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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
30/07/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
MinderCare is a study of a digitally enabled dementia care service for people living at home with confirmed or suspected dementia. The service uses low-burden sensors placed in the home, such as movement sensors, door sensors, smart plugs, and a sleep mat. These sensors do not require the person with dementia to operate them. They collect information about patterns such as sleep, activity, routines, night-time behavior, and possible signs of health deterioration.
The study aims to assess whether MinderCare can identify clinically important changes, whether it is feasible and acceptable for people living with dementia, carers, and health and social care professionals, and whether it may support more timely care. The study will also examine whether people receiving MinderCare have different outcomes from similar people receiving usual care, using routinely collected linked health and care records.

Who can participate?
People aged 50 years or older who live at home and have a confirmed or suspected diagnosis of dementia may be eligible. People who lack capacity may participate if a personal or nominated consultee is available. The absence of a study partner is not an exclusion criterion. Study partners and health or social care professionals may also be invited to take part in relevant assessments, surveys, interviews, or focus groups.

What does the study involve?
The MinderCare team installs sensors in the participant's home. Information from the sensors is processed by the Minder platform, which generates summaries and alerts. These are reviewed by the monitoring and clinical MinderCare teams. If an alert appears clinically relevant, the clinical team may contact the participant or carer, provide advice, update care plans, or liaise with health and social care professionals already involved in the person's care.
Participants and study partners may complete assessments at baseline and every 6 months and at study exit. Some participants, carers, and professionals may be asked to take part in optional interviews or focus groups.
The study will also compare outcomes for people receiving MinderCare with outcomes for similar people receiving usual care. This comparison will use linked health and care records to

identify similar people who are not receiving MinderCare. The comparison will examine outcomes such as Days Alive and Out of Hospital over 12 months, hospital admissions, healthcare use, care transitions, mortality, and healthcare costs.

What are the possible benefits and risks of participating?
The study may support earlier detection of clinically relevant changes and more timely care. The system uses non-invasive devices and is considered low burden. MinderCare is not a real-time emergency response service, so usual emergency and safety arrangements remain necessary.

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 October 2027.

Who is funding the study?
The study is funded by LifeArc and the UK Dementia Research Institute at Imperial College London (UK)

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

Integrated Research Application System (IRAS)
345123

Central Portfolio Management System (CPMS)
63023

Grant Code
DRI-LA2023/4

Study information

Scientific Title
MinderCare: protocol for a mixed-methods evaluation of a digitally enabled dementia care service

Acronym
MinderCare

Study objectives
Current study objectives as of 30/07/2026:
MinderCare evaluates whether a digitally enabled dementia care model, combining passive in-home sensors, algorithm-derived digital biomarkers, monitoring-team review, and nurse-led clinical triage, can detect clinically relevant changes in people living with dementia and support timely care within routine NHS and social care pathways. The study will assess digital biomarker performance, feasibility, acceptability, sustainability, participant and carer outcomes, comparative effectiveness, and healthcare resource use. Comparative effectiveness will be assessed using a target trial emulation with electronically matched external controls derived from linked health and care records. Update

Previous 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

Primary study design
Interventional

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

Study type(s)
Other

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

Interventions
Current interventions as of 30/07/2026:
Interventions MinderCare is a digitally enabled dementia care model that combines passive in-home monitoring with monitoring team review and nurse-led clinical triage to support proactive care for people living with confirmed or suspected dementia at home. The study will evaluate the performance of MinderCare digital biomarkers, the feasibility and acceptability of delivering the service within routine NHS and social care pathways, participant and carer outcomes, healthcare utilisation, and health-economic impact.

The main prospective cohort will include 100 people living with confirmed or suspected dementia. This sample size is expected to provide sufficient alert-level and participant-level observations to estimate key digital biomarker performance metrics with accompanying 95% confidence intervals across a range of clinical and behavioural outcomes, informed by previous experience from related Minder studies. Where available, study partners will also be invited to participate in assessments and follow-up. A comparative-effectiveness component will use linked electronic health record data to construct an electronically matched external usual care control cohort, using a target trial emulation framework.

Following expression of interest, eligibility and capacity to participate will be assessed before enrolment. Capacity will be assessed on an ongoing basis throughout the study. Written informed consent will be obtained from participants who have capacity. For participants who lack capacity, advice will be sought from a personal or nominated consultee in accordance with applicable UK guidance. Where a study partner is involved, written informed consent will also be obtained from the study partner.

