ATTILA - Assistive Technology and Telecare to Maintain Independent Living At Home for People with Dementia

Assistive technology and telecare (ATT) are relatively new ways of delivering care and support to people with social care needs. The provision of sensors, passive monitoring and alerting devices are claimed to support the independence of people with social care needs, to reduce the burden on unpaid care-givers such as family members, and to save councils with Adult Social Services responsibilities (CASSRs) money as ATT can reduce levels of community care, prevent unnecessary hospital admissions, or admission into residential or nursing care. The current economic situation has meant that increasing numbers of local authorities in England are renewing interest in ATT, and developing local strategies to use it along with, or instead of, community care.

However, at present, the evidence base to support claims about the impact and effectiveness of ATT is limited. Although the first attempts to use ATT in the UK were with people with dementia, not many with this diagnosis were included in the Whole System Demonstrator project. It has been estimated that over the next two decades the number of people aged 85 and over will increase by two-thirds (Wanless, 2006). Over half of all users of adult social care are aged 65 and over (Department of Health 2003) and a steep rise in the numbers of people living with dementia is expected over the next few decades. The financial cost of caring for people with dementia is significant (Knapp & Prince 2007) and the social and psychological cost to unpaid care givers is great: carer breakdown is a common reason for the unplanned admission of older people – many of whom will have dementia - into permanent residential care (Bebbington et. al 2001).

ATTILA is a randomised controlled trial which compares outcomes amongst people with dementia who receive ATT and those who receive equivalent community services but not ATT. The working hypothesis of the trial is that fewer people in the ATT group will go into institutional care over the six year period for which the study is funded. ATT services are usually provided or arranged by local authorities who will support the identification of eligible people for this study, along with relevant health services. Those recruited will be people who have recently been referred to a CASSR or health service for support and have met national eligibility criteria as defined by the Care Act 2104, or the healthcare service equivalent criteria. They will also be people who are living with dementia (any age, though the majority are likely to be elderly) and are living independently in community settings. Baseline measures will take place once consent has been obtained from the person with dementia or, if the person is incapable of consenting, a consultee, and their unpaid carer. Repeat testing using cognitive and functional scales will be carried out at specified time points during the study or until the person is withdrawn from the trial.

ATTILA aims to randomise a total of 500 service users, in a 1:1 ratio, to ATT (intervention) and non-ATT (control) groups in a multicentre trial in thirteen CASSR sites in England (Croydon, Lambeth, Southwark, Barnsley, Blackburn, Blackpool, Cambridgeshire, Lancashire, Norfolk, Nottingham, Oxford, Suffolk, and West Sussex). The trial will compare the effects of assessment followed by provision of ATT services versus assessment followed by control intervention, consisting of equivalent non-ATT services, determined and deployed via the host CASSR or health service. Technology offered to the control group will be limited to non-electronic ATT items (e.g. walking sticks, frames, chair/bed raisers etc.), smoke and CO detectors, and simple pendant alarms only. Two co-primary trial outcomes will be (i) time in days from randomisation to institutionalisation (defined as permanent transition from living in own home to nursing or residential care) and (ii) cost effectiveness (costs will be calculated by attaching nationally applicable unit cost measures to health and social service use, and costs of ATT provided, using a modified version of the Client Service Receipt Inventory). Secondary outcomes will be (i) burden in care givers, using the 22 item Zarit Caregiver Burden Interview); (ii) Quality of life in care givers using SF-12v2; (iii) number of serious adverse incidents involving manualised significant compromises of patient safety; (iv) data on acceptability & reliability of ATT packages. A supplementary ethics application, covering a more developed qualitative dimension to this study, is in preparation.

ATTILA Trial Management Group

Psychiatry

Robert Howard (CI) 020 7848 0545
Professor of Old Age Psychiatry and Psychopathology
Department of Old Age Psychiatry, Institute of Psychiatry
Box 070, De Crespigny Park, London SE5 8AF
robert.j.howard@kcl.ac.uk

Craig Ritchie 0207 3861233
Senior Clinical Research Fellow
Centre for Mental Health, Imperial College London
Claybrook Centre, Charing Cross Campus
37 Claybrook Rd, London W6 8LN
c.ritchie@imperial.ac.uk

Alistair Burns 01613 067942
Professor of Older Adult Psychiatry
School of Community Based Medicine
University of Manchester, Jean McFarlane Building, 3rd floor
Oxford Rd, Manchester M139PL
alistair.burns@manchester.ac.uk

John T. O'Brien 01223 760682
Foundation Professor of Old Age Psychiatry
Department of Psychiatry, University of Cambridge
Level E4, Box 189, Addenbrooke's Hospital
Hills Road, Cambridge, CB2 0QQ
john.obrien@medschl.cam.ac.uk

Andrew Bateman 01353 652169
NeuroRehabilitation Clinical Lead for CCS NHS Trust
Honorary Post: Affiliated Lecturer, Dept of Psychiatry, University of Cambridge
Oliver Zangwill Centre for Neuropsychological Rehabilitation
Princess of Wales Hospital
Ely, CB6 1DN
andrew.bateman@ozc.nhs.uk

Chris Fox 01603 593583
Clinical Senior Lecturer in Psychiatry
School of Medicine, Health Policy and Practice
University of East Anglia
Norwich, Norfolk NR47TJ
chris.fox@uea.ac.uk

Iracema Leroi 01613 067942
Clinical Senior Lecturer in Psychiatry
School of Community Based Medicine, University of Manchester
Jean McFarlane Building, 3rd floor
Oxford Rd, Manchester M139PL
iracema.leroi@manchester.ac.uk

Rupert McShane 01865 741717
Consultant Psychiatrist
Oxford Health NHS Foundation Trust
Warneford Hospital, Old Road, Headington
Oxford OX3 7JX
Rupert.mcshane@obmh.nhs.uk

Statistics

Richard Gray 01865 743537
Professor of Medical Statistics
Clinical Trial Service Unit, Richard Doll Building,
Old Road Campus, Roosevelt Drive, Oxford OX3 7TF
richard.gray@ctsu.ox.ac.uk

Health Economics

Martin Knapp 0207 848 0174
Professor of Health Economics, King's College London
Department of Old Age Psychiatry, Institute of Psychiatry
De Crespigny Park, London SE5 8AF
m.knapp@iop.kcl.ac.uk

Social Care

John Woolham
Senior Research Fellow
Social Care Workforce Research Unit
Kings College London
Virginia Woolf Building, 22 Kingsway
London WC2R 2LS
john.woolham@kcl.ac.uk

Occupational Therapy

Barbara Dunk 0203 2281628
OT Consultant for Assistive Technology
Mental Health of Older Adults Group
South London & Maudsley NHS Foundation Trust
115 Denmark Hill, The Maudsley SE58AZ
barbara.dunk@slam.nhs.uk

Kirsty Forsyth 07976 245314
Professor of Occupational Therapy
Queen Margaret University
Edinburgh EH21 6UU
kforsyth@qmu.ac.uk

Health Psychology

Stanton Newman 0207 0405767
Professor of Health Psychology
School of Community and Health Sciences
City University, Northampton Square
London EC1V 0HB
stanton.newman.1@city.ac.uk

Anna Davies 0207 7040 0876
Health Psychology Research Associate
School of Community and Health Science
City University, University Building A224
St John St, London EC1VoHB
anna.davies.2@city.ac.uk

Fiona Poland 01603 593630
Senior Lecturer in Health and Society
School of Allied Health Professionals, University of East Anglia
Norwich, Norfolk NR7 4TJ
f.poland@uea.ac.uk

Data Monitoring and Ethics Committee

Chair and Independent Old Age Psychiatrist

Professor James Lindesay 0116 258 8161
Department of Health Sciences, Psychiatry for the Elderly,
Leicester General Hospital,
Gwendolen Road,
Leicester LE5 4PW,
jebl1@le.ac.uk

Independent Statistician

Dr Tracey Young 0114 2220837
Senior Researcher in Health Economics
School of Health and Related Research (ScHARR)
University of Sheffield, Regent Court, 30 Regent Street
Sheffield S1 4DA
t.a.young@sheffield.ac.uk

Trial Steering Committee

Chair

Dr Peter Bentham 0121 301 2070
Consultant in Working Age Dementia,
The Barberry Centre,
25 Vincent Drive,
Birmingham B15 2FG,
peter.bentham@bsmhft.nhs.uk

