ISRCTN24994668 https://doi.org/10.1186/ISRCTN24994668

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

Submission date
24/06/2025

Recruitment status
Recruiting

Registration date
25/06/2025

Overall study status
Ongoing

Last Edited
22/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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 2027

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

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Nicola Cornally

ORCID ID
https://orcid.org/0000-0003-0644-0026

Contact details
Brookfield Health Science Complex, University College Cork
Cork
Ireland
T12 YN60
+353 21 4901458
n.cornally@ucc.ie

Additional identifiers

Integrated Research Application System (IRAS)
353731

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

Study design
Parallel-group cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

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(s)
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

Key secondary outcome(s))
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)

Completion date
31/12/2027

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
0

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
30/03/2026

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Czech Republic

Ireland

Italy

Netherlands

Poland

Portugal

Study participating centre
To be added later
-
-
England
-

Sponsor information

Organisation
University College Cork

ROR
https://ror.org/03265fv13

Organisation
Masarykova univerzita (MUNI)

Organisation
Jagiellonian University (Uniwersytet Jagielloński)

Organisation
University of Turin (Università degli Studi di Torino)

Organisation
Radboud University Medical Center

ROR
https://ror.org/05wg1m734

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Organisation
Universidade Católica Portuguesa

ROR
https://ror.org/03b9snr86

Funder(s)

Funder type
Government

Funder Name
European Union (grant no. 101137270)

Funder Name
Innovate UK

Results and Publications

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 non-publicly available repository, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes