ISRCTN71000991 https://doi.org/10.1186/ISRCTN71000991

MINDER Health Management Study for Dementia: A study to refine and evaluate technologies in the home to monitor and manage the health of people with dementia

Submission date
08/10/2018

Recruitment status
No longer recruiting

Registration date
10/10/2018

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Over 850,000 people living in the UK have been diagnosed with dementia. This number is expected to double over the next 20 years. People with dementia receive little routine monitoring by health care providers, with this responsibility falling to their family and friends. This means that, despite best efforts, there can be delays in picking up health issues such as urinary tract infections, falls or problems with mobility which may result in the person with dementia requiring more care from family and friends or being admitted to hospital. We have developed an Internet of Things (IoT) technologies system – using connected environmental sensors and healthcare devices – to monitor the person with dementia in their own home. This system is known as the TIHM for Dementia System of Care, and has been tested previously in a randomised controlled trial (ISRCTN46184518). Installed in the person with dementia's home, it gathers information from the environment and connected healthcare devices (e.g. blood pressure monitor, weighing scales). This information is fed into a predictive algorithm which is designed to alert a team of clinicians monitoring the system 24 hours a day, seven days a week to any health issues the person with dementia may have. This team will then telephone the person with dementia or their carer to offer healthcare advice and support. This study aims to refine and evaluate the TIHM for Dementia System of care ready for wide use.

Who can participate?
People with dementia can participate along with their live-in or nominated carer if they are currently living in the community and receiving 10 or more hours per week of home care. Persons with dementia need to be aged 50 years or older and have a confirmed diagnosis of dementia (any type) and meet all other study inclusion criteria.

What does this study involve?
Participants will use the TIHM for Dementia System of Care for 6 months. This will involve the person with dementia being remotely-monitored in their home. Most of this monitoring will take place automatically, however the person with dementia and their carer may be asked to also

take measurements, such as blood pressure, temperature and pulse. People with dementia and their nominated carers will be asked to complete some questionnaires at the beginning, middle (after 3 months) and end (at 6 months) of the study. They may also be invited to take part in an interview with a researcher about their experience of using the system; these will take place at the middle and end of the study. After using the TIHM for Dementia System of Care for 3 months and as a result of feedback from the questionnaires and interviews, the technologies installed in the person with dementia's home may be reviewed and changed. Participants will then continue to use TIHM for Dementia for the remaining 3 months.

What are the possible benefits and risks of participating?
There is the opportunity to help improve current health care and support for people with dementia and their carers by helping to refine and evaluate a novel health monitoring and management system. Participants will also benefit from the additional continuous healthcare support the system provides.
Taking part in this study presents minimal risk; however, the TIHM for Dementia System of Care is an experimental system. People with dementia and their carers may find it intrusive to have sensors in their home and difficult or time-consuming to use devices. The system does not replace usual care and participants will be asked to contact their standard care provider (e.g. GP or A&E department) should they feel the need to do so.

Where is this study run from?
Six care commissioning groups (CCGs) in Surrey and North East Hampshire

When is the study starting and how long is it expected to run for?
July 2018 to August 2025 (updated 01/02/2021, previously: July 2019)

Who is funding the Study?
1. NHS England (UK)
2. Innovate UK (UK)

Who is the main contact?
Prof Emma Ream
e.ream@surrey.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Emma Ream

ORCID ID
http://orcid.org/0000-0001-5436-8036

Contact details
School of Health Sciences
Faculty of Health & Medical Sciences
University of Surrey
Guildford
United Kingdom

GU2 7XH
+44 (0)1483 689319
e.ream@surrey.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
version 5

Study information

Scientific Title
MINDER Health Management Study for Dementia - Phase 1.5

Acronym
MINDER

Study objectives
This study aims to refine and evaluate the TIHM for Dementia intervention (ISRCTN46184518) ready for implementation and scale-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland, 10/08/2018, ref: 18/ES/0075

Study design
Single-arm mixed-method adaptive observational cohort study with embedded process and cost evaluation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet

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

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

Interventions
This study uses the TIHM for Dementia System of Care, an Internet of Things (IoT) health monitoring and integrated management system. This system gathers information about the person with dementia through environmental sensors installed in their home and devices which monitor their daily activity and vital signs (e.g. GPS tracker, blood pressure monitor, thermometer, weighing scales). The IoT relays this information to a dedicated monitoring team through a computer-based alert system, which uses machine learning algorithms to provide the team with actionable-information and alerts for health and social care concerns. The monitoring team then contacts the patient and/or their carer to offer advice. Dementia Navigators also provide support for non-emergency issues. Patients are monitored by the TIHM for Dementia system 24 hours a day, seven days a week for their six months of participation.