Independent Old Age Psychiatrist

Professor Rob Jones 0115 823 0417
School of Community Health Sciences,
Division of Psychiatry,
The Institute of Mental Health,
Nottingham University Innovation Park,
Triumph Road, Nottingham
rob.jones@nottingham.ac.uk

Independent Statistician

Dr Louise Brown 020 7670 4607
Senior Statistician
MRC Clinical Trials Unit at UCL,
Institute of Clinical Trials & Methodology,
5th Floor, Aviation House, 125 Kingsway
London WC2B 6NH
l.brown@ucl.ac.uk

Plus Robert Howard (CI),
Ms Gillian Harrison & Ms Sue Tucker (service user representatives from the Alzheimer's Society)

Service user representatives

Gillian Harrison 0208 998 2223
90 Corringway
Ealing, London W5 3HA
ziller@btinternet.com

Sue Tucker 01947 880948
Milldyke,
Thorpe Lane
Robin Hoods Bay, Whitby
North Yorkshire YO22 4RN
tunaleytucker@mail.com

ATTILA Study Office

For general queries, supply of trial materials, and collection of data:

Department of Old Age Psychiatry, Institute of Psychiatry, Box 070, De Crespigny Park, London SE5 8AF

Tel: 020 7848 0509; e-mail: rebecca.gathercole@kcl.ac.uk

Trial Manager (Kings College London)	020 7848 0509	rebecca.gathercole@kcl.ac.uk
Trial Administrator (Oxford)	01865 765 615	emma.harper@ndph.ox.ac.uk

Randomisation

Telephone: 0800 585323(toll free in UK)

Clinical Queries during office hours should be directed to one of the Clinical Co-ordinators, or to an appropriate member of the Trial Management Group. Other queries should be directed to the ATTILA Study Office.

Trial Sponsor: King's College London, London and South London and the Maudsley NHS Foundation Trust
Sponsor Contact: King's Health Partners Clinical Trials Office, 16th Floor, Guy's Tower, London SE1 9RT**;**
tel: 0207 188 5732; Fax: 0207 1888330; Email: jackie.pullen@kcl.ac.uk

MREC number: 12/LO/1816 **ISRCTN number:** ISRCTN86537017

CONTENTS

Signatures

Chief Investigator
Name: Professor Robert Howard (Professor of Old Age Psychiatry and Psychopathology)
Address: Department of Old Age Psychiatry
Institute of Psychiatry, PO Box 070, De Crespigny Park, London SE5 8AF
Telephone: + 44 (0)20 7848 0545
Fax: +44 (0)20 7848 0632
Email: robert.j.howard@kcl.ac.uk

_____ _____

Chief Investigator's signature **Date**

_____

Print name

_____ _____

Principal Investigator's signature **Date**

_____

Print name

1. BACKGROUND AND RATIONALE

There are approximately 800,000 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 in 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. People living with dementia who move from their own homes into institutional care often experience a loss of independence and quality of life. NHS and Social Services aim to support people with dementia to live safely in their own homes for as long as possible because of this.

Assistive technology and telecare (ATT) are relatively new ways of delivering care and support to people with social care needs. The provision of sensors, passive monitoring and alerting devices are claimed to offer opportunities to support the independence of people with social care needs, to reduce the burden on unpaid care-givers such as family members, and to save and councils with adult social care responsibilities (CASSRs) money, as ATT can reduce levels of community care, prevent unnecessary hospital admissions, and delay or prevent admission into residential or nursing care.

The first uses of electronic ATT in the UK were to provide support for people with dementia and their carers (Mitchell, 1996, Woolham & Frisby, 2002; Fisk, 2003, Woolham 2006a). From these early initiatives, within the space of a decade, interest in telecare has developed from a fringe interest of a handful of enthusiasts to a multi-million pound industry commanding government support, a Department of Health strategy and increasingly, the use of telecare in local authority settings as a mainstream service (see, for example, DH 2009a). However, as interest in telecare has increased, the specific focus on its application for those living with dementia has diminished. (Woolham et. al. 2006b) The performance indicators that followed the Preventive Technology Grant (DH 2005) encouraged the widest possible use of telecare without any clear indication of what telecare was supposed to 'prevent'. Poole (2007) has argued that CASSRs should see telecare as a long term investment, deploying it at an early stage and not expecting immediate savings. This has contributed to a situation in which the focus of local authorities has been on the mainstreaming of telecare across all care groups without always making particular reference to the needs of specific groups, such as people with dementia. The current economic situation, and deep cuts in CASSR funding from Westminster, have meant that increasing numbers of local authorities in England are renewing interest in telecare, and developing local strategies to use it in widespread ways, whilst others already have well developed telecare services that can be deployed along with, or instead of, community care.

In spite of the increase uptake of ATT, the evidence base supporting its use is limited. The DH funded Whole System Demonstrator study (WSD) set up several years ago to find out about the impact and effectiveness of telecare (Giordano & Clark, 2010, Bower, et. al 2011, Davies & Newman, 2011). This well designed trial will provide robust evidence when findings are published. However, individuals with dementia were not specifically included in the WSD trial, resulting in few participants having dementia. This, together with the relative lack of dementia-specific studies in ATT, has created a

significant gap in our knowledge. Although there are comparatively large numbers of qualitative studies, audits and service evaluations, there are few studies with sufficient rigour to offer any degree of generalisibility (Barlow 2006), and sometimes different views on how 'success' can be measured (Brownsell 2009). One study in dementia has suggested that used appropriately, ATT is highly cost effective, but limitations in design and methodology constrain the generalisibility of the findings (Woolham 2006). Hence, there remains an urgent need for a well-designed study to guide policy direction. The National Institute for Health Research Health Technology Assessment programme has, therefore, funded such a trial: **ATTILA** ('**A**ssistive **T**echnology and **T**elecare to maintain **I**ndependent **L**iving **A**t Home for People with Dementia').

ATTILA is a multi-centre, pragmatic, randomised controlled trial which compares outcomes amongst people with dementia who receive ATT and those who receive equivalent community services without ATT. Blinding will not be undertaken as it is not practicable. The working hypothesis of the trial is that fewer people in the ATT group will enter institutional care over the five year period for which the study is funded. ATT services are usually provided or arranged by local authorities who will support the identification of eligible people. Those recruited to the study will be people who have recently been referred to a CASSR or health service for support and have met eligibility criteria.

As well as measuring the amount of time that participants remain at home, ATTILA will also look at the costs of all the care that the study participants will receive together with the costs that would have been incurred if they had needed to enter residential care. ATTILA will measure quality of life among its participants, to test the assumption that the provision of these technologies would improve quality of life. Furthermore, caring for a person with dementia can be extraordinarily burdensome and exhausting for family and friends and ATTILA will also look at the levels of stress and burden in the people who are their caregivers and examine the effects of provision of these technologies. Finally, ATTILA will collect information from caregivers about their experience of using the technologies and the interventions put in place around them. A supplementary ethical application will be made in support of additional qualitative research at a later date.

2. TRIAL OBJECTIVES AND DESIGN

2.1 Trial hypotheses and objectives

The ATTILA trial aims to test the following hypotheses:

- 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 the community.
- 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.
- 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 those with dementia.

- A final objective is the collection of qualitative and quantitative data from those with dementia, 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.

These hypotheses will be tested by the following primary and secondary objectives:

Primary objectives:

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

Secondary objectives:

- 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 those with dementia and their caregivers.
- To collect qualitative and quantitative data from people living with dementia and their formal and informal care-givers about their experience of using these technologies.

The secondary objectives will be evaluated using the following tools:

(i) Burden and psychological morbidity in caregivers measured with the 22-item version of the Zarit Burden Interview, the Standard Trait Anxiety Inventory (STAI) and the Centre for Epidemiological Studies Depression Scale (CES-D10) at baseline, 12, 24, 52 and 104 weeks;

(ii) Quality of Life in caregivers with the SF-12v2, at baseline, 24, 52 and 104 weeks;

(iii) Number of serious adverse events (including deaths) involving manualised significant compromises of participant safety;

(iv) Quantitative data on acceptability and reliability of ATT packages collected from participants, caregivers and health and Social Services teams. This will include analysis of drop-outs from engagement with the technology and the frequency of the technology being delivered to the home but 'remaining in the drawer'.

