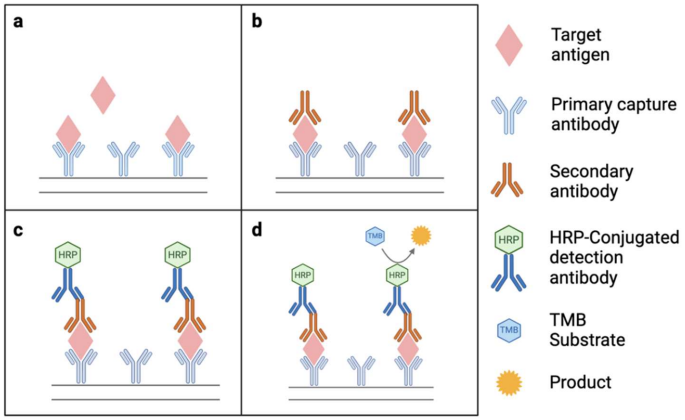

Figure 2.5 Principle behind a double antibody sandwich ELISA using HRP labelled enzyme and TMB substrate. (**a**) Target antigen binds to pre-coated primary capture antibody and unbound antigen washed out. (**b**) Incubation with secondary detector antibody. (**c**) Incubation with enzyme-conjugated antibody. (**d**) Colour developed with substrate.

Seven Eppendorf® tubes were labelled with expected cortisol concentrations (Figure 2.6) and prepared with 300 µL of Standard Diluent. 1.0 mL Standard Diluent was added to lyophilised standard to create the highest concentration solution, and once completely dissolved 300 µL of reconstituted standard was pipetted into the first

labelled tube and mixed thoroughly. 300 μL was then transferred from the first tube to the second, and the process repeated until a concentration of 15.6 ng/mL was reached. The final tube contained solely Standard Diluent, acting as a negative control. Prior to the immunoassay, neat urine was diluted with Sample Diluent or phosphate buffered saline (PBS) in a ratio of 1:3 following a review of literature.

100 μL of standard solutions and 100 μL of each sample in duplicate were pipetted into their corresponding wells on the microplate before sealing and incubating at 37°C for 90 minutes. The plate was washed twice following the washing procedure outlined in Appendix 5.3 and then 100 μL of Biotinylated Antibody solution was added to each well, which had been prepared 30 minutes prior to addition by diluting with Antibody Diluent in a ratio of 1:100 (antibody to diluent). The plate was covered and incubated at 37°C for 60 minutes then proceeded with three washes. 100 μL of Enzyme Conjugate solution was added to all wells, which had been prepared 30 minutes prior by dilution with Enzyme Diluent in a proportion of 1:100 (enzyme to diluent). The plate was then re-sealed and incubated at 37°C for 30 minutes, then proceeded with five washes. Colour Reagent was then prepared by mixing Colour Reagent A and Colour Reagent B in a ratio of 9:1. The resulting solution was then added at 100 μL to each well, and the plate was sealed an incubated at 37°C for a final time protected from light. The plate was removed from incubation once a visible colour gradient of standard solutions appeared, controlled to within 30 minutes. 100 μL of Colour Reagent C was pipetted into each well and then thoroughly mixed through gentle plate agitation, which was then processed using a microplate reader at 450 nm within 10 minutes of assay completion.

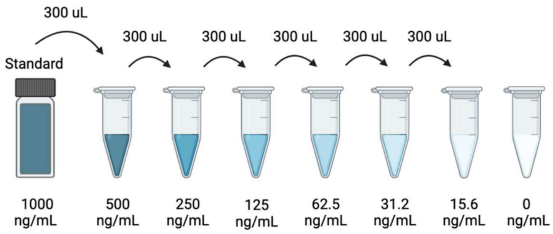

Figure 2.6 Dilution of standard stock solution to produce a two-fold dilution series for human COR ELISA.

The blank well OD was subtracted from the absorbance values obtained from the serial dilution and plotted in Microsoft Excel to produce a standard curve for human COR concentration in ng/mL (Figure 2.7).