After enrolment, passive sensors will be installed in the participant's home by the MinderCare monitoring team. The sensor configuration will be tailored to the participant's home environment and preferences and may include a sleep mat, movement sensors, door sensors, smart plugs, and a gateway hub. Participants without home Wi-Fi may receive a study-provided router. Participants may also opt for a reduced sensor configuration, including sleep-mat-only installation, if preferred. Installation or re-installation usually takes less than two hours and includes confirmation of connectivity, explanation of device function, and an opportunity to address questions or concerns.

Once the devices are installed and activated, sensor data will be transmitted to the Minder platform. Digital biomarker algorithms will generate summaries, reports, and alerts relating to clinically relevant changes such as infection risk, sleep disruption, changes in activities and routines, and night-time safety. Alerts and reports will be reviewed by the MinderCare monitoring and clinical teams. The monitoring team will undertake first-line review to identify likely technical artefacts and validate alerts before escalation. The clinical team will review escalated alerts, undertake clinical triage, contact participants or carers where appropriate, provide advice, update care plans, and liaise with relevant health and social care professionals through approved NHS communication routes.

Participants and, where available, study partners will complete baseline assessments at or around the time of installation. Follow-up assessments will be repeated every 6 months and again at withdrawal or study exit. Assessments include measures of clinical status, cognition, neuropsychiatric symptoms, activities of daily living, participant and carer wellbeing, quality of life, service use, and system usability. The baseline assessment battery may be staggered across multiple visits to reduce participant burden and fatigue. Each visit may take up to approximately 2 hours.

Throughout participation, planned and unplanned contacts may take place by telephone, video call, email, or home visit according to participant preference and clinical need. Planned contacts will support clinical review, study engagement, and collection of ground-truth information. Unplanned contacts may occur in response to alerts, technical issues, or emerging clinical concerns. The nature, duration, and outcome of contacts will be recorded.

Previous 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)
Current primary outcome as of 30/07/2026:
The study has two primary outcome-measure domains:
1. Digital biomarker algorithm performance in the prospective MinderCare cohort will be measured against clinical ground-truth data using alert-level and event-level metrics, including sensitivity, specificity, positive predictive value, negative predictive value, false-alert rate, area under the ROC curve, timeliness of detection, and time from alert to clinical action
2. Days Alive and Out of Hospital (DAOH) in the comparative-effectiveness target trial emulation will be measured over 12 months from the activation-index date and compared between activated MinderCare plus usual care and electronically matched usual-care controls

Previous primary outcome:
Performance of algorithms measured based on the accuracy of alerts throughout the participation in the study

Key secondary outcome(s)
Current secondary outcomes as of 30/07/2026:
1. Healthcare utilisation, clinical events, care transitions, institutionalisation, and mortality measured during study participation and, where applicable, over 12 months from the activation-index date using linked electronic health records, population health datasets, and information obtained through planned and unplanned clinical contacts. Healthcare utilisation outcomes include GP consultations, emergency department attendances, hospital admissions, inpatient bed-days, outpatient appointments, ambulance calls where available, and cause-specific hospitalisations.
2. Participant clinical status and health-related characteristics measured using the Dementia Proforma and Client Service Receipt Inventory (CSRI) at baseline and every 6 months, as well as at withdrawal or study exit.
3. Cognitive function measured using Addenbrooke’s Cognitive Examination III (ACE-III) at baseline and every 6 months, as well as at withdrawal or study exit.