2.2 Trial design and randomisation

ATTILA is a pragmatic randomised controlled trial over 260 weeks without blinding that will take place in the homes of people living with dementia and who are eligible to receive a package of care. The trial will compare outcomes in two groups of participants randomised to one of two study arms: either (i) receiving an assessment of needs followed by the installation of appropriate ATT devices and response services which will be deployed by the CASSR or health service; and (ii) receiving an assessment of needs followed by the installation of an ATT package restricted to only smoke and carbon monoxide detectors, key safe and a pendant alarm if indicated, also arranged by the CASSR. The key outcomes will be time to institutionalisation and cost-effectiveness of the intervention.

The trial is not funded to source, assess for or deploy ATT. Our approach is therefore to work alongside CASSRs which have been charged by the Department of Health with responsibility for establishing and developing local ATT services.

2.3 Ethical considerations

There are important ethical issues to be considered in any piece of research involving people who are living with a diagnosis of dementia.

Ethics and RCT design

Probably the most difficult ethical question that conduct of the trial will raise is whether it is ethical to deny access to the technologies to those participants who are randomised to the control arm of the study. Although there is an emerging body of research evidence suggesting benefits of ATT, most of this is based on small scale and qualitative studies. Whilst much of this supports the use of assistive technologies in maintaining safety in some specific cases and situations, the current evidence base is insufficient to conclude that effectiveness and utility have been proven. For this reason, we consider that it is ethical to conduct a trial as proposed to provide conclusive evidence about the impact of ATT on the lives of people with dementia and their care-givers.

Seeking consent

Other important ethical issues exist. These will be briefly described along with the approach the team will adopt to address them. Our overall approach is to assume that consent is not an 'event' but a process. We will therefore actively seek reaffirmed consent on all the occasions we contact participants and seek their data.

Release of personal data by the CASSR

Before local researchers can contact people who may be eligible to take part, they will need to be given contact details of those concerned. This is deemed to be 'personal data' and therefore subject to the requirements of the Data Protection Act. We will, depending on the wish of the CASSRs, either agree a data exchange protocol to allow for the exchange of personal data, or introduce a simple protocol to the assessment procedures in the CASSR over the recruitment period, so that social work practitioners will ask newly referred - and eligible – people, for their permission for their contact details to be released to us so we can contact them.

Informed consent

It is essential that, as part of the information and consenting procedures it is made clear to potential participants and their caregivers what taking part in the study will entail, that they do not have to take part in the trial and that the care that they will continue to receive from the NHS and Social Services teams will not be adversely affected if they choose not to participate or wish to withdraw from the trial at any point.

Mental capacity

A diagnosis of dementia does not necessarily mean that the person cannot consent to take part in the study and careful, but tactful, checks will be made to establish capacity to consent. When the

person does not have capacity, we will seek to identify someone known to the participant who would be prepared to act as the participant's consultee, within the meaning of the Mental Capacity Act.

Case accountability

Case accountability for the provision of services will rest at all times with the host CASSR. We will record services, support, and ATT provided but not intervene in the way this is deployed (unless our advice is sought by the CASSR). Although we think that potential concerns about the ethics of withholding ATT for members of a control group are misplaced, we recognise the concerns that participants, their unpaid care-givers, and staff may have about this, particularly as in some sites, ATT is being actively 'marketed' as beneficial. Case accountable staff will therefore, in practice, retain the right to suggest, for example, that participants in either intervention or control group be admitted into residential care, or, in the case of control participants, recommend ATT if they feel that without it, the person's ability to remain living safely in the community would be jeopardised. The research team will monitor for adverse incidents and will act to remove any participant from either group if they assess that it is not in the best interests of the participant to continue in the study. The independent data monitoring committee will meet to review all adverse events data together with effectiveness and efficacy data at least every six months and will recommend stopping the trial early if it becomes apparent from primary outcome data that efficacy has been established or the frequency of adverse events indicates that effectiveness of the intervention is overwhelmingly likely.

Participant benefit

In practice, participants in trials of this kind benefit from taking part as involvement can produce positive effects. Our objective, however, is to produce evidence that will be of benefit to people living with dementia and their care-givers by providing an evidence base that can provide a robust basis for service development. The team is well placed to carry out the research because between us we have extensive experience of the successful conduct of clinical trials with people with dementia. We also have members of our team with specific expertise in dementia, the use and evaluation of ATT in dementia, statistics, health economic evaluation, social care and quantitative and qualitative research methodologies. The team also cover a number of large population centres from which we can recruit the comparatively high numbers of participants that the trial requires. Large scale clinical trials are expensive to conduct but they provide the definitive answers to important clinical questions and have the potential to drive the development and implementation of clinically and cost-effective interventions within the NHS and Social Care.

3. OUTCOME MEASURES

3.1 Primary efficacy parameter

The co-primary trial outcomes will be (i) time to institutionalisation and (ii) cost effectiveness of the ATT intervention.

(i) Time in days from randomisation to institutionalisation

This is defined as permanent transition from living in own home to nursing or residential care home or to admission to an acute care facility that results in permanent placement in a residential care or nursing home.

(ii) Cost-effectiveness

Costs will be calculated by attaching nationally applicable unit cost measures to health and social service use and the costs of ATT provided. These data will focus on assistive technology and telecare, healthcare and other service utilisation patterns and (unpaid) caregiver inputs and will be collected at baseline, 12 weeks, 24 weeks, 52 weeks and 104 weeks for each participant using a modified version of the Client Service Receipt Inventory (Beecham & Knapp 2001, appendix 19). Unit costs will be attached using national figures taken from the PSSRU annual compendium where available.

Assistive technology and telecare costs will likely need to be calculated anew, and in this we will be guided by methods and experience gained in a major national trial of telecare and telehealth: the Whole Systems Demonstrator (Professor Knapp leads the economic evaluation in that study). Appendix 29 (Costing the ATTILLA Intervention) describes methods to calculate the costs of providing the assistive technology and telecare intervention, including a detailed plan for the collection of data required to cost the intervention. In summary, as part of this work we propose to carry out interviews of key informants (Local Authority operational/middle managers, Local Authority commissioners of telecare and managers of telecare provider organisations). This will involve brief interviews and some correspondence with key informants. Methods for selecting and recruiting the informants and sample emails containing proposed interview questions are given in an annex on pages 5-10.

In addition, we plan to request data on the telecare equipment provided to participants by the Local Authorities and telecare provider organisations. Arrangements may vary substantially between sites in terms of which organisations provide assistive technology and telecare (AAT) equipment (Local Authorities or telecare provider organisations). Arrangements also may vary in terms of the systems in place for recording the equipment provided. The key informant interviews will allow us to map out where these ATT equipment records are kept in each site. The project team will negotiate access to ATT equipment records, subject to data sharing agreements between the organisations and the project team being in place. This planned extraction of participants' ATT equipment data will be covered by the existing participant consents for the collection of data from health and social care records.

Data on carer time and task inputs will come from the CSRI, and will be valued using (and comparing in sensitivity analyses) replacement wage and opportunity cost approaches.

Cost-effectiveness analyses will be of two types, each conducted from two perspectives: (a) health and social care, and (b) societal.

(i) The first cost-effectiveness analysis type will measure costs only up to the point that a study participant goes into a care home or hospital and not beyond ('community costs'), and then examine cost-effectiveness in achieving the primary outcome (days from randomisation to institutionalisation in the two year period). This analysis will show the incremental cost of community based support of each additional institutional day avoided. The second analysis type will measure costs for the whole two year period including costs of care home and hospital stays ('total costs'), and then examine cost-effectiveness where the outcome is EQ-5D-5L change, over the two year period.

(ii) We can also use the EQ-5D-5L to generate QALY measures. Incremental cost-effectiveness ratios will be computed, and cost-effectiveness acceptability curves plotted, generated from the net health benefit approach and using bootstrap regression for a range of values of willingness to pay for the corresponding outcomes. In each case, we will also be able to carry out these analyses at 24 and 52 weeks.

3.2 Secondary efficacy parameters

(i) 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 22-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 one's 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 five 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 Centre for Epidemiological Studies Depression Scale (CED-D10, appendix 16) and the Standard Trait Anxiety Inventory (STAI, appendix 15).

(ii) Quality of life

We will measure health-related quality of life in caregivers using the SF-12v2 (Jenkinson et al 1999, appendix 14).

(iii) Number and severity of serious adverse events

As in any trial, serious adverse events (requiring GP or hospital care) will be recorded and reported. Details of how we propose to do this are presented below in section 6 which deals with safety monitoring procedures.

