Assistive technology for memory support in dementia (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Assistive technology for memory support in dementia

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

Primary objective

To assess the efficacy of AT for memory support in people with dementia in terms of daily performance of Activities of Daily Living (ADL) and dependency. Furthermore, the effects on perceived quality of life of people with dementia will be explored.

Secondary objective

To identify the variety, quality, and feasibility of the available interventions for people with dementia, and thereby gain insight into the applicability of AT to support people with dementia with their memory problems. The impact on informal carer burden, self esteem, mood and feeling of competence and the formal carers' work satisfaction, work load, and feelings of competence will be studied as well.

BACKGROUND

Daily life without Information Communication Technology (ICT) is almost unthinkable to many people nowadays. ICT serves many purposes including safety, navigation, or social contact and is applied in many environments, including health and social care settings. New developments in health care to support people in improving their well-being by means of ICT are encouraged by governments (Kamel Boulous 2009). Also, the European Commission stimulates the development of Assistive Technology to prevent people with disabilities being excluded from society by funding programmes like e-Inclusion and Ambient Assisted Living (AAL) (European Commission 2010). Consequently, in the last two decades ICT has increasingly been developed to support people with cognitive impairment, for example related to dementia, in their daily lives.

ICT-based devices developed for people with dementia are usually referred to as Assistive Technology (AT), but other terminology is also used, including telecare, cognitive prosthetics, technology-based reminding support, and pervasive computing. AT has been developed to support people with dementia and their carers to manage their daily activities and to enhance safety. Several reports describe designing AT for groups with cognitive impairment (Cahill 2007; Hanson 2007; Meiland 2007; Mulvenna 2010; Nugent 2008; Rialle 2008; Sixsmith 2007; Sterns 2005; Van der Roest 2008). Some successful AT devices like electronic pill boxes, picture phones, or mobile tracking devices are already commercially available but, due to the lack of well-designed trials and small sample sizes in trials, their usefulness and effectiveness for people with dementia are not always clear. Furthermore, a wide range of devices and a diversity of people with cognitive impairments are involved in the different studies, which makes it difficult to draw firm conclusions on the usefulness and effectiveness of AT for this target group (Lauriks 2007; Topo 2009).

In their review, Lauriks 2007 described that AT is intended to support people with dementia in the four areas of general and personalised information; practical support with regard to symptoms of dementia; social contact and company; and health monitoring and perceived safety. This review will focus on memory problems, one of the most common symptoms in people with dementia. These problems have a high impact on functioning in daily life. Many people with dementia, as well as their informal carers, report a lack of adequate support for memory problems (Van der Roest 2009). In addition to the more traditional means of memory support, for example diaries, written signs, journals or notes, ICT applications could offer effective alternatives. It is expected that electronic memory support devices will enable people with dementia to live more independently and will alleviate carer burden (Cahill 2007).

Description of the condition

The dementia syndrome is usually caused by a chronic or progressive disease of the brain. The most common forms of dementia are Alzheimer's Disease and vascular dementia. Dementia causes impairment in higher cortical functioning, including memory, thinking, orientation, comprehension, and judgement. The cognitive impairment in dementia is often preceded by the deterioration of emotional control, social behaviour, or motivation (WHO 2007). Performing tasks of daily living becomes increasingly difficult. Initially the more complex instrumental activities of daily living (IADL) are affected and then later on personal ADL tasks are affected (Liu 2007; Öhman 2001; Sikkes 2009; Van Wielingen 2004). Functional decline is one of the core diagnostic criteria as it is common in all types of dementia (American Psychiatric Association 1994). As the disease progresses people experience more and more functional problems in daily living, eventually becoming totally dependent on the help of others (Agüero-Torres 1998; Wimo 1999). Many people in the most advanced stages of dementia are admitted to a long-term care facility to receive full time care. It is estimated that in high income countries approximately 34% of the people with dementia live in long-term care facilities (Alzheimer's Disease International 2010). Worldwide, approximately 5% of all people over 65 years have dementia and with the population ageing this number is estimated to double every 20 years, to reach 115 million by 2050 (Alzheimer's Disease International 2009).

