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Technology Integrated Health Management (TIHM) for Dementia: a study of technologies in the home to monitor and manage the health of people with dementia

Submission date
20/09/2018

Recruitment status
No longer recruiting

Registration date
10/10/2018

Overall study status
Completed

Last Edited
02/10/2020

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 healthcare 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. New technologies for monitoring and managing conditions such as dementia in the person's home hold much promise. It is hoped technologies can support not only patients but also their carers in managing their condition at home by detecting any health problems early to avoid unnecessary hospital admissions. This study forms part of the NHS Test Bed Programme, launched in 2015, with the aim of developing and testing of cutting-edge digital products and services. This study presents an Internet of Things (IoT) technologies system – that is, using 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. Installed in the person with dementia's home, it gathers information from the environment and connected healthcare devices (e.g. blood pressure monitoring, weighing scales). This information is fed into a predictive algorithm which designed to alert a team of clinicians monitoring the system 24 hours a day, 7 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 evaluate the TIHM for Dementia System of Care. Specifically, it aims to explore how effective TIHM for Dementia is at reducing and delaying admissions to hospital and care homes, and improving the well-being of patients and their carers. We will also evaluate the TIHM for Dementia System to see how well it did at alerting the monitoring team to health issues. Finally, we will evaluate the process of setting up and running the study as part of the NHS Test Bed Programme by interviewing the people involved.

Who can participate?
People with dementia can participate along with their live-in or nominated carer. 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?
People with dementia and their carers will be randomly allocated to either use the TIHM for Dementia System of Care or continue with their usual care. People will take part in this study for 6 months and will be asked to complete some questionnaires at the beginning, middle (after 3 months) and end (at 6 months).

What are the possible benefits and risks of participating?
There is the opportunity to help improve current health care for people with dementia by testing a novel monitoring and management system and contribute to the future development of the TIHM for Dementia System of Care. For those randomised to use the TIHM for Dementia System of Care, there is also the opportunity to benefit from the additional 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 burdensome to use devices. The system may not detect all health issues; therefore, participants will be asked to contact a standard care provider (e.g. their GP or an A&E department) should they feel the need to do so.

Where is this study run from?
This study is run across 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?
This study is closed to recruitment. Recruitment ran from 01/03/2017 to 30/11/2017.

Who is funding the Study?
This study is funded by NHS England and Innovate UK

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IUK project 102589

Study information

Scientific Title
Technology Integrated Health Management (TIHM) for Dementia Study

Acronym
TIHM for Dementia

Study objectives
The overall aim of this study is to evaluate the effectiveness of a domiciliary Internet of Things (IoT) intervention for persons with dementia (PwD) and their carers, known as the TIHM for Dementia System of Care. The primary objective is to determine whether, compared to standard care, the IoT intervention plus standard care affects hospital admission rates. Standard care refers to any care from local General Practitioners (GPs) or secondary mental health teams.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Surrey Research Ethics Committee, 18/11/2016, ref: 16/LO/1802

Study design
Single-site repeated-measures evaluator-masked parallel-group stratified exploratory randomised controlled trial (RCT)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

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
Patients will be randomised 1:1 to either the TIHM for Dementia System of Care (Intervention arm) or standard care (control arm)

Intervention arm: TIHM for Dementia System of Care – an Internet of Things (IoT) health monitoring and management system. This system gathers information about the person with dementia through environmental sensors installed in their home and devices which monitor their whereabouts and vital signs (e.g. GPS tracker, blood pressure monitor, thermometer, weighing scales). The IoT relays this information to a dedicated monitoring team, via an algorithm design to detect health concerns. The monitoring team receives an alert on their computer interface when a health concern is detected. The monitoring team then contacts the patient to offer advice. Patients are monitored by the TIHM for Dementia system 24 hours a day, 7 days a week for their 6 months of participation. Patients and their nominated carers are required to complete some paper-based questionnaires before they start using the system at baseline, 3 months and on completing at 6 months.

Standard Care arm: Standard care is any care a person with dementia receives from their general practitioner (GP) or secondary mental health team.

Intervention Type
Device

Primary outcome measure
Hospitalisation as measured through carer self-reporting using the Client Service Receipt Inventory (CSRI) questionnaire taken at baseline, 3 months and 6 months.

Secondary outcome measures
1. Duration of hospital stay (carer self-report)
2. Time to admission to residential care (carer self-report)
3. Incidence and severity of neuropsychiatric symptoms experienced by the PwD assessed using the Neuropsychiatric Inventory (NPI)
4. Activities of daily living of the PwD assessed using the Bristol Activity of Daily Living Scale (BADL)
5. Health-related quality of life (HR-QoL) of the PwD assessed using Dementia Quality of Life Measure (DEMQOL), DEMQOL-proxy and EQ-5D-5L questionnaires

6. HR-QoL of carers assessed using EQ-5D-5L and Adult Carer Quality of Life questionnaires
7. Carer burden assessed using the Zarit Caregiver burden scale
8. Technology acceptance assessed using the Technology Acceptance Model Measure (TAM)
9. Attitudes towards technology assessed using Global Attitude Towards Technology Measure: Technophobia

All measures taken at baseline, 3 months and 6 months.

Overall study start date
01/11/2016

Completion date
31/07/2018

Eligibility

Key inclusion criteria
Person with dementia:
1. Aged over 50 years
2. Living at home in the community
3. Confirmed diagnosis of mild-to-moderate dementia made at least 3 months previously
4. Stable dementia - if on dementia medication had a stable dose for 3 months prior to recruitment
5. Baseline standard Mini–Mental State Examination (MMSE) score of greater than or equal to 14
6. A live-in or nominated carer providing at least 10 hours care per week

Carer:
1. Aged 18 years or over
2. Nominated carer (by their relative/friend with dementia) who had known the person with dementia for at least 6 months
3. Able to attend research assessments with the person with dementia
4. Sufficient functional English to allow completion of the assessment instructions

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500 (700 people with dementia; 700 carers; 100 professionals)

Key exclusion criteria

Person with dementia:
1. In residential care
2. Unable to communicate verbally
3. Unable to provide informed consent
4. In receipt of any investigational drug within 30 days of consenting
5. Requiring regular elective hospital admission for monitoring of physical health
6. Receiving treatment for a terminal illness
7. Insufficient functional English to allow completion of assessment instructions
8. Unstable mental state including severe depression, severe psychosis, agitation and anxiety, requiring medication change over the previous 3 months
9. Severe sensory impairment
10. Active suicidal ideas

Carers:
1. Insufficient functional English to allow completion of assessment instructions
2. Unstable mental state including severe depression, severe psychosis, agitation and anxiety, requiring medication change over the previous 3 month
3. Severe sensory impairment
4. Active suicidal ideas
5. Unable to communicate verbally
6. Unable to provide written informed consent

Date of first enrolment
01/03/2017

Date of final enrolment
30/11/2017

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
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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

The findings of this study are embargoed until the end of November 2018 after which they will be published in peer-reviewed journals.

Intention to publish date
31/12/2020

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