(iv) Quantitative and qualitative data

Data on acceptability, applicability and reliability of ATT intervention packages will be collected using the Carer Technology Acceptance Questionnaire (SUTAQ) (Appendix 18). This questionnaire is currently being validated using data from the Whole System Demonstrator Project (WSD). We

anticipate that informal caregivers experiences will provide examples of ways in which their lives, well-being and care-giver roles will have been enhanced and/or undermined by the use of these technologies. Their diversity of experience and reasons for differences will be explored through semi-structured interviews of purposively-sampled groups that will include a range of types of: (1) caregivers who have used the ATT for at least six months; (2) caregivers who have requested ATT withdrawal after installation, and (3) caregivers who have refused ATT when offered. This qualitative strand of the proposed study will require a supplementary ethical application as at the present time the research team is securing additional resources to enable this part of the study to take place.

4. PATIENT ENTRY

Participants will be people with any dementia diagnosis, or suspected dementia, who are living in the community and will be from one or more of three constituencies:

- **(i)** People who seek help or support from local authorities social care services in the areas that have agreed to support the trial (Barnsley, Blackburn, Blackpool, Cambridgeshire, Croydon, Lambeth, Lancashire, Oxfordshire, Southwark, Suffolk, and West Sussex), and meet local eligibility criteria.
- **(ii)** People supported by the services of the NHS and are referred to Social Services, and meet local eligibility criteria,
- **(iii)** People who are recruited from the caseload of NHS services for older adults and referred to local social services, and meet local eligibility criteria.

Those referred from the NHS will usually have to meet eligibility criteria for social care because this will often determine if ATT can be provided.

4.1 Screening for eligibility and preliminary information visit

All study procedures, including the initial visit and consent visit, will take place in the participants' homes. At the first appointment, participants potentially meeting the study inclusion criteria will be assessed for eligibility based on the following inclusion and exclusion criteria:

Inclusion criteria:

Participants will be participants with all dementia diagnoses, both with and without capacity, and will include individuals with young-onset and later-onset dementias, or evidence of memory difficulties or possible dementia. Additionally, all participants must meet the following criteria:

- **(i)** Have a professionally assessed need for ATT from a health or social care professional
- **(ii)** Be a community resident
- **(iii)** Live in a dwelling suitable for the installation of ATT

Exclusion criteria:

- **(i)** People already receiving an ATT intervention (excluding non-linked smoke detector or carbon monoxide detector, key safe or pendant alarm) or where ATT has previously been provided but has not been used;
- **(ii)** People unlikely to comply with follow-up e.g. due to an unstable medical or psychiatric condition;
- **(iii)** People participating in another clinical trial involving an intervention for dementia;
- **(iv)** Where there is an urgent need of a care package due to immediate and severe risks to self or others.

Sources and method of recruitment

There will be several routes for participant recruitment. NHS services (mental health, community care, primary care or otherwise) will likely be the first-line sources for recruitment. We will extend recruitment beyond the NHS to local authorities and include all people with dementia, or suspected dementia. Those referred from the NHS will have to meet eligibility criteria for social care.

After assessing eligibility of new referrals for both social care support and the ATTILA trial, participating services will ask if their contact details can be made available to a named individual in a local research team. Once identified, the research worker will contact this person and arrange to visit them and an unpaid carer who knows them well. Potential participants who meet the eligibility criteria will have the possible benefits and risks of participation in the study explained. Following this, the participant will be given a general outline of three possible options: (1) taking part in ATTILA with the intervention (i.e. ATT package or regular support package without ATT), decided by randomisation, (2) declining to participate in ATTILA, and (3) taking more time to consider their decision about whether or not to participate. Those who are interested in taking part in the study will be given a participant and carer information leaflet (see Appendices 2-4) to find out more about the study before deciding whether or not to participate. After a full explanation of the intervention options and the manner of treatment allocation, all suitable participants will be invited to take part in the randomised component of the trial. If urgent provision of support services is required, then consent will be sought at that visit so that they can be immediately randomised. Otherwise information about the study can be left with the prospective participant and, should they require more time to consider participation, the researcher will return at a later date to take consent and subsequently randomise the participant. After randomisation, assessment for ATT and provision of ATT services (within limits set by randomisation) will be left entirely up to the local authority or health service operational teams concerned.

Written, informed consent will be sought from those agreeing to take part in ATTILA. Consent will also be obtained from the carer using the carer consent form in the study folder (see Appendices 7). If the participant lacks capacity, a professional or personal consultee will be involved to ensure that participation in the study is in the person's best interests (according to guidelines established in the Mental Capacity Act Code of Practice 2007; (see Appendix 6 for consultee form). Where appropriate, data sharing agreements will have previously been agreed with the CASSRs and health services concerned to ensure that the transfer of personal data from local authority to research team is lawful

(see Appendices 6-8 for consent forms). If consent is not given, the participant will not be included and any personal data will be removed from research team records and destroyed. Reasons why those who are potentially eligible do not consent to take part will be recorded on a screening log in the ATTILA study folder.

Randomisation of participants will occur via the study office. To minimise the delay in receipt of services, randomisation will take place immediately following consent. The outcome of the randomisation process will be passed on to an agreed operational link in the CASSR so that assessment and ATT as appropriate can be arranged. Responsibility for assessment for, and deployment of, all ATT and non-ATT based forms of support will rest at all times with the CASSR. (See Appendix 11 for randomisation form).

4.2 Randomisation

Participants will be randomised using telephone-based randomisation and data entry portal provided by the Oxford Clinical Trial Service Unit. Treatment allocation will be via a minimised randomisation procedure stratified by the criteria below. This information will be obtained by the local study team following consent and during the screening process.

(i) Gender
(ii) Age (<65, 65-80, 80+)
(iii) Risk of wandering or leaving the home inappropriately (Low, Moderate, High)
(iv) Safety risk within the home(Low, Moderate, High)
(v) Level of caregiver support available (Live-in caregiver, caregiver visits at least once daily, caregiver visits less often than daily).

This stratification procedure will be reviewed by the Trial Steering Committee after the first 100 randomisations.

Randomisation will be carried out centrally by the ATTILA Study Office (Tel. 0800 585323). A minimisation randomisation procedure will be used to reduce the risk of chance imbalances between arms with respect to known prognostic factors.

Rationale for the use of minimisation:

Minimised randomisation is an accepted and widely-used procedure for allocating participants to treatment arms in clinical trials. Scott et al. (2002), for example, conclude that: 'From the evidence presented in this review, we believe minimisation to be a highly effective allocation method and recommend its wider adoption in the conduct of randomized clinical trials'. This method ensures no possible foreknowledge of treatment allocation and thus no risk of selection bias. Minimisation has the practical advantage of avoiding chance imbalances in treatment allocation within a prognostic subgroup.

Procedures to follow for randomisation:

After informed consent has been obtained and baseline assessments have been completed, randomisation will be carried out centrally by the ATTILA Study Office. The person randomising will answer all of the telephone questions and will complete the ATTILA randomisation form (Appendix 11)

before calling to help in preparing for them. Alternatively, randomisation forms may be faxed - or scanned and e-mailed - to the ATTILA study office which will call back with a treatment allocation. After all the necessary details have been provided, the allocated treatment will be specified. The baseline assessments should be labelled with the participant's intervention assignment number and posted to the ATTILA Study Office in the Freepost envelopes provided in the study folder. The participant's GP should be notified that they are in ATTILA and a specimen 'Letter to GP' is provided for this purpose, unless the participant refuses (Appendix 9).

5. INTERVENTION AND FOLLOW-UP PROCEDURES

5.1 Trial intervention

Each participant who is eligible for the study and has signed the consent form will be randomised to *either* (i) an ATT needs assessment followed by the provision of an ATT package deployed by the host CASSR, or, (ii) a control which is the ATT needs assessment followed by provision of ATT limited only to non-monitored smoke and carbon monoxide detectors, a key safe and pendant alarm, deployed according to assessed need by the CASSR.

Planned interventions

The detailed description of the interventions that follows reflects guidance from the Medical Research Council (MRC) framework for complex interventions and demonstrates, as per the MRC recommendations, how the research team considered the three most important questions that researchers should ask themselves when designing such complex interventions.

