

In-Touch: person-centered palliative care to improve comfort and connection in advanced dementia

Submission date 24/06/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The In-Touch project is a research study looking at how to improve the quality of life and care for people with advanced dementia living in nursing homes, as well as support for their family caregivers. The study is testing a new approach that combines two types of support: group sessions that use gentle, sensory activities to comfort and connect with residents (based on Namaste Care), and conversations between nursing staff and family caregivers to help plan future care (based on the Family Carer Decision Support intervention). The study is taking place in seven European countries.

Who can participate?

Nursing homes can take part if they have at least 30 beds, are typical for their country, are within two hours of the partner university, and can recruit enough residents.

Residents can take part if they have advanced dementia and a family caregiver who is involved in their care. The caregiver doesn't need to be a legal representative.

Nursing home staff and unpaid volunteers who help care for these residents can also take part.

What does the study involve?

Residents will be invited to take part in gentle, multi-sensory group sessions designed to bring comfort and connection. Their family caregivers will be invited to have structured conversations with nursing staff to help plan care that respects the resident's needs and wishes. Staff and volunteers will also be involved in delivering the sessions and supporting the residents.

What are the possible benefits and risks of participating?

Taking part may help improve the comfort and well-being of residents with dementia. Family caregivers may feel more supported and confident in making care decisions. Staff may feel more skilled and satisfied in their work.

There are no major risks expected, but some participants may find it emotional to talk about future care or end-of-life issues. Participation is voluntary, and people can stop at any time.

Where is the study run from?
University College Cork (Ireland)

When is the study starting and how long is it expected to run for?
January 2024 to December 2028.

Who is funding the study?
European Union Horizon programme and Innovate UK.

Who is the main contact?
Professor Nicola Cornally, n.cornally@ucc.ie

Study website
<https://palliativeprojects.eu/in-touch/>

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
353731

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EU Grant agreement ID: 101137270

Study information

Scientific Title

In-Touch: Implementation of a person-centered palliative care iNtervention To imprOve comfort, QUality of Life and social engagement of people with advanced dementia in Care Homes

Acronym

In-Touch

Study objectives

The evidence-informed and stakeholder co-created In-Touch intervention (i.e., Namaste Care integrated with the Family Carer Decision Support (FCDS) intervention) for nursing home residents with advanced dementia effectively improves residents' comfort and a range of other resident, family and staff outcomes.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 21/05/2025, lékařská fakulta Univerzity Karlovy Etická komise (Ruská 87/2411, 100 00 Praha 10, Prague, Nil known, Czech Republic; Nil known; eticka.komise@lf3.cuni.cz), ref: UK3LF/320332/2025-1
2. Approved 11/03/2025, Comitato di Bioetica di Ateneo (Via Bogino 9, Torino, 10123, Italy; +39 011 670 4377; staff.cba@unito.it), ref: 0234986
3. Submitted 14/03/2025, Clinical Research Ethics Committee Of the Cork Teaching Hospitals University College Cork (Lancaster Hall 6 Little Hanover Street, Cork, T12 E30P, Ireland; +353(0) 21 4901901; crec@ucc.ie), ref: Nil known
4. Approved 24/06/2025, METC Oost-Nederland (Radboudumc, Philips van Leydenlaan 25 (route 348), Nijmegen, 6525 GA, Netherlands; 31(0)24 3613154; METCoost-en-CMO@radboudumc.nl), ref: 2025-18187
5. Submitted 20/05/2025, Komisja ds. Etyki Badań Naukowych Uniwersytetu Jagiellońskiego Collegium Medicum (31-066 Kraków ul Skawińska 8, Kraków, Nil known, Poland; 502 186 434; katarzyna.szczerbinska@uj.edu.pl), ref: Nil known
6. Submitted 12/06/2025, Health & Social Care Research Ethics Committee B (Office of Research Ethics Committees NI Unit 4 Lissue Industrial estate Moira Rd, Lisburn, BT28 2RF, United Kingdom; +44 (0) 2895 361408; RECB@hscni.net), ref: 25/NI/0094
7. Not yet submitted 30/06/2025, Comissão de Ética para a Saúde da Universidade Católica Portuguesa (CES-UCP) (Palma de Cima, Lisboa, 1649-023, Portugal; +351 217 214 000; ces.ucp@ucp.pt), ref: Nil known
8. Not yet submitted 30/06/2025, Comissão de Ética das Residências Montepio (Rua Julieta Ferrão, nº10 - nº5, Lisboa, 1600-131, Portugal; +351 217 815 500; geral@residenciasmontepio.pt), ref: Nil known

