

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

<b>Submission date</b> 20/09/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/10/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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## Contact information

### Type(s)

Scientific

### Contact name

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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  
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

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?
<a href="#">HRA research summary</a>			28/06/2023	No	No