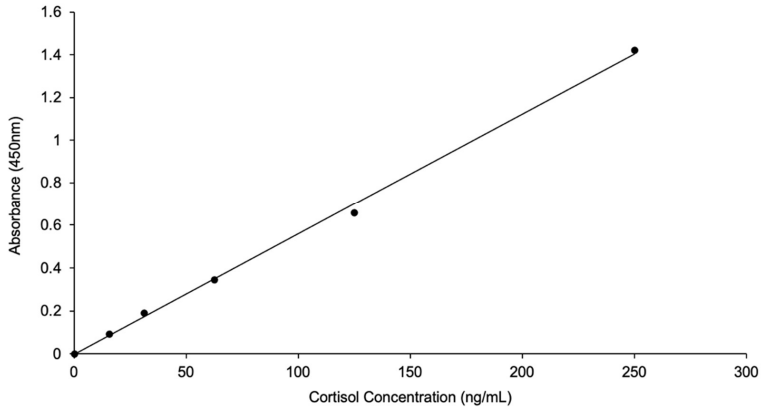

Figure 2.7 Standard curve for human COR concentration.

Duplicate absorbance readings for participant samples were averaged and the negative control OD was subtracted from each value. Dilute cortisol concentrations were derived using the standard curve data in Excel and then multiplied by the dilution factor to correct for dilution during the immunoassays, generating actual cortisol concentrations in ng/mL. For each participant, COR concentration for each session was also displayed as a percentage change from baseline COR concentrations."

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A4

Code	Age	Sex	Diagnosis	HR session 1	HR session 4	Cortisol session 1	Cortisol session 4	Dopamine session 1	Dopamine session 4	Nose temp. session 1	Nose temp. session 4	NCSOM session 1	NCSOM session 4
People with Dementia													
A1	74	M	Alzheimer's	↓	↓	↓	↓	↓	↓	↑	↑	↑	↑
A2	80	F	Alzheimer's	↓	↓	↓	↓	↓	↑	↓	↑	↑	↑
A3	58	M	Alzheimer's	↓	↑	↑	↑	↑	↓	↓	↓	↑	↑
A4	82	F	Mixed	↓	↓	↑	↓	↓	↓	↑	↓	↑	↑
A5	75	M	Mixed	↓	↓	↑	↓	↓	↑	n/a	n/a	↑	↑
A6	79	F	Alzheimer's	↓	↓	↓	↑	↑	↓	n/a	n/a	↑	↑
Healthy Controls													
B1	54	F	N/A	↓	↓	↓	↓	↑	↑	↓	n/a	↑	↑
B2	58	M		↓	→	↓	↓	↓	↑	↓	n/a	↑	↑
B3	20	F		↓	↓	↑	↑	↑	↓	→	n/a	↑	↑
B4	51	F		↓	↓	↑	↑	↓	↑	n/a	n/a	↑	↑
B5	22	F		↓	↓	↑	↑	↓	↑	n/a	n/a	↑	↑
B6	76	F		↓	↓	↓	↓	↑	↑	↓	↓	↑	↑
B7	75	F		↓	↓	↑	↓	↓	↓	n/a	n/a	↑	↑
B8	68	F		↓	↓	↓	↓	↓	↑	↓	↑	↑	↑

HR= Heart rate NCSOM= Namaste Care Session Outcome Measure score

Table 21 Master results table showing increases/decreases in all measures

Decrease in score	
Increase in score	
No change	

Appendix 5

Phase 3 – Results Sharing, Co-Interpretation and Knowledge Mobilisation

Notes from round table discussions

NB Where comments are duplicated, they will only be presented once with an * to denote frequency, and due weight will be given to those opinions in the discussion.

Comments from study participants.

"I hadn't known about Namaste Care, but Nicola came as a speaker to my friendship group, and I heard about it then. I must admit I was sceptical at first, I suppose it was fear of the unknown. But having experienced it as a participant, I am now a total convert. I'd recommend it to anyone."