The intervention is comprised of an assessment in order to determine the level of need and services required as well as a well-established model for the application of ATT interventions in people with dementia. In practice, this will involve the installation of simple, battery operated, stand-alone technologies and/or telecare (a range of devices and sensors which communicate and relay messages to an external call centre where an appropriate response is arranged). The generic components of the overall dementia ATT model are described in the next section and are encompassed in the two parts of the intervention described below: Part A, assessment of ATT service needs; and Part B, installation of suite of ATT devices. The installation and selection of the technology to be deployed will be the responsibility of the local authorities involved. The input of the study team regarding the assessment and selection of technology may, however, be considered by the local authority.

Intervention Part A: Assessment of ATT service needs

Each participant will undergo an assessment in order to determine the level of need and what services they require.

Intervention Part B: Installation of the suite of ATT devices

Commercially available ATT devices that we and others have successfully piloted to promote independent home-living for people with dementia will encompass the suite of devices offered to participants randomised to the ATT arm of the study. The devices used will be decided by the local authority not the ATTILA team.

Analysis of ATT needs assessment

As there is variation in the ATT needs assessments conducted by the CASSRs, an Occupational Therapist led analysis of the ATT needs assessments will be developed, in order to identify the quality of ATT needs assessments across sites. A content analysis was completed of the ATTILA site ATT needs assessment documentation in order to establish the quality standard across ATTILA sites. This analysis was consistent with 14 items on the Model of Human Occupation Screening Tool (MOHOST, appendix 28). Each ATT needs assessment will, therefore, be rated using these 14 MOHOST items by research Occupational Therapists in the ATTILA team at Queen Margaret University, Edinburgh. This will establish a) each site's compliance with their own quality standard (as identified through their own documentation), b) allow an accurate description of the frequency of the issues addressed in the ATT needs assessments across sites, c) identification of the frequency of the risk for each of the areas addressed in the ATT needs assessment. The ATT recommendations identified within the ATT needs assessment will also be coded using the Technology Checklist (appendix 22), allowing for consistency between "recommended" and "installed" to be interrogated.

5.2 Other treatments or interventions

Interventions, such as other experimental clinical trials (pharmacological or non-pharmacological), will not be permitted during the duration of ATTILA. However, since this is a pragmatic study, treatment as usual for the participant's dementia and other medical conditions will continue. Apart from this, installation of the trial ATT interventions and undertaking the follow–up assessments, all other aspects of participant management will remain at the discretion of the general practitioner or secondary care team as appropriate. Participants will be managed as is considered best for them, with no special treatments, no laboratory or other special investigations, and no extra follow-up required. Concomitant medications and other non-pharmacological interventions (such as user groups etc.) should, however, be recorded on the ATTILA participant follow-up form (Appendix 20) at 12 weeks, 24 weeks, 52 weeks and 104 weeks for each participant.

5.3 Assessment visits and follow-up telephone calls

Assessment visits will be undertaken following randomisation and then at weeks 12, 24, 52 and 104. A follow-up telephone call will be undertaken at weeks 130, 156, 182, 208, 234 and 260. Ideally, follow-up assessments and telephone calls should be undertaken whether or not participants choose to remain in the allocated study arm. Follow-up is discontinued when:

- the participant reaches 260 weeks, or
- the participant enters institutional care or dies, or
- the participant withdraws consent to follow-up assessments, or
- the participant is irretrievably lost to follow-up, or
- the trial ends in December 2018

ATTILA Study Flowchart

	Week -1	Eligibility & Randomisation Screening	Face-to-face follow-up assessments					Telephone follow-up assessments					
			Week 0	Week 12	Week 24	Week 52	Week 104	Week 130	Week 156	Week 182	Week 208	Week 234	Week 260
Participant information	X												
Inclusion Criteria		X											
OT ATT needs assessment at home	X												
Capacity Assessment	X	X (Prior to consent)	X	X	X	X	X						
Informed Consent		X											
Randomisation data		X											
Inform local authority of randomisation outcome		X											
Install intervention (ATT or alternatives)			X										
SMMSE			X										
Bristol Activities of Daily Living Scale (BADLS)			X				X						
EuroQol EQ-5D-5L			X	X	X	X	X						
EuroQol EQ-5D-5L Proxy (carer)			X	X	X	X	X						
SF-12v2 Health Questionnaire (carer)			X	X	X	X	X						
Standard Trait Anxiety Inventory Short-Form (STAI-6) (carer)			X	X	X	X	X						
Centre for Epidemiological Studies Depression Scale (CES-D10)			X	X	X	X	X						
Zarit Burden Inventory (carer)			X	X	X	X	X						
Service User Technology Acceptance Questionnaire (SUTAQ) (carer)				X	X	(Or at withdrawal from ATT package)							
Client Service Receipt Inventory (carer)			X	X	X	X	X						
Follow-up Form				X	X	X	X	X	X	X	X	X	X
Technology Checklist			X	X	X	X	X						
Adverse Events			X	X	X	X	X	X	X	X	X	X	X

5.4 Minimising loss to follow-up

The trial aims to minimise the number of participants who withdraw from the study and, especially, the numbers with missing follow-up assessments.

Participants or their carers commonly fail to comply with study protocols for several reasons, which may include:

Dissatisfaction or concern with the study allocation

Change (or lack of change) in the participant's condition or circumstances, particularly with respect to their safety at home, sometimes justifies withdrawal from the study in the opinion of the participant, carer, research team, or case accountable CASSR staff.

Many participants who do not comply with study allocation may be agreeable to continue to be followed-up. In this case, ATTILA outcome data will be collected in accordance with the protocol. The reason for withdrawing from ATTILA treatment allocation (e.g. withdrawal of consent, change in circumstances) and the use of off-protocol assistive technology (if any) should be recorded on the participant follow-up form.

Discontinuation of follow-up assessments

Participants may choose to discontinue study assessments. In this case, the local PI or research worker will attempt to ascertain the reason for the discontinuation of follow-up assessments, without compromising their right to withdraw at any time without giving a reason, and record this on the participant follow-up form. Note that, unless the participant specifically revokes their earlier consent for information about their progress to be sent to the ATTILA Study office, information relevant to primary outcome measures, in particular residential status, will continue to be collected and participant information will be retained in the trial database and used for intention-to-treat analyses of study outcomes.

Loss to follow-up

Loss to follow-up will be minimised by all available means, including use of centrally held NHS records, and will be monitored both locally and centrally. A participant will only be regarded as lost to follow-up with the agreement of the recruiting PI and the trial manager.

Participant transfers

For participants moving from the area or to another doctor or hospital, every effort will be made for the participant to be followed up. If another centre agrees to take over responsibility for the assessments, it will need to be set up as an ATTILA site, a copy of the participant's study documentation sent to the new site, and the participant will have to sign a new consent form. Until this occurs, the participant remains the responsibility of the original centre. The ATTILA Study office will facilitate this process.

5.5 Expected duration of trial

Completion for an individual participant is defined as completion of up to 260 weeks on the trial intervention or discontinuation of follow-up for any reason. The trial may, however, be stopped earlier by the Trial Steering Committee if the Independent Data Monitoring and Ethics Committee (IDMEC), in accordance with the IDMEC charter, recommend to the Trial Steering Committee that the trial be stopped. The criteria for stopping the trial will be established as part of standard operating procedures of the IDMEC (see section 8.4) at their first meeting.

6. SAFETY MONITORING PROCEDURES

Specification, timing and recording of safety parameters

Safety will be assessed at the 12, 24, 52 and 104 week visits via a face to face interview of the participant's carer by the researcher who will systematically enquire about changes in the participant's health, any compromises of participant safety or changes in living circumstances between assessments. This will be supplemented by discussion where possible with care workers, and the researcher will also use observation to assess the participant's living situation. Safety will also be assessed at the 130, 156, 182, 208, 234 and 260 week telephone call to the participant's carer by the researcher.

Procedures for recording and reporting adverse events

The adverse event reporting arrangements that apply to investigational medicinal products are not applicable, or appropriate, for ATTILA. The main focus is to capture as complete information as possible on compromises of participant safety that might be preventable by use of assistive technology. An adapted version of the adverse event reporting scheme will therefore be used in ATTILA:

Adverse Event (AE): Any compromise of participant safety.

Serious Adverse Event (SAE):
Any compromise of participant safety that:

- **(i)** Results in death;
- **(ii)** Is life-threatening;
- **(iii)** Requires hospitalisation or prolongation of existing hospitalisation;
- **(iv)** Results in persistent or significant disability or incapacity;
- **(v)** Requires intervention of emergency services
- **(vi)** Results in admission to permanent residential care

Note the term 'severe' is often used to describe the intensity (severity) of a specific event. This is not the same as 'serious', which is based on participant/event outcome or action criteria.