Study design

Parallel-group cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Mixed-methods design including nested economic and process evaluation

Study setting(s)

Care home

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions

We will conduct a two-arm, parallel-group, pragmatic, cluster-randomised controlled trial with nursing homes in each of the seven participating countries, with embedded process and economic evaluation. Care as usual and intervention will be performed at the cluster level and outcomes will be measured at the participant level. All participating nursing homes will undergo an initial baseline data collection period. Following this, intervention sites will receive training on the In-Touch program, while control sites will only receive general trial information. The intervention or care as usual will then be implemented for 12 months, by the site staff.

Intervention Arm: The In-Touch intervention consists of two key components:

1. In-Touch Daily Sessions are delivered to the residents and these are sensory-based, person-centred group activities delivered by trained nursing home staff, based on the Namaste Care programme. The sessions focus on engaging residents through gentle touch, soothing music, aromatherapy, meaningful activities, and social interaction to improve their comfort and quality of life. Sessions will ideally take place twice daily for two hours in a designated, calm space within the nursing home over a 12-month period.
2. In-Touch Family Meetings occur with the family members and are structured discussions facilitated by trained staff, using the Comfort Care Booklet, to guide the conversation on shared decision-making about the resident's care. The meetings help families understand the progression of dementia, discuss preferences for current and future care, and facilitate advanced care planning. The meetings will take place twice during the study for family members of residents enrolled in the intervention arm of the cRCT.

Control Arm: Residents in the control nursing homes will receive care as usual and will not be excluded from the normal psychosocial activity of the nursing home or any other care/therapy interventions recommended for them. Care as usual will be described for each control site as part of the baseline situational analysis.

While the primary outcome is measured at 3 months will also plan to collect data at 3 additional time points [T2, (6 months), T3 (9 months), T4 (12 months)] this is the same for both study arms.

For intervention sites, there will be an additional 6 months of limited data collection focused on post-trial sustainability. This extended period allows researchers to assess the long-term viability and impact of the In-Touch program beyond the initial trial phase.

Randomisation will be performed using a computer-generated randomisation procedure computer randomised schedule with a 1:1 allocation ratio of nursing homes matched for size to one of the arms, intervention or care as usual. The randomisation will be provided by a statistician who is not part of the In-Touch team, based in the Health Research Board Clinical Research Facility at University College Cork.

Intervention Type

Behavioural

Primary outcome measure

Resident comfort assessed with the observational Discomfort Scale – Dementia of Alzheimer Type (DS-DAT) collected at baseline and at 4 time points with 3 monthly intervals over a 12 month period

Secondary outcome measures

Collected at baseline and at 4 time points with 3 monthly intervals over a 12 month period, where applicable:

1. Quality of life is measured using the Quality of Life in Late-Stage Dementia scale (QUALID)
2. Pain is measured using the Pain Assessment in Advanced Dementia scale (PAINAD)
3. Agitation is measured using the Cohen-Mansfield Agitation Inventory – Short Form (CMAI-SF)
4. Neuropsychiatric symptoms are measured using the Neuropsychiatric Inventory – Nursing Home version (NPI-NH)
5. Social engagement is measured using Resident Daily Activity Logs at baseline, and continuous for 12 months
6. Psychotropic medication use is measured using medication administration records
7. Adverse events (pressure ulcers, infections, and hospital transfers) are measured using clinical records
8. Care planning is measured using Chart Extraction Tool and Family Meeting Activity Logs at baseline and continuous for 12 months
9. Decisional conflict is measured using the Decisional Conflict Scale
10. Anticipatory and post-death grief are measured using the Prolonged Grief Disorder Scale (PG-13)
11. Personal quality of life (family) is measured using the EuroQol 5-Dimension Questionnaire (EQ-5D)
12. Satisfaction with care is measured using the Satisfaction With Care – End-of-Life in Dementia scale (EOLD-SWC)
13. Perceived comfort in dying is measured using the Comfort Assessment in Dying scale (EOLD-CAD)
14. Understanding of dementia as a terminal illness is measured using a single item in the Family Survey
15. Burnout is measured using the Maslach Burnout Inventory (MBI)
16. Job satisfaction is measured using a 7-point Likert scale
17. Personal quality of life (staff) is measured using the EuroQol 5-Dimension Questionnaire (EQ-5D)
18. Attitudes and perceptions of dementia care are measured using the Person-Centred Care

