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The ATTILA Trial: Assistive Technology and Telecare to maintain Independent Living At home for people with dementia

Submission date
14/12/2012

Recruitment status
No longer recruiting

Registration date
18/12/2012

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

There are approximately 700,000 people with dementia in the UK, many of whom will require nursing or residential care home accommodation when their illness has progressed to the point at which they can no longer live independently in their own homes with safety. Living Well with Dementia - the theme of the 2009 National Dementia Strategy for England involves helping people with dementia to maintain their independence within their own homes and ensuring that the quality of their lives are maintained. The loss of independence and quality of life associated with the transition to living in a Care Home are apparent, and the NHS and Social Services support of sufferers to live safely in their own homes for as long as possible are beneficial to this. Assistive Technology and Telecare, when individually tailored to a patient's needs and integral to their careplan, offer a way in which the home of a person with dementia can be made safer for them by reducing the specific risks associated with the memory and orientation difficulties that accompany the illness.

Particular risk to continued independence, such as wandering away from home in the middle of the night and becoming lost or setting fires with forgotten pans on the cooker or cigarettes put down in unsafe places, can be tackled by specific pieces of technology, linked to a 24-hour response centre. While it might seem obvious that such interventions are beneficial, only a well conducted clinical trial can provide high quality evidence that these technologies really do help to maintain independent living for people with dementia.

We aim:

To establish whether assistive technology and telecare interventions safely extend the time that people with dementia can continue to live independently in their own homes and whether this is cost-effective.

To establish whether these technologies can significantly reduce the number of incidents involving serious risks to safety and independent living, including acute admissions to hospital, reduce stress in family and other informal caregivers and increase quality of life for dementia sufferers and their caregivers.

To collect qualitative and quantitative data from dementia sufferers and their formal and informal caregivers and members of the NHS and Social Services teams who care for them about the experience of receiving these technologies.

Who can participate?
Older adults with memory difficulties and a fair Access to Care Services assessment that indicates significant need.

What does the study involve?
Participants will be visited at home where an assessment will be made to see how electronic devices could possibly help. Questions will be asked about the health of the participant and the services they use, and the carer will also be asked about their own health. After this we will arrange for the devices to be installed and arrange occasional follow-up visits over the next two years.

What are the possible benefits and risks of participating?
The main benefit of taking part is the participant knowing that this research will help us to treat people like them more effectively in the future. The devices they are given may help to support them better at home, and if the participant is put into the group which is offered the wider range of newer devices this may mean that fewer home visits from carers are needed. The carer could be helped as they may have less concerns about harm coming to the person they care for. Controlled trials carry potential risks of negative consequences for participants, since some participants will be forgoing access to a potentially beneficial component of care during the duration of the trial. The electronic devices may not work properly, or may not meet the needs of the person you care for in the right way. Electronic devices may support people in a way which means that they need fewer visits from care workers. This might cause some people to feel less supported or lonelier. We do not know whether there will be any difference between the standard and newer devices in this regard. It is important to note that, in either group, if the care and support the person you care for receives does not adequately meet their needs, it will have to be changed and they may not be able to stay in the study.

Where is the study run from?
The study is based at the Institute of Psychiatry, Kings College London, but research workers and Principle Investigators will be based at the participating sites across the country.

When is the study starting and how long is it expected to run for?
The trial will begin in January 2013 and will run for four years.

Who is funding the study?
The Department of Healths Health Technology Assessment programme.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
HTA: 10/50/02

Study information

Scientific Title
The ATTILA Trial: Assistive Technology and Telecare to maintain Independent Living At home for people with dementia a randomised controlled multi-centre clinical trial

Acronym
ATTILA

Study objectives
The aims of the ATTILA trial are to test the following hypotheses:
1. That the application of assistive technology and telecare (ATT) will significantly extend the time that people with dementia can be helped to continue to live independently and safely in their own homes.
2. That assistive technology and telecare (ATT) interventions are cost-effective in the management of risk and maintenance of independence in people with dementia living in their own homes.
3. That provision of assistive technology and telecare (ATT) interventions to people with dementia living at home will significantly reduce the number of incidents involving serious risks to safety and independent living, particularly those involving acute admissions to hospital, reduce burden and stress in family and other informal caregivers and increase quality of life for dementia sufferers.
4. A final objective is the collection of qualitative and quantitative data from dementia sufferers, their formal and informal caregivers and members of the Community Mental Health and Social Services teams about the experience of the use of ATT interventions.