Assessment of preventability

The potential preventability of the SAE by use of assistive technology (AT) will be assessed and categorised by the local PI using their judgement into one of the following five categories:

(i) ***Not preventable by assistive technology*** – event or its consequences would have been the same with or without ATT
(ii) ***Unlikely preventable*** – event or consequences unlikely to be altered by ATT
(iii) ***Possibly preventable*** – possible that event or its consequences might have been prevented or mitigated by ATT
(iv) ***Likely preventable*** – reasonable to believe event or its consequences might have been prevented or mitigated by use of ATT
(v) ***Definitely preventable*** – event or consequences would have been prevented or mitigated by ATT

In analyses of the ATTILA trial, *possibly, likely and definitely preventable* categories will be considered as preventable.

Reporting responsibilities

The Local Principal Investigator or other member of the research team should complete an SAE form (appendix 26) for all serious compromises of participant safety. In addition, all other compromises of participant safety will be recorded on follow-up forms and reviewed by ATTILA's independent Data Monitoring Committee (IDMEC) at regular intervals.

Case accountability will, at all times, rest with the CASSR who will have sole responsibility for deploying telecare and establishing any monitoring or social response requirements associated with the ATT. However, members of each local ATTILA research team will liaise with local CASSR operational teams and inform them immediately if compromises of participant safety are observed or drawn to their attention.

7. SIZE, STATISTICS, AND DATA MONITORING PROCEDURES

7.1 Sample Size

The two primary outcome measures are time to transition to institutional care and cost-effectiveness. 50% of participants with a BADLS score of 15 or greater will transition to institutional care after 24 months (based on observed institutionalisation rates in participants from the AD2000 cohort). A reduction in the estimated 24-month transition to care home rate by 30% (i.e. 50% institutionalised at 2 years reduced to 35%) would require the involvement of 500 participants, allowing for 10% attrition due to death while still community resident. This equates to an average of 55 days of longer independent home life for each participant who has received assistive technology and telecare. The trial would therefore be powered to detect a mean institutionalisation delay of just under eight weeks. Expert opinion suggests that eight weeks is close to the minimum clinically important difference in delaying institutionalisation. Smaller differences in time to institutionalization might be cost-effective,

but only if quality of life of participants and caregivers are improved and/or non-institutional costs are reduced.

7.2 Analysis

Statistical analysis will be by Intention-To-Treat (ITT). All participants who are randomised will be included in the comparison and analysed according to their randomised allocation, including those who discontinue the ATTILA study. Wherever possible, we will continue to collect follow-up data from these participants after they leave the study, so that the dataset will be as complete as possible.

The primary outcome of time to institutionalisation will be analysed using standard log rank methods and will include all events even those occurring after two years. Continuous outcome measures, e.g. quality of life and functional ability measures will be analysed using repeated measures regression techniques to maximise statistical power. Exploratory subgroup analyses will be undertaken, appropriately cautiously, to investigate any influence of the baseline prognostic factors (gender, age, risk profile, support structure) on outcome.

For qualitative data, thematic analysis will be undertaken, to develop themes emerging inductively from data and narrative analysis of longitudinal elements to identify acceptable and less acceptable practices and features of AT equipment use. A collaborative analytic strategy will involve appropriate research team members and service user/carer researchers, to enhance validity and to help integrate qualitative and quantitative findings. This will be subject to a supplementary application for ethical review.

Local, site specific reports will be produced by each local ATTILA research site. These will be produced towards the end of the fieldwork period. The timing of reports and local content will be subject to local negotiation and discussion between the local PI and designated senior managers within the CASSR.

Handling of potential bias and heterogeneity across centres

Since there may be some heterogeneity in the practice of the occupational therapists and Local Authorities in identifying needs and provision of ATT across the different centres, between-centre heterogeneity will be explored. We will do this by grouping together centres based on the quality of the ATT provision (i.e. good/average/poor) in stratified analyses.

Handling of missing data

Reasons for withdrawing from the study will be collected and, since stopping the ATTILA intervention is likely to be informative (e.g. a failure or intolerance of the intervention), this information will be used in sensitivity analyses to investigate and reduce the impact of missing data.

Handling of reports of death

Deaths among community-resident participants will be sub-categorised as those that occur as a consequence of an identified risk that ATT might have prevented or mitigated and other deaths. The number of deaths that were considered potentially affected by ATT in the two study groups will be compared in in a secondary analysis.

Competing risk analysis

At baseline, we will collect data on the categories of risk (safety within the home and risk of wandering) and the recommended ATT intervention to protect against this risk. Similarly, compromises of participant safety will be sub-categorised in the same way and we will then undertake secondary analyses of the efficacy of appropriate ATT in preventing identified risks. In cases where two types of technology are recommended that might both reduce a particular risk we may undertake competing risk analyses to try to disentangle the relative efficacy of each intervention. However, the study might be under powered to find any real differences.

8. ORGANISATION

To ensure the smooth running of ATTILA and to minimise the overall procedural workload, it is proposed that each centre should designate individuals who would be chiefly responsible for local coordination of clinical and administrative aspects of ATTILA. The ATTILA Study Office, working together with DeNDRoN or MHRN networks (where available), will provide as much assistance as they can to local co-ordinators and investigators in obtaining Trust approval in each centre, identifying, assessing and recruiting participants, and helping resolve any local problems that may be encountered.

8.1 Local Principal Investigator

Each centre should nominate one person to act as the Local Principal Investigator (PI). Their responsibilities will include:

- Liaising with local GPs, psychiatrists, nurses, Social Services and Clinical Research Networks.
- Liaison with all who refer participants to the centre to encourage them to consider suitable participants for ATTILA. Local procedures will need to be developed to ensure assessment and discussion of individual potential participant's suitability for ATTILA at team meetings, providing eligible participants with ATTILA information sheets, arranging appointments to discuss taking part in the study, obtaining consent and randomisation and arranging for the intervention. The members of the research team who will obtain consent will be agreed upon by the study team. Ensuring that all staff involved in the care of the participants with dementia are reasonably well informed about the study. This will involve distributing the ATTILA materials to all relevant staff, displaying the wall-chart where it is likely to be read, and distributing the ATTILA newsletters. A regularly updated PowerPoint presentation will be provided to centres so that they can be shown from time to time, especially to new staff.

Ensuring compliance with research governance requirements

This involves obtaining management approval for ATTILA, ensuring that all members of the clinical team are familiar with the protocol and trial procedures, in particular serious adverse event reporting, maintaining the Local Study Site File with copies of trial materials, approval documents, consent forms and any other required documents as advised by the ATTILA Study office.

8.2 Local Study Coordinator

It is suggested that each Centre should designate one person as Local Study Coordinator. This role might suit a higher trainee in old age psychiatry or, if available, a research nurse. The Local Study Coordinator would be responsible for ensuring that all eligible participants are considered for ATTILA, that participants are provided with ATTILA information sheets and have an opportunity to discuss the study as required, registering participants to ensure that ATTILA intervention packs are available when potential participants are identified, obtaining consent, randomisation, obtaining study packs from the study centre when participants are randomised, and ensuring follow-up assessments are undertaken as scheduled in the protocol. The ATTILA Local Study Coordinator will also ensure that ATTILA trial forms and questionnaires are completed and administered as scheduled (unless some contraindication develops). Again, this person would be sent updates and newsletters, would be invited to ATTILA progress meetings and appropriately credited in study reports.

8.3 Trial Steering Committee

The Trial Steering Committee (TSC) is responsible for the independent supervision of the scientific and ethical conduct of the trial on behalf of the Trial Sponsor and funding bodies. The TSC will review data, on progress of the trial including recruitment, protocol adherence, serious adverse events, trial publications and will determine the future progress of the trial in light of regular reports from the IDMEC and Trial Management Group (TMG). The TSC has the power to prematurely close the trial. The TSC will meet annually or more often if the chair determines a reason for doing so. In addition to the independent voting members (listed inside front cover), the TSC will include the ATTILA Chief Investigator, Trial Manager and Statistician, and representatives from the funding body and Sponsor.

8.4 Data monitoring and research governance

This trial will encompass elements of both NHS and local authority jurisdiction. It will therefore be necessary to comply with governance arrangements in both the NHS and the local authorities. The detail below refers to the NHS governance arrangements. We anticipate that we will have to comply with local authority governance arrangements and we will do this on case-by-case basis.