Assessment Tool (P-CAT)

19. Competence and communication self-efficacy are measured using the Sense of Competence in Dementia Care Staff scale (SCIDS)

Overall study start date

01/01/2024

Completion date

31/12/2028

Eligibility

Key inclusion criteria

1. Nursing homes must have a typical number of beds with a minimum of 30, representing the predominant provider type in that country
2. Nursing homes must be located within a two-hour travel time from the partner university
3. Nursing homes must be able to recruit a sufficient number of eligible residents
4. Residents must have advanced dementia, defined as moderately severe to severe dementia according to FAST stage 6 or 7
5. Residents must have a family caregiver (care partner, care supporter, or advocate) involved in their care and support, including in care decisions
6. The participating adult family caregiver is not required to have legal representative status or decision-making authority for the resident
7. Nursing home staff and unpaid volunteers involved in the care of eligible residents are also included

Participant type(s)

Health professional, Resident, Other

Age group

Senior

Sex

Both

Target number of participants

284 nursing home resident – family caregiver (care partner) dyads

Key exclusion criteria

1. Nursing homes that already provide Namaste Care or the FCDS intervention at baseline
2. Nursing homes that participate in another clinical trial or research study involving residents with dementia
3. Residents for whom there is no consenting family caregiver available to take part in the trial
4. Residents who are unable or unwilling to be brought to a common social space
5. Residents who are actively dying, with death expected in the coming days or weeks as judged by nursing home staff
6. Residents who are acutely unwell or have been recently transferred from acute care and are not well enough to participate
7. Residents who have capacity to consent and refuse to take part in the trial

Date of first enrolment

01/01/2026

Date of final enrolment

30/07/2026

Locations

Countries of recruitment

Czech Republic

England

Ireland

Italy

Netherlands

Northern Ireland

Poland

Portugal

United Kingdom

Study participating centre

To be added later

United Kingdom

-

Sponsor information

Organisation

University College Cork

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Sponsor type

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<https://ror.org/03265fv13>

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Sponsor type

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ROR

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Sponsor type

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ROR

Funder(s)

Funder type

Government

Funder Name

European Union (grant no. 101137270)

Funder Name

Innovate UK

Results and Publications

Publication and dissemination plan

Study findings will be published in peer-reviewed journals and presented at conferences. Summaries will be shared with stakeholders, including care providers, policymakers, and the public. Open-access training materials will support further implementation. Results will be disseminated through scientific publications, public reports, social media, and events. All materials will be open access. The European Association of Palliative Care (EAPC) and partner organisations will support broad communication to professionals and families.

Intention to publish date

30/04/2028

Individual participant data (IPD) sharing plan

The quantitative non-identifiable resident-level raw and processed data will be made findable and shared for reuse and/or verification. Staff data when sufficient numbers or omitting characteristics ensures non-identifiability. Codebooks and questionnaires / eCRF in Castor as necessary. Readme.text to explain the data and data structure.

Quantitative data will be archived in Data Acquisition Collection (DAC) and/or a Research Documentation Collection (RDC) in the Radboud Data Repository (RDR), and made findable and potentially shared for reuse at EU repository Zenodo when the project ends, and also aggregate qualitative data may be considered for archiving in a repository.

The pseudonymized data will be accessible in the RDR repository under restricted access by the research team, and the data may be anonymized (links to IDs destroyed) when moved to Zenodo at the end of the project. Requests for access to pseudonymized or anonymized data will be checked by the Consortium Executive Committee of In-Touch, against the conditions for sharing the data as described in the signed Informed Consent and the consortium agreement.

IPD sharing plan summary

Stored in publicly available repository, Stored in non-publicly available repository