Due to their condition, people with dementia increasingly rely on the support of others. This help is frequently provided by informal carers, family, or relatives who provide unpaid care. If informal care is no longer sufficient, feasible, or not available, paid staff step in to provide support (as formal carers). The estimated global costs for dementia are currently estimated to be USD 604 billion, of which the majority is attributed to informal care (42%) and social care (care provided by community care professionals and in long-term care settings) (42%). The direct medical costs are much lower (16%) (Alzheimer's Disease International 2010). With an estimated increase in costs of 85% by the year 2030, Alzheimer's Disease International stresses the urgent need to develop cost-effective packages of medical and social care for people with dementia.

Description of the intervention

People with dementia experience prospective or retrospective memory problems, or both. The type of memory impairment experienced is dictated by the underlying condition, the resultant site, and the extent of the brain lesion. Prospective memory (PM) is essential for living independently as it involves remembering to do things in the future without any prompting; whilst retrospective memory (RM) involves recalling or recognizing information that one has acquired in the past (Maylor 2002). Recent research showed that people with mild dementia would appreciate devices that could support their PM and RM; remind them of events at

prescheduled points in time such as taking medication, eating, or keeping appointments; and could help them to locate lost items, remember names of people, the day and time (Nugent 2007). Depending on the function that an electronic device is developed for, the devices have specific requirements. Some ATs can be customised on, or react to, the environment or its' user in a dynamic way, for example locomotion sensors that only activate a warning, alarm, or camera if no movement is detected for a defined period of time. Other devices are used as stand-alone, like electronic calenders; whilst some are integrated into a more comprehensive system placed in the living environment of its' user, like the COGKNOW device (Meiland 2007). Devices can also be mobile, for example tracking systems, enabling the user to take the device with them outside their home. AT devices that aim to support general prospective memory functioning need to be more advanced and might gain less effects than AT devices for retrospective memory problems, since the retrospective memory is in general less disturbed than the prospective memory in dementia.

How the intervention might work

People with memory problems often rely on others around them or on static reminders or cues like written notes or diaries to support their memory. By providing an AT that reminds them of meaningful events, previous daytime activities, or guides them through complex situations or tasks, people with dementia may act more independently. They will attain their daily goals (for example appointments, activities), may be less agitated or confused, and will experience a better quality of life; and their informal carers may experience less burden (Cahill 2007). Naturally the assistive technology should be adapted and fine-tuned to dementia-related and other personal and context-related factors (Dröes 2010). Levels of technology used for AT devices vary from low technology to personalised technology and context aware (smart) environments. Electronic calendars are examples of low technology devices, not taking into account whether or not the person with dementia follows the given reminder. More context aware devices do exist, like mobile tracking devices that automatically give a warning when a person with dementia is leaving his or her familiar area. Although technology for context aware environments does exist, it is not yet part of mainstream provision due to its current sensitivity to errors and false alarms.

Why it is important to do this review

Many assistive devices have been developed for memory support in people with cognitive impairment, such as dementia. However, the usefulness, user-friendliness, and intended effects of these devices, especially for people with dementia, are not always evident or studied. Although reviews of (electronic) memory aids do exist (Bharucha 2009; Caprani 2006; Fritschy 2004; Lauriks 2007; Lindenberger 2008; Topo 2009), a systematic review of studies focusing on the efficacy of AT for memory support in people with dementia is lacking. It is important to review to what extent the efficacy, usefulness, and user-friendliness of these devices has been proven, and to assess the quality of such studies. This will help to gain insight into the existing evidence-based supportive devices. A comprehensive overview of evidence-based devices will guide people with dementia and their informal and professional carers in selecting a prospective memory device that meets the needs of its' user. The review will also provide useful information for AT developers in this rapidly growing area, by addressing the gaps in, and possible shortcomings of, the state-of-the-art in AT for memory support.

