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MinderCare: translational research and digitally enabled care

Submission date
15/01/2025

Recruitment status
Recruiting

Registration date
21/01/2025

Overall study status
Ongoing

Last Edited
06/02/2026

Condition category
Nervous System Diseases

[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 MinderCare study aims to test a smart home system called Minder, developed by the UK Dementia Research Institute. The system uses sensors and medical devices to provide early warnings for potential health issues (e.g., infections) and safety concerns (e.g. wandering) of people with dementia. The researchers will link directly with health and care professionals and provide them with information that can be used to support clinical and care decision-making. The study aims to test the accuracy and reliability of the early warning flags. Information will be collected on the outcomes and experience of MinderCare to understand whether it could and should be made more widely available as a mainstream service for people with dementia.

Who can participate?
The study seeks approximately 100 individuals aged over 50 years with a confirmed or suspected diagnosis of dementia, along with up to 100 study partners (i.e., people caring for patients with dementia). Additionally, the study will recruit up to 50 healthcare professionals for qualitative research activities (e.g., interviews and/or focus groups).

What does the study involve?
Participants will have internet-enabled devices installed in their homes to monitor movement, activity, sleep and general health. The MinderCare team will support participants with any technical issues and monitor their health. Participants will complete some assessments at the start and after 6 months. The team will regularly contact participants to monitor their well-being and address any alerts generated by the system.

What are the possible benefits and risks of participating?
Benefits include early detection of health issues and timely support from healthcare professionals. The study is low-risk and uses non-invasive, commercially available devices. However, the system is not set up for real-time emergencies, so participants may need additional safety measures like a pendant alarm.

Where is the study run from?
The study is led by Imperial College London in collaboration with Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2023 to June 2027

Who is funding the study?
The study is funded by LifeArc via the UK Dementia Research Institute

Who is the main contact?
Margherita Tecilla, Project Manager, m.tecilla@imperial.ac.uk

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
345123

ClinicalTrials.gov (NCT)
Nil known

Grant Code
DRI-LA2023/4

Central Portfolio Management System (CPMS)
63023

Study information

Scientific Title
Minder translational research and digitally enabled care for dementia (MinderCare)

Acronym
MinderCare

Study objectives
MinderCare is a feasibility study designed to integrate novel technology into direct dementia care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2024, North East – Newcastle and North Tyneside 2 (address: not available; +44 (0)207 104 8086, +44 (0)207 104 8140, +44 (0)207 104 8055; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 24/NE/0190

Study design
Non-randomized; Both; Design type: Screening, Prevention, Process of Care, Device, Psychological & Behavioural, Management of Care, Active Monitoring, Cohort study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Dementia

Interventions
This feasibility study will explore the impact of the MinderCare system on patients' and carers' healthcare access and quality of life. A sample of 100 patients will allow us to estimate means and standard deviations for continuous outcome measures and proportions for categorical outcome measures, both with accompanying 95 CI%s. One key set of outcome measures relates to the accuracy of the digital biomarkers we will be generating. From the previous experience of running a related trial (Minder Health Management study), the assessment of around 100 people living with dementia is sufficient to evaluate the accuracy and performance of digital biomarkers /algorithms across a range of outcomes. Following expression of interest, participants will be visited by the MinderCare monitoring or clinical team at baseline, at 6 months (and if possible at 12 months, exit battery) visits.

Eligibility and capacity to participate will be assessed prior to the baseline visit. Capacity will be assessed on an ongoing basis throughout the study. Consent to participate will be obtained from both the participant with dementia and the study partner during the baseline visit. Device installation will also occur during baseline visit(s). After the devices are installed, participants will start the study. Data gathered from the devices will be monitored by the MinderCare Monitoring team. Alerts generated by the devices and our developed algorithms will be collected and reviewed by the MinderCare Monitoring team to rule out any technical errors and confirm the validity of the alerts before they are escalated to the Clinical team, who will proceed with their triage and use of the information to support their clinical decision-making processes. In addition, regular reports (“Minder Reports”) will be provided to the clinical team (or upon requests from the participant’s GP and clinical consultants) summarising data and alerts.