Data monitoring and ethics committee (DMEC)

The trial will be submitted for adoption by DeNDRoN and by the Mental Health Research Network in clinical centres where there is no DeNDRoN coverage and registered with Clinicaltrials.gov, a publicly accessible database, before any participants are recruited. In accordance with high standards of research governance, we will ensure that all researchers receive training in Good Clinical Practice (GCP). We will set up a Trial Steering Group and an Independent Data Monitoring and Ethics Committee (IDMEC) prior to the start of the study in compliance with the guidelines provided by the

HTA. Investigators will conduct safety monitoring of the trial according to the written standard operating procedures agreed by the King's College (London) Joint Clinical Trials Office. According to these procedures, the criteria for a serious adverse event are: results in death; is life-threatening; requires hospitalisation or prolongation of existing hospitalization; or results in persistent or significant disability or incapacity. Copies of the adverse event forms will be sent to the chair of the IDMEC.

Research governance

Research governance approval will be sought from the relevant NHS organisations and where necessary local authority host organisations. King's College London (KCL) will be the sponsor. On a day-to-day basis, sponsor-level activities will be carried out by the KCL Joint Clinical Trials Office (JCTO), with reporting lines to the sponsor who will ensure that all obligations are adhered to. The study will be conducted in accordance with JCTO and study-specific Standard Operating Procedures and Work Instructions. All trial staff will be appropriately qualified and will be trained in those aspects of GCP appropriate to their role in the study. The Trial Manager will undertake at least one annual monitoring visit to each site to review compliance with the study protocol and principles of GCP. However, this is a relatively low risk study and 100% site data verification is not appropriate. Research and Development approval will be sought from all NHS organisations in which all recruited participants are located and the study will be open to audit by the research governance teams in those organisations. We will follow *Research in the NHS – Human Resources (HR) Good Practice* in determining which members of the research team require an honorary research contract (providing those individuals with NHS indemnity in respect of negligent harm) and pre-engagement (e.g. CRB/DBS) checks, and which simply require letters of access. Since the research spans multiple NHS organisations, we will seek research passports as appropriate. University professional liability insurance will further indemnify university employees in respect of liabilities arising from protocol design.

Independent oversight of the study will be provided by a Trial Steering Committee (TSC) with an Independent Chair, other independent experts representing the major areas of clinical and methodological expertise and two consumer representatives. A representative of the HTA Programme will also be invited to attend. The standing membership of the Trial Steering Committee will also include two principal investigators, the trial statistician and the trial manager. The Trial Steering Committee will meet at the start and end of the trial and twice-yearly through the life of the trial. In order to monitor accumulating data on participant safety and treatment benefit, an Independent Data Monitoring and Ethics Committee will be established. This will meet approximately annually and will advise the Trial Steering Committee should the interim analyses provide 'proof beyond reasonable doubt' that either ATT or no ATT is superior in terms of the primary outcome measures.

8.5 Ethics & Regulatory Approvals

Specific ethical approval

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (1996) and Good Clinical Practice (GCP-ICH 1997). All researchers working on the trial will receive training in GCP-ICH guidelines. The study will also be conducted in compliance with all relevant future acts and regulations.

The integrated form for both site-specific information (SSI) and R&D approval at all participating NHS sites will also be approved prior to recruitment at each site. Annual progress and safety reports and a final report at conclusion of the trial will be submitted to the MREC and the HTA within the timelines defined in the Regulations.

Informing potential trial participants of possible benefits and known risks

Potential participants and their caregivers will be asked by the referring clinician or social care professional to give verbal consent for their contact details to be shared with the research team. They will then be contacted by the local research worker and sent copies of the information sheets if requested, and a time for an information meeting or a follow-up phone call will be arranged. The invitation materials will include details of how to contact the research team if they have any questions about the study. Those who express an interest will have their perception of the potential benefits and risks explored by research staff before written informed consent to participate is sought. Our experience suggests that, for the overwhelming majority of participants in dementia trials, discussing these issues is a positive experience. But, some people with dementia and their caregivers may find the data collection procedures, in particular some of the aspects of the interviews that discuss mental health issues, tiring or distressing. We will ensure that the researchers collecting data are trained and supervised to anticipate and manage this. Should information about benefits or risks become available from the trial or from other studies, this will be communicated to all participants in a project newsletter. At all points of contact it will be stressed that participation is voluntary and that participants may withdraw at any point without this decision affecting their normal clinical or social care.

Obtaining informed consent from participants

NRES guidance on the content and format of participant information and consent documentation will be followed. We will also involve our consumer representatives to ensure that these documents and all other written trial materials are fit for purpose. Information about the study will be given to potential participants and their caregivers. In accordance with the Mental Capacity Act 2005, the process of assessment of capacity to consent and securing consent will be regarded as an iterative process and will be reviewed at each stage. Once an expression of interest in participating has been received, an appointment will be made for a member of the research team to visit the potential participant in their home. The purpose of this visit will be to ensure that they have received and understood the study information and the implications of their involvement. As many of the potential participants will have significant cognitive impairment, careful consideration will be given to the consent process. At each stage of involvement, the participant will be asked to give consent appropriate to their level of understanding, ranging from written informed consent to verbal or non-verbal communication of assent, of which account will be taken in assessing willingness to participate. Nothing will be done with a participant to which he or she appears to object, either verbally or non-verbally. In addition, we will make allowance for the loss of mental capacity in a participant during the course of the study; If it is deemed that a participant has lost capacity then the carer, or next of kin, will be approached to act as consultee. They will be informed of this when consent is initially taken. If there are concerns about the potential participant's present capacity and ability to give informed consent, then a nominated consultee will be approached. If no family caregiver can be identified for this, a consultee can be nominated by the study team but they must have no other connection with the research project. A

detailed consent protocol and a consent checklist will be developed for the interviewer to follow so that all aspects of the correct procedure will be followed in obtaining consent.

Proposed time period for retention of relevant trial documentation
All trial documentation and data will be retained for a minimum of 15 years.

8.6 Quality assurance

Recruitment to ATTILA will be undertaken by NHS clinical staff working in CMHTs and Memory Assessment Services as well as from older adult social workers and assistive technology services in local authorities. They will be experienced in the assessment of client service needs. All Investigators and staff employed by the grant will be trained in GCP, the use of the assessment tools and trial guidance. Wherever possible, the same rater will be used for all baseline and follow-up ratings on each individual participant. The Trial Manager will maintain a Trial Master File containing the essential trial documents in accordance with GCP and the EU Clinical Trial Directive. In addition, each site will be provided with an Investigator Site File which will contain the essential trial documents.

The trial will be carried out in accordance with this protocol and the ATTILA Standard Operating Procedures (SOPs). Trial specific functions will be conducted in accordance with these and will ensure the procedures within the trial are carried out in the same way in each centre.
Monitoring of this trial to ensure compliance with the protocol and Good Clinical Practice will be managed and overseen by the King's Health Partners Clinical Trials Office (KHP CTO) Quality Team, in accordance with KHP CTO SOPs, on behalf of the Sponsor. Each site will take part in a site initiation, to ensure appropriate staff training, resources and essential documents are in place. During the course of the trial the study files will be reviewed for appropriate documentation of participant consent and participation in the trial, and a sample of data will be verified against participant notes in accordance with the risk assessment and monitoring plan for the trial. The Investigator(s) will provide direct access to source data and other documents (e.g. participants' case sheets, etc.) to permit trial-related monitoring, audits, REC review, and regulatory inspections (where appropriate). At the end of the trial each site will be formally closed down once trial activity at the site has ceased.

The Chief Investigator will act as custodian for the trial data. All trial data will be stored on a password-protected computer and archived in line with the Medicines for Human Use (Clinical Trials) Amended Regulations 2006 as defined in the KHP CTO Archiving Standard Operating Procedure (SOP). Trial data may be accessed by those connected to the study team on application to and at the discretion of the CI.

8.7 Data handling

Outcome data will be entered onto case report forms and then mailed in FREEPOST envelopes to the statistical office at the Oxford CTSU and entered into a web-based data entry portal provided by CTSU. A suite of administrative software will be developed to send out reminders for follow-up visits, chase-ups of overdue or missing clinical research forms, etc.

8.8 Publication policy

The results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals. A meeting of the Trial Steering Committee and ATTILA collaborators will be held after the end of the study to allow discussion of the main results prior to publication. The success of ATTILA depends entirely on the wholehearted collaboration of a large number of research workers, social services and healthcare employees, psychiatrists, psychologists and others. For this reason, chief credit for the main results will be given not to the committees or central organisers but to all those who have significantly contributed to the study. All grant holders and members of trial committees, together with anyone who during the course of the study recruited substantial numbers of participants into the study and research workers at these centres who have been involved with the trial for more than 12 months, would have authorship rights as part of the ATTILA Trialists Group. Presentations or publications pertaining to the ATTILA trial must not be made without the prior agreement of the Trial Management Group.

8.9 Financial aspects

Funding to conduct the ATTILA trial is provided by the Department of Health's Health Technology Assessment programme (reference number 10/50/02). The duration of the grant is from December 2012 to November 2018. The grant will be administered by King's College London and sub-contracts will be drawn up for the Study Office at CTSU, University of Oxford and for other sites.

8.10 Project timetable and milestones

We plan to commence the trial on 1st December 2012, allowing realistic time to gain ethical and research governance approval and finalise the trial protocol.
Months 1 to 6 we will recruit and train the members of the trial team, finalise set-up and testing of the database and complete preparation of the centres including local R&D approval processes.
Months 6 to 43 we will recruit participants and commence the collection of outcomes data. Participants will be recruited at an estimated rate of 1 per centre per week to meet our target of 500 randomised.
Months 43 to 67 we will complete all follow-up and outcome assessment; data collection, checking and correction; and closing of the study.
Months 67 to 70 we will complete data analysis, report writing and preparation of the main papers for publication.

9. REFERENCES

Barlow, J. (2006) Building an evidence base for successful telecare implementation – updated report of the Evidence Working Group of the Telecare Policy Collaborative chaired by James Barlow – November 2006 http://ssia.wlga.gov.uk/media/pdf/f/4/APPENDIX_B_CSIP_Telecare.pdf accessed 08.05.12

Bebbington, A., Darton, R., & Netten, A. (2001) Care Homes for Older People: Vol. 2 admissions, needs and outcomes . The 1995-96 National Longitudinal Survey of Publically Funded Admissions London, Personal Social Services Research Unit.

Beecham J and Knapp M (2001) Costing psychiatric interventions. In: Thornicroft G (Ed) Measuring Mental Health Needs 2nd Edition. London. Gaskell.

Bharucha AJ, Anand V, Forlizzi J, Dew MA, Reynolds CF, Stevens S, Wactlar H (2009) Intelligent assistive technology applications to dementia care: current capabilities, limitations and future challenges. American Journal of Geriatric Psychiatry 17 88-104.

Bower, P., Cartwright, M., Hirani, S.P., Barlow, J., Hendy, J., Knapp, M., Henderson, C., Rogers, A., Sanders, C., Bardsley, M., Steventon, A., Fitzpatrick, R., Doll, H., & Newman, S., (2011) BMV Health Services Research 11: 184 http://www.biomedcentral.com/1472-6963/11/184.

Brownsell, S., (2009) Measuring the 'success' of telehealth evaluations Journal of Assistive Technologies 3 (4)p.12-20.

Bucks RS, Ashworth DL, Wilcock GK, Siegfried K (1996) Assessment of activities of daily living in dementia: development of the Bristol Activities of Daily Living Scale. Age and Ageing 25 113-120.

Davies, A., & Newman S., Evaluating telecare and telehealth interventions (2011) WSDAN briefing paper, The Kings Fund, London.

Department of Health (2003) The Government's Expenditure Plans 2003 Local Authority Personal Social Services Gross Expenditure by Client Group 2001-02 Chapter 6 p.73.

Department of Health (2005) Building Telecare in England. London Dept. of Health http://www.dh.gov.uk/assetRott/04/11/56/44/04115644.pdf

Department of Health (2009a) Transforming Adult Social Care London, DH.

Department of Health (2009b) Living well with Dementia: A National Dementia Strategy. London, Department of Health

EuroQoL Group (1990) EuroQoL: a new facility for the measurement of health-related quality of life. Health Policy 16 199-208.

Fisk, M., Social Alarms to Telecare: older peoples services in transition (2003) Bristol, The Policy Press.

Giordano, R., Clark, M. & Goodwin, N., (2010). *Perspectives on telehealth and telecare: Learning from the 12 Whole System Demonstrator Action Network (WSDAN) sites Briefing Paper.* The King's Fund

Gitlin LN, Winter L, Dennis MP (2010) Assistive devices caregivers use and find helpful to manage problem behaviours of dementia. Gerontechnology 9 408-414.

Goldberg D, Williams P (1988) A users guide to the General Health Questionnaire. London NEFRNelson.

Howard R, Phillips P, Johnson T, O'Brien JT. Sheehan B, Lindesay J, Bentham P, Burns A, Ballard C, Holmes C, McKeith I, Barber R, Dening T, Ritchie C, Jones R, Baldwin A, Passmore P, Findlay D, Hughes A, Macharouthu A, Banerjee S, Jones R, Knapp M, Brown RG, Jacoby R, Adams J, Griffin M, Gray R (2010) *Determining the minimum clinically important differences for outcomes in the DOMINO trial.* International Journal of Geriatric Psychiatry PMID: 20848576.

Hughes CP, Berg L, Danziger WL, Coben LA, Martin RL (1982) A new clinical scale for the staging of dementia. British Journal of Psychiatry 140 566-572.

Jenkinson C, Stewart-Brown S, Petersen S, Paice C (1999) Assessment of the SF-36. Journal of Epidemiology and Community Health 53 46-50.

Knapp, M., & Prince, M., (2007) Dementia UK: a report into the prevalence and cost of dementia prepared by the Personal Social Services Research Unit (PSSRU at the London School of Economics and the Institute of Psychiatry at Kings College London, for the Alzheimer's Society. London, Alzheimer's Society

Lauriks S, Reinersmann A, Van der Roest HG, Meiland FJM, Davies RJ, Moelaert F, Mulvenna MD, Nugent CD, Droes RM (2007) Review of ICT-based services for identified unmet needs in people with dementia. Ageing Research Reviews 6 223-246.

Leggett AN, Zarit S, Taylor A, Galvin JE (2010) Stress and burden among caregivers of patients with Lewy body dementia. The Gerontologist doi:10.1093/geront/gnq055.

Marshall, M., (Editor) (2010) ASTRID: A Social and Technological Response to meeting the needs of Individuals with Dementia and their carers.

Mitchell, R, (1996), An Evaluation of Falkirk's Mobile Community Alarms Service (Unpublished, Falkirk Council, Scotland.

Molloy, D.W., Alemayehu E, Roberts R (1991) Reliability of a standardised mini-mental state examination compared with the traditional mini-mental state examination. American Journal of Psychiatry 148 102-105.

Penninx, B.W., Ferruci L, Leveille S.G., Rantanen T, Pahor M, Guralnik J.M., (2000) Lower extremity performance in nondisabled older persons as a predictor of subsequent hospitalization. Journal of Gerontology and Biological Medical Sciences 55 691-697.

Poole, T., (2006) Wanless Social Care Review Appendix: Telecare and older people London, Kings Fund. http://www.kingsfund.org.uk/publications/appendices_to.html

Rockwood K, Minitski A, Song X, Steen B, Skoog I (2006) Long-term risks of death and institutionalization of elderly people in relation to deficit accumulation at age 70. Journal of American Geriatric Society 54 975-979.

Scott NW, McPherson GC, Ramsay CR, Campbell MK (2002) The method of minimization for allocation to clinical trials, a review. Controlled Clinical Trials 23 662-674.

Smith SC, Lamping DL, Banerjee S, Harwood RH, Foley B, Smith P, Cook JC, Murray J, Prince M, Levin E, Mann A, Knapp M (2007) Development of a new measure of health-related quality of life for people with dementia: DEMQOL. Psychological Medicine 37 737-746.

Woolham J, Frisby B (2002) Building a local infrastructure to support the use of assistive technology in the care of people with dementia. Research Policy and Planning 2011-24.

Woolham J (2006a) The effectiveness of assistive technology in supporting independence of people with dementia: the Safe at Home project. Hawker. London.

Woolham J, Gibson G, Clarke P (2006b) Assistive Technology, Telecare and Dementia: Some Implications of Current Policies and Guidance. Research Policy and Planning 24 149-164.