OBJECTIVES

Primary objective

To assess the efficacy of AT for memory support in people with dementia in terms of daily performance of Activities of Daily Living (ADL) and dependency. Furthermore, the effects on perceived quality of life of people with dementia will be explored.

Secondary objective

To identify the variety, quality, and feasibility of the available interventions for people with dementia, and thereby gain insight into the applicability of AT to support people with dementia with their memory problems. The impact on informal carer burden, self esteem, mood and feeling of competence and the formal carers' work satisfaction, work load, and feelings of competence will be studied as well.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and cluster randomised trials with blinded assessment of outcome will be included in the review (including those with inadequate sequence allocation). As the development of AT is a relatively new area, we do not expect to find many RCTs on this topic.

Types of participants

Participants need to be diagnosed with dementia according to the Diagnostic and Statistical Manual IV (American Psychiatric Association 1994) or ICD-10 (WHO 2007). If diagnostic information on participants is not described in potential studies, primary authors will be asked for additional diagnostic information. If the provided information is according to the criteria set, these studies will be included. No further inclusion criteria for participants shall be applied.

Types of interventions

The interventions that will be included in the review evaluate an assistive device, driven by electronics with the single aim of supporting memory problems. The electronic device under evaluation could be stand alone or integrated in a service system (remotely configurable), stationary or mobile. The devices under study will most likely require configuration or help with setting-up by carers. The focus will primarily be on the person with dementia, but the impact on carers will be reviewed as well. Interventions that evaluate a combination of devices that are provided with different aims will not be included. The control interventions may either be 'care as usual' or non-technological psychosocial interventions (including interventions that use non-electronic assistive devices) aimed at supporting memory problems.

Types of outcome measures

The primary outcome measures regarding the efficacy of the AT under study will relate to ADL and the level of dependency of people with dementia. The secondary outcome measures will relate to clinical and care-related outcomes of the AT for people with dementia, to their perceived quality of life and well-being, and also on the effects of AT on their carers, informal carers for community-based interventions and formal carers for institutional-based interventions. Adverse events of AT for people with dementia and (in)formal carers will also be reported. The validity and reliability of the outcome measures used will be reported. All reported time frames will be included. All outcomes measured will be listed.

Primary outcomes

Daily functioning

- Activities of daily living (ADL): personal (PADL) and instrumental (IADL)
- Level of dependency (self report or proxy report)
- Admission to long-term care (for community-based interventions)

Secondary outcomes

User reports

- Experienced autonomy (self report)
- Experienced usefulness and user-friendliness of AT (self report)
- Adoption of AT

Clinical

- Cognitive functioning
- Neuropsychiatric symptoms (behavioural and mood problems)

Care

- Need for informal care
- Need for formal care

Well-being

- Perceived quality of life or well-being (self report or proxy report)

Informal carer

- Carer burden
- Self esteem
- Feelings of competence

Formal carer

- Work satisfaction
- Workload
- Feelings of competence

Adverse events

- Clinical
- Care
- Informal carer
- Formal carer

Search methods for identification of studies

Relevant studies will be identified by searching various databases from January 1990 to date.

Electronic searches

We will search ALOIS (www.medicine.www.medicine.ox.ac.uk/aloisox.ac.uk/alois), the Cochrane Dementia and Cognitive Improvement Group Specialized Register. The search terms used will be: technology, device, ICT, assistive, orthotic.

ALOIS is maintained by the Trials Search Co-ordinator of the Cochrane Dementia and Cognitive Improvement Group and contains dementia studies identified from the following.

1. Monthly searches of a number of major healthcare databases: MEDLINE, EMBASE, CINAHL, PsycINFO and LILACS.
2. Monthly searches of a number of trial registers: meta Register of Controlled Trials; Umin Japan Trial Register; WHO portal (which covers ClinicalTrials.gov; ISRCTN; Chinese Clinical trials Register; German Clinical trials register; Iranian Registry of Clinical trials, and the Netherlands National Trials Register, plus others).
3. Quarterly search of the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*).
4. Monthly searches of a number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australian Digital Theses.