"I felt it was beneficial. It made me feel more relaxed. The one-to-one session made me feel as if the person delivering the session really cared about my wellbeing."

"I looked forward to the visits. I found it relaxing. I enjoyed the massages and the poetry readings, and it improved my sleep. I was able to deliver Namaste Care to a relative because of what I learned from it."

"First and foremost, the carer herself (Nicola) was a delightful friendly young person to have in our home. Non-patronising because of our elderly status as it were, and non-threatening as some medics are (but not all of them.) I really did feel better after Nicola's visit- both mentally and physically. It meant a lot to me. Thank you, Nicola and the good old NHS, for providing services such as these."

"It was lovely to have someone who appreciates Beatles music! She was very friendly and made you feel at ease. It was good to have someone who is coming rather than to have donezepil and serratin as a matter of course. It's understanding the wider aspect and giving a quality of attention. Well done, Nicola."

Comments from dementia professionals: **Denotes frequency of comment*

- Currently there is very little input for care and wellbeing of people with dementia.**
- Namaste Care has tremendous impact on wellbeing, stress and anxiety reduction.**
- Namaste Care is relaxing. ****
- Namaste Care improves wellbeing and quality of life.
- Namaste Care should be essential provision across the NHS and all providers.****
- There is a proven tool (the Namaste Care Outcome Measure) that can be embedded into routine dementia care in care homes, people's homes etc. to support delivery of a therapeutic intervention.
- What's not to like about it (Namaste Care)?**
- Namaste Care is a tool to provide emotional care.
- It may delay admission into long term care provision.**
- Embed it into dementia education standards and frameworks.**
- Share information with large organisations such as AGE UK.
- Embed into 'Skills for Care' guidance.
- Provides a framework for the caregiver and the user.
- There's a benefit for the caregiver/Namaste provider- improving wellbeing. Staff wellbeing is of high importance for staff retention.**
- What else is there that's offered to people with advanced dementia and who may be towards end of life?
- Inclusion in NHS improvement guides and toolkits.**
- Needs the support of NICE.**
- These findings need to be presented to senior NHS managers and medics.
- From our experience, Namaste Care improves wellbeing and can help with de-escalation, rather than using medication.****
- Further collection of data as outlined in the presentation would be good.***
- Enables family and carer engagement/better quality of life.**
- If embedded in practice, there's no extra cost.
- The other users (participants without dementia) support the evidence.
- We see huge changes in clinical presentation when we use Namaste Care.
- It is calming and relaxing for both the patient and the staff member.

- There should be local authority buy-in with commissioned care to ensure a responsibility to deliver Namaste Care.
- Therapy dogs could be used as part of Namaste Care.
- Music therapy could be expanded.
- Namaste Care has a long-lasting effect (up to 24 hours.)
- Namaste Care helps people feel more comfortable.

General comments:

- There's a cost benefit to care and the NHS over the longer term.
- It could be applied to other mental health challenges.
- Namaste Care is achievable.
- It gives a feeling of making a difference.
- Needs to be in dementia strategies, as it is often introduced bottom up, so also need to be top down and joined up.
- The reach- the amount of people who could benefit is huge.
- Namaste Care is inclusive- it's not all about professionals.
- Positive progress is being made in Namaste Care research.
- High impact across multiple areas of benefit- carer health, primary care, hospital admissions, cost effectiveness, reduced medication, enabling people to stay at home, sustainability.
- "If you get it right for people with dementia, you get it right for everyone."

Key themes summarised:

1. Current provision for people living with advanced dementia needs improvement.
2. The study finding that Namaste Care induces a feeling of relaxation and sense of wellbeing is supported by people's experience and feedback.
3. Namaste Care should be an integral part of dementia care provision.
4. Namaste Care should be included in guidance for health and social care providers (e.g. NICE.)
5. Namaste Care is also good for the caregiver's wellbeing.
6. Namaste care is cost effective and can reduce the need for medication to manage behavioural symptoms of dementia.