During each home visit, participants and study partners will be asked to fill in questionnaires about their physical and mental health well-being. The baseline battery can be staggered over two visits to reduce the demand on participants' time and the impact of fatigue on engagement if needed. Each visit can take up to 2 hours. Throughout their involvement, planned and unplanned contact will be happening via phone calls in response to technical issues or alerts and to support study engagement. The participant will be invited to take part in the optional blood collection and both the participant and the carer to engage in PPIE activities.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MinderCare system

Primary outcome(s)
Performance of algorithms measured based on the accuracy of alerts throughout the participation in the study

Key secondary outcome(s))
1. Healthcare usage, clinical events, transitions in care, and mortality rate measured via access to healthcare records and information obtained through planned and unplanned well-being calls during study participation
2. Health-related metrics measured using the Dementia Proforma and Client Service Receipt Inventory (CSRI) at baseline, 6 months, and 12 months (if applicable)
3. Activities of daily living measured using The Bristol Activity of Daily Living (BADL) scale at baseline, 6 months, and 12 months (if applicable)
4. Quality of life measured using the EuroQol-5D (EQ-5D) and Adult Carer Quality of Life Questionnaire ACQoL scales at baseline, 6 months, and 12 months (if applicable)
5. Neuropsychiatric symptoms assessed using the Neuropsychiatric Inventory–Questionnaire (NPI-Q) at baseline, 6 months, and 12 months (if applicable)
6. Depression evaluated using the Patient Health Questionnaire (PHQ-9) at baseline, 6 months, and 12 months (if applicable).
Cognitive functions assessed using Addenbrooke's Cognitive Examination III (ACE III) at baseline, 6 months, and 12 months (if applicable)
7. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) scale at baseline, 6 months, and 12 months (if applicable)
8. System usability evaluated using the System Usability Scale (SUS) at baseline, 6 months, and 12 months (if applicable).
9. System reliability, accessibility, and acceptability assessed throughout study participation:
9.1. System reliability evaluated based on the nature and frequency of technical and human factor issues (e.g., devices being moved or unplugged)
9.2. System accessibility evaluated by tracking the number of participants who lack Wi-Fi at enrollment and require SIM-enabled routers to participate
9.3. System acceptability measured based on reasons for non-enrollment (via the screening log) and SUS scores.
10. System acceptance and usability by healthcare/social care professionals assessed using the Technology Acceptance Model (TAM) at baseline (professional group).
11. Participants' and healthcare professionals' experiences with system alerts, including utility, acceptability, accessibility, and service satisfaction, assessed via interviews/focus groups /PPIE (Patient and Public Involvement and Engagement) activities throughout the study duration.

Completion date
01/06/2027

Eligibility

Key inclusion criteria
Participants must meet the following criteria for study entry:
1. Confirmed or suspected diagnosis of dementia (any type), male or female 50 years of age and older at baseline. Suspected dementia will be verified as follows:
1.1. Within a hospital clinic letter or discharge report written by the medical team referring to ‘suspected dementia’ or cognitive decline with/without a recent episode of delirium (ICD 10 F05 Delirium) and recommendation for referral to Memory Services diagnostic clinic
1.2. Patients prescribed with the following: cholinesterase inhibitors without a corresponding diagnosis of Alzheimer’s Disease or dementia; donepezil; rivastigmine; galantamine; memantine.
2. Participants who lack the capacity to provide informed consent must have a personal or nominated consultee representative.

Where a potential study partner is available, they must meet the following criteria:
1. Willing and able to provide informed consent to be in the study.
2. Aged 18 years or over

The absence of a study partner will not constitute an exclusion criterion as we are keen to make the study as inclusive as possible.

Professionals and members of the public sample for PPIE activities:
1. Adults (>= 18 years)
2. Willing to provide informed consent

Participant type(s)
Health professional, Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
The following are the exclusion criteria for the participant:
1. People with co-morbid unstable mental illness for example active psychosis/substance misuse under the care of CMHT at screening and baseline.
2. People who currently have active suicidal ideas.
3. People who are receiving treatment for terminal illness at screening and baseline or under the care of a palliative care team.

Where a potential study partner is available, the following are the exclusion criteria for the study partner:
1. People who are unable to communicate verbally.
2. People who are unable to provide written informed consent to be part of the study.

Professional and members of the public sample for PPIE activities:
1. Unwilling to provide written informed consent

Date of first enrolment
03/03/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare NHS Trust
St Mary's Hospital
The Bays
South Wharf Road
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W2 1NY

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
LifeArc

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. At this stage, the researchers anticipate publishing a portion of the data through DPUK, with further details to follow in due course.

IPD sharing plan summary
Stored in publicly available repository