To view a list of all sources searched for ALOIS, see About ALOIS on the ALOIS website.

Additional separate searches will be run in many of the above sources to ensure that the most up-to-date results are retrieved. The search strategy that will be used for the retrieval of reports of trials from MEDLINE (via the Ovid SP platform) can be seen in Appendix 1.

Further searches will be carried out in the following specialist sources.

- PiCarta (until date).
- OT seeker (until date).
- ADEAR (until date).
- Ageline (until date).
- AgeInfo (until date).
- Social Care Online (until date).
- Centre for Reviews and Dissemination (CRD) Databases (until date).
- The Collection of Computer Science Bibliographies (until date).
- DBLP Computer Science Bibliography (until date).
- Networked Computer Science Technical Reference Library (NCSTRL) (until date).
- Computing Research Repository (CoRR) (until date).
- IEEE Computer Society Digital Library (until date).
- Springer Link Lecture Notes (until date).
- HCI Bibliography: Human-Computer Interaction Resources (until date).
- Inspec (until date).
- J-STAGE: Japan Science and Technology Information Aggregator, Electronic (until date).

For each database the search will be adapted. There will be no language restriction.

Searching other resources

Additionally, Google Scholar and OpenSIGLE will be searched for grey literature. References of identified articles will be handsearched using the snowball method in order to find other potentially relevant studies.

Data collection and analysis

The first review author (HvdR) will execute the search strategy as described, supported by the second review author (JW).

Selection of studies

The search results will be merged using reference management software and duplicate records removed. Study titles and abstracts will be screened for appropriateness by HvdR and JW working independently. Obviously irrelevant reports will be removed. Multiple reports of the same study will be linked.

Full text versions of potentially relevant reports will be obtained and examined independently by HvdR and JW to assess compliance with the predefined eligibility criteria. When suitability of a study is unclear, after examining the full text the corresponding author will be contacted to request clarification or additional information, or both. Both authors will compare and discuss their selection of titles until agreement is reached. If uncertainty on inclusion remains after discussion, the third and fourth review authors (RMD and MO) will be consulted. Studies excluded because of poor quality will be identified in the 'Characteristics of excluded studies' table together with the reasons for exclusion.

Data extraction and management

Data from the selected studies will be independently extracted by HvdR and JW, using a predesigned data collection form that will be pilot tested prior to its use. Data from multiple reports of the same study will be collated onto one form. Study names will not be masked. Agreement on data extraction will be sought by means of discussion between HvdR and JW. If there is disagreement, the third and fourth review authors (RMD and MO) will be consulted. Study authors will be contacted for any missing data. Data categories will include the following.

- Method: study design; study dates and duration; sequence generation; allocation sequence concealment; blinding of participants, personnel and outcome assessors.
- Participants: total number of participants, reasons why excluded, type of setting, number of locations, diagnostic criteria, age, gender, and country.
- Interventions: total number of interventions and comparators, and description of the content for each

intervention; type of technology used, categorised by function of device under study according to relevant ISO 9999:2007 classifications (British Standard 2007); integrity and fidelity measures such as adherence, quality of delivery, and participant's responsiveness.

- Outcomes: total number of outcome measures, and time points collected and reported. For each outcome measured: definition, procedure, upper and lower limits of scales and direction, validity and reliability of instruments used.
- Results: number of participants allocated and analysed in each group and for each outcome of interest; sample size, participants lost to follow-up; summary data and estimate of effect with confidence level and P value for for each intervention group; subgroup analyses.
- Miscellaneous: funding source, ethical approval, consent procedures, key conclusions.

Dichotomous measures: the numbers in each of the two outcome categories within each of the intervention groups.
Continuous measures: the mean value, standard deviation (SD) and number of participants (N) for each outcome measurement in each intervention group at each time point.
Ordinal measures: as RevMan does not enable the meta-analysis of ordinal measures, shorter scales will be converted to dichotomous data by combining adjacent categories, based on clinical relevance; and longer scales will be treated as continuous data, and the potential resulting bias noted.