Intervention Type
Device

Primary outcome measure
The composition of an optimised TIHM for Dementia System of Care solution based on:
1. Direct cost: Data on service use and patterns of unpaid care and support provided by families and friends will be recorded by a modified version of the Client Service Receipt Inventory (CSRI). Costs will be attributed to service use using NHS reference costs and unit costs from the Personal Social Services Research Unit (PSSRU, www.pssru.ac.uk). This will be assessed at the baseline and after 3 and 6 months
2. Service-use data, collected via a modified CSRI at the baseline and after 3 and 6 months
3. System performance, captured in real-time through data captured by the system itself on alerts related to technical performance
4. User-acceptability, assessed using an investigator designed tool developed based on the TAM at the baseline and after 3 and 6 months

Secondary outcome measures
The following are assessed at the baseline and after 3 and 6 months:
1. Incidence of A&E attendance, assessed using a modified version of the Client Service Receipt Inventory (CSRI)
2. Duration of hospital stay, assessed using a modified version of the Client Service Receipt Inventory (CSRI)
3. Incidence and severity of neuropsychiatric symptoms experienced by the person with dementia (PwD), assessed using the Neuropsychiatric Inventory–Questionnaire (NPI)
4. Incidence of urinary tract infections, agitation and falls experience by the PwD, assessed using a modified version of the Client Service Receipt Inventory (CSRI)
5. Health Related Quality of Life (HR-QoL) of the PwD, assessed using:
5.1. DemQoL
5.2. EQ-5D-5L
6. HR-QoL of carers, assessed using the EQ-5D-5L
7. Carer burden, assessed using the Zarit Burden Interview
8. Technology acceptance, assessed using an investigator-developed tool

Overall study start date
02/07/2018

Completion date
01/08/2025

Eligibility

Key inclusion criteria
Person with dementia:
1. Male or female 50 years of age and older at baseline with a confirmed diagnosis of dementia (any type) by specialist assessment
2. Willing and able to provide informed consent
3. Standard MMSE score at baseline interview over 12
4. Living in the community
5. Receiving 10 or more hours per week of home care
6. Have a live in or nominated carer
7. Have sufficient functional English to allow completion of the assessment instruments
8. If on anti-dementia medication (cholinesterase inhibitors and/or memantine), on a stable dose for three months prior to recruitment

Carers of people with dementia:
1. Willing and able to provide informed consent
2. Single nominated informal carer (relative/friend) who has known the person with dementia for at least 6 months and is able to attend research assessments with the person with dementia
3. Have sufficient functional English to allow completion of the assessment instruments
4. Aged 18 or over

Professional (including health care, technology professionals) sample:
1. Aged 18 or over
2. Involved in the delivery of care/data monitoring/technical delivery of IoT intervention of people with dementia
3. Willing to provide informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
230 (100 people with dementia; 100 carers; 30 professionals)

Key exclusion criteria

People with dementia:
1. In a residential care home
2. Receipt of any investigational drug within 30 days prior to consenting
3. People with unstable mental state including severe depression, severe psychosis, agitation and anxiety whom their medication was change over the last 4 weeks
4. People with severe sensory impairment
5. Unable to communicate verbally
6. Currently have active suicidal ideas
7. People who require regular elective hospital admission for their physical health monitoring
8. People who are receiving treatment for terminal illness

Carers of people with dementia:
1. Unable to communicate verbally

Professionals:
Does not meet inclusion criteria

Date of first enrolment
20/08/2018

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
United Kingdom
KT22 7AD

Sponsor information

Organisation
Surrey and Borders Partnership NHS Foundation Trust

Sponsor details
Abraham Cowley Unit
Holloway Hill

Chertsey
England
United Kingdom
KT22 7AD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00f83h470

Funder(s)

Funder type
Government

Funder Name
NHS England

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in high-impact peer-reviewed journals
2. Dissemination at subject specific conferences
3. Research report for funders

Intention to publish date
01/08/2026

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No