More details can be found at http://www.hta.ac.uk/2880

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - Queen Square, Provisional approval given, subject to minor amendments, application resubmitted (10.12.2012) and awaiting final approval, study reference: 12/LO/1816

Primary study design
Interventional

Study design
Randomised controlled multi-centre clinical trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental health, neurology and aging

Interventions
All participants will be assessed to identify areas where assistive technology and telecare can support participants and caregivers in the safe undertaking of occupational activities identified as important for them through the provision of enhanced risk management.

The experimental group will receive specific types of assistive technology and telecare determined by needs identified in the assessment. This will involve the installation of simple, battery operated, stand-alone technologies and/or telecare (a range of linked sensors which communicate via a monitoring centre to appropriate responders).

The control group will receive no treatment and will just be offered standard devices such as a smoke alarm and pendent alarm.

Follow up for two years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
There will be two co-primary outcome measures.

1. Time in days from randomisation to institutionalisation (defined as permanent transition from living in own home to nursing or residential care home) or to an admission to acute care facility that results in permanent placement in care home.
2. Cost-effectiveness of provision of assistive technology and telecare. Costs will be calculated by attaching nationally applicable unit cost measures to health and social service use and the costs of assistive technology and telecare provided
collected with a modified version of the Client Service Receipt Inventory (CSRI) (Beecham and Knapp 2001) for each participant at baseline, 12, 24, 52 and 104 weeks.

Data on both formal and informal caregiver inputs will be used to attach imputed values and EQ5D (EuroQoL Group 1990) and DEMQOL (Smith et al 2007) data will be used to calculate patient-specific QALYs.

Key secondary outcome(s)

1. Burden in caregivers. We will measure both burden associated with care-giving and levels of psychological distress among the principal caregivers of participants at baseline, 12, 24, 52 and 104 weeks. The 12-item short version of the Zarit Burden Interview (ZBI) questions caregivers experiences in terms of emotional, physical and social strains or difficulties that result from their role as a caregiver. Items include topics such as feeling ones own health has suffered, feeling that care-giving has affected relationships with family and friends and how burdened one feels. Caregivers respond by indicating how often they experience each item and responses are scored on a 5-point scale ranging from never to frequently. Higher burden is indicated by a higher score and the combined 12 items have high reliability (alpha=.86) (Leggett et al 2010). We will assess psychological distress with the 12-item General Health Questionnaire (GHQ) to identify symptoms of common mental health difficulties such as anxiety and depression (Goldberg and Williams 1988).
2. Quality of life. We will measure health-related quality of life in patients at baseline, 24, 52 and 104 weeks using either DEMQOL; a 28-item interviewer-administered questionnaire that is self-reported by a person with dementia; or DEMQOL-Proxy; a 31-item questionnaire that is reported by a caregiver. DEMQOL has high levels of reliability and internal consistency in patients with mild to moderate dementia (alpha=.87) (Smith et al 2007). We will measure health-related quality of life in caregivers using the SF-12 (Jenkinson et al 1999).
3. Number and severity of serious adverse events. As in any trial, serious adverse events (requiring GP or hospital care) will be recorded and reported. We will develop a manual to describe, grade (in terms of severity or dangerousness) and record significant compromises of participant safety (e.g. fire setting, falls, episodes of getting lost and requiring assistance to find way home) during trial participation. Protocols will be agreed with local organisations to enable immediate response to emergency situations.
4. Quantitative and qualitative data on acceptability, applicability and reliability of the assistive technology and telecare intervention packages will be collected using the Carer Technology Acceptance Questionnaire (currently in preparation from work of the Whole Systems Demonstrator project). We anticipate that informal caregivers may fall into two groups; a group who report that their lives and wellbeing have been enhanced by the use of these technologies and a group who report that the use of the technologies has undermined their role as the caregiver. The reasons for differences between these groups will be explored through semi-structured interviews of groups that will include:
4.1. Caregivers who have used the kit for at least 6 months
4.2. Caregivers who have requested kit withdrawal after installation, and
4.3. Caregivers who have refused kit when offered

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Clinical Dementia Rating of 1, 2 or 3
2. Fair access to care services (FACS) assessment indicates significant need
3. Working telephone line connected to home

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Total final enrolment
495

Key exclusion criteria
1. Patient already receiving an ATT intervention or has previously been provided with ATT but has failed to utilise it
2. Unstable medical condition

Date of first enrolment
01/06/2013

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Old Age Psychiatry The Institute of Psychiatry
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment - HTA (UK)

Results and Publications

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?
Results article		05/05/2021	09/08/2021	Yes	No
Protocol article	protocol	23/10/2013		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	HTA report	01/03/2021	24/03/2021	Yes	No