Assessment of risk of bias in included studies

The selected studies will be critically evaluated by HvdR and JW working independently. For RCTs the criteria as derived from the Cochrane Collaboration's tool for assessing risk of bias will be used (Higgins 2008a), namely risk of bias due to: selection, performance, attrition, detection, and reporting. In a meta-analysis, risk of bias within cluster RCTs include: issues of recruitment, baseline imbalance, sample size, number or loss of clusters, incorrect analysis, and inclusion of both cluster and individually randomised trials or trials with different types of clusters.

Measures of treatment effect

A single summary statistic will be calculated to represent the effect found in each study as follows.
Dichotomous (binary) measures: odds ratio (OR) and risk difference (RD) with 95% confidence intervals (CI).
Continuous measures: mean difference (MD) between baseline and post-intervention endpoint, and change, weighted mean difference (WMD) for data using the same scales and standardized mean difference (SMD) for data using different scales.
Studies will be weighted according to size and degree of variability.

Unit of analysis issues

The analysis will take into account the level at which randomisation occurred with each study. Studies with non-standard designs will not be excluded, and appropriate analysis methods will be used (Higgins 2008b). If an incorrect analysis method is reported then an approximate analysis will be attempted, along with the necessary sensitivity analysis of any assumptions made.

Dealing with missing data

Wherever possible, the original investigators will be contacted to request missing data. If standard deviations (SDs) are not reported and further information is not obtained from the investigators, they will be calculated via the standard error of the mean (SEM). The amount and type of missing data related to participants lost to a study that can not be obtained from the original investigators will be described in the 'Characteristics of included studies' table and the potential impact discussed, which will depend on the extent of missing data. Intention-to-treat (ITT) analysis will be conducted by imputing outcomes for the missing participants using the last observation carried forward approach.

Assessment of heterogeneity

Variability between the included studies will be reported as follows.

- Clinical: participants, interventions, technology, and outcomes.
- Methodological: study design and risk of bias.
- Statistical: if the observed intervention effects are more different from each other than would be expected due to chance alone.
- Technology: type of technology.

Substantial statistical heterogeneity will be suggested by the following indicators: poor overlap of confidence intervals on forest plots; high Chi^2 values, $P > 0.10$, and I^2 statistic > 50%.

Assessment of reporting biases

Reporting biases will be detected using funnel plots, to assess if the association between estimated intervention effects and a measure of study size (such as the SEM or log OR) is greater than might be expected to occur by chance. Funnel plot asymmetry (indicating small study effects) will initially be tested by visual inspection. If more than 10 studies are found to be eligible, funnel plots will be tested by linear regression of the intervention effect estimates on their SEMs, weighted by 1 (variance of the intervention effect estimate) for continuous measures; and linear regression of the log ORs on its SEM, weighted by the inverse of the variance of the log OR for dichotomous measures (Egger 1997). If small scale study effects are found, sensitivity analysis will be conducted to compare the fixed-effect model and random-effects model estimates of the intervention effects.

Data synthesis

Results of all studies will be pooled in the first instance regardless of the type of AT used in the intervention, but based on outcome measures. This is because we do not expect to find many studies that evaluate similar devices. If allowed by the data, results will be pooled by type of assistive device used and diagnostic subgroups (different types of dementia). In the first instance, fixed-effect models will be used. If heterogeneity is detected then random-effects models will be used (Deeks 2008). If the data can not be pooled for reasons of incomparability, study results will be summarized and reported separately.

Reports on usefulness and user-friendliness will not generate change scores since these measures will only be administered in experimental groups. Meta-analyses on these results will not be performed, but summary statistics (N, mean values and standard deviations) shall be reported.