4. Activities of daily living measured using the Bristol Activities of Daily Living Scale (BADL) at baseline and every 6 months, as well as at withdrawal or study exit.
5. Neuropsychiatric symptoms measured using the Neuropsychiatric Inventory Questionnaire (NPI-Q) at baseline and every 6 months, as well as at withdrawal or study exit.
6. Participant and carer quality of life measured using the EuroQol-5D (EQ-5D) and Adult Carer Quality of Life Questionnaire (ACQoL) at baseline and every 6 months, as well as at withdrawal or study exit.
7. Depression and anxiety measured using the Patient Health Questionnaire-9 (PHQ-9) and Generalised Anxiety Disorder-7 (GAD-7) at baseline and every 6 months, as well as at withdrawal or study exit.
8. System usability, user satisfaction, perceived ease of use, and intention to use measured using the System Usability Scale (SUS), surveys, interviews, and focus groups with participants, study partners, and health and social care professionals. The SUS is completed at baseline and every 6 months, as well as at withdrawal or study exit. Optional participant and/or study partner interviews are conducted approximately 2 months after installation and again at 6 months or de-installation/study exit. Health and social care professional surveys, focus groups, and follow-up interviews are conducted during study implementation and follow-up.
9. Feasibility, acceptability, reach, retention, implementation, sustainability, and operational workload of the MinderCare service assessed using recruitment and retention data, screening logs, contact logs, clinical review records, technical support logs, and qualitative interviews or focus groups. Recruitment, screening, retention, contact, clinical review, and technical support data are collected throughout recruitment and study participation. Qualitative interviews with participants and/or study partners are conducted approximately 2 months after installation and again at 6 months or de-installation/study exit; health and social care professional surveys, focus groups, and follow-up interviews are conducted during study implementation and follow-up.
10. System reliability, accessibility, and technical performance assessed throughout study participation using device connectivity data, Wi-Fi availability, need for study-provided routers, device reliability, technical failures, system downtime, data completeness, missingness, and reasons for non-enrolment or withdrawal. These data are collected continuously throughout active monitoring from sensor activation until withdrawal or study exit.
11. Alert and clinical workflow outcomes, including alert burden per participant, alert burden per 100 participants, alert distribution, redundant alert ratio, time from alert to review, clinical response ratio by response pathway, time from alert to action, and serious missed events where identifiable. These data are collected continuously throughout active monitoring from sensor activation until withdrawal or study exit.
12. Health-economic outcomes measured using linked health and care records, including secondary care costs, primary care costs, prescribing and medication costs, total direct healthcare costs, social care costs where data are available and of sufficient quality, and projected budget impact of wider implementation. Routine linked health and care record data will be extracted during or after study follow-up for the relevant follow-up period.

Previous secondary outcomes:
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).
7. Cognitive functions assessed using Addenbrooke's Cognitive Examination III (ACE III) at baseline, 6 months, and 12 months (if applicable)
8. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7) scale at baseline, 6 months, and 12 months (if applicable)
9. System usability evaluated using the System Usability Scale (SUS) at baseline, 6 months, and 12 months (if applicable).
10. System reliability, accessibility, and acceptability assessed throughout study participation:
10.1. System reliability evaluated based on the nature and frequency of technical and human factor issues (e.g., devices being moved or unplugged)
10.2. System accessibility evaluated by tracking the number of participants who lack Wi-Fi at enrollment and require SIM-enabled routers to participate
10.3. System acceptability measured based on reasons for non-enrollment (via the screening log) and SUS scores.
11. System acceptance and usability by healthcare/social care professionals assessed using the Technology Acceptance Model (TAM) at baseline (professional group).
12. 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
30/09/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/07/2026:
Participants are eligible if they:
1. Have a confirmed or suspected diagnosis of dementia of any subtype
2. Are aged 50 years or older at baseline
3. Live at home in the community
4. Are able to provide informed consent or, if they lack capacity, have a personal or nominated consultee available

Where a study partner is involved, the study partner must be aged 18 years or older and willing and able to provide informed consent. The absence of a study partner is not an exclusion criterion. The study is intended to include people who live alone or are socially isolated. Potential participants who do not fully understand spoken or written English may be included with translation or interpreter support, provided that consent or consultee procedures can be completed appropriately and study procedures can be delivered safely.

Previous 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
Current exclusion criteria as of 30/07/2026:
Participants are excluded if they:
1. Have unstable comorbid mental illness requiring secondary mental health care at screening or baseline, including active psychosis or substance misuse
2. Have active suicidal ideation
3. Are receiving treatment for a terminal illness or are under palliative care at screening or baseline
4. Lack capacity and do not have a personal or nominated consultee

Where a study partner is involved, they are excluded only if they are unable to participate in study procedures, including communication required for consent and follow-up, or are unable to provide written informed consent.

Health and social care professionals will be excluded if they are unwilling or unable to provide written informed consent or unable to participate in relevant study procedures, including surveys, interviews, or focus groups.

Previous 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.

Professionals 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
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare NHS Trust
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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
Current IPD sharing plan as of 30/07/2026:
Data collected as part of the MinderCare study will be made available through Dementia Platform UK in accordance with applicable data-sharing policies, governance approvals, participant consent, and data-protection requirements.
Study data are stored on Imperial College London-hosted servers within the secure University research cloud environment and in REDCap. Identifiable information is stored separately on an NHS secure drive accessible only to authorised ICHT staff, with hard-copy documents kept securely at the NHS site.
Healthcare utilisation, clinical events, mortality, institutionalisation, and costs will be assessed using linked electronic health records and population health datasets, including Discover-NOW where applicable.

Previous 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		22/06/2026	15/07/2026	No	No