Subgroup analysis and investigation of heterogeneity

Clinical variables which might modify the efficacy of assistive technology interventions and which might form the basis of subgroup analyses, should sufficient data be available, are:

- people with different types of dementia;
- level of dementia;
- age;
- gender;
- institutional versus community setting;
- living together with carer versus living alone;
- technology type (stand-alone, integrated, mobile);
- level of technology (ranging from low technology to context aware).

Sensitivity analysis

Decisions taken throughout the systematic review process including, but not limited to: which studies were included, cut-off points for age, or outcome measure values used will be recorded and reviewed on completion. A sensitivity analysis will be performed to address the following questions.

- Are the findings influenced by the choice of statistical model?
- Is there bias in the study methods?
- Are the findings robust to different assumptions (missing data, ITT analysis)?

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

Source	Search strategy
MEDLINE (via Ovid SP)	1. exp Dementia/ 2. Delirium/ 3. Wernicke Encephalopathy/ 4. Delirium, Dementia, Amnestic, Cognitive Disorders/ 5. dement*.mp. 6. alzheimer*.mp. 7. (lewy* adj2 bod*).mp. 8. deliri*.mp. 9. (chronic adj2 cerebrovascular).mp. 10. ("organic brain disease" or "organic brain syndrome").mp 11. ("normal pressure hydrocephalus" and "shunt*").mp. 12. "benign senescent forgetfulness".mp. 13. (cerebr* adj2 deteriorat*).mp. 14. (cerebral* adj2 insufficient*).mp. 15. (pick* adj2 disease).mp. 16. (creutzfeldt or jcd or cjd).mp. 17. huntington*.mp. 18. binswanger*.mp.

(*Continued*)

	19. korsako*.mp. 20. or/1-19 21. "cognit* impair*".mp. 22. exp *Cognition Disorders/ 23. MCI.ti,ab. 24. ACMI.ti,ab. 25. ARCD.ti,ab. 26. SMC.ti,ab. 27. CIND.ti,ab. 28. BSF.ti,ab. 29. AAMI.ti,ab. 30. MD.ti,ab. 31. LCD.ti,ab. 32. QD.ti,ab. 33. AACD.ti,ab. 34. MNCD.ti,ab. 35. MCD.ti,ab. 36. ("N-MCI" or "A-MCI" or "M-MCI").ti,ab. 37. ((cognit* or memory or cerebr* or mental*) adj3 (declin* or impair* or los* or deteriorat* or degenerat* or complain* or disturb* or disorder*)).ti,ab 38. "preclinical AD".mp. 39. "pre-clinical AD".mp. 40. ("preclinical alzheimer*" or "pre-clinical alzheimer*").mp 41. (aMCI or MCIa).ti,ab. 42. ("CDR 0.5" or "clinical dementia rating scale 0.5").ti,ab 43. ("GDS 3" or "stage 3 GDS").ti,ab. 44. ("global deterioration scale" and "stage 3").mp. 45. "Benign senescent forgetfulness".ti,ab. 46. "mild neurocognit* disorder*".ti,ab. 47. (prodrom* adj2 dement*).ti,ab. 48. (episodic* adj2 memory).mp. 49. ("preclinical dementia" or "pre-clinical dementia").mp. 50. or/21-49 51. 20 or 50 52. technology.ti,ab. 53. ("information communications technology" or ICT).ti,ab. 54. Technology/ 55. exp Self-Help Devices/ 56. orthot*.ti,ab. 57. prosthetic*.ti,ab. 58. device*.ti,ab. 59. telecare.ti,ab. 60. electronic.ti,ab. 61. digit*.ti,ab. 62. "pervasive computing".mp 63. or/52-62 64. 51 and 63 65. randomized controlled trial.pt.

(*Continued*)

	66. controlled clinical trial.pt. 67. randomized.ab. 68. placebo.ab. 69. drug therapy.fs. 70. randomly.ab. 71. trial.ab. 72. groups.ab. 73. or/65-72 74. (animals not (humans and animals)).sh. 75. 73 not 74 76. 64 and 75

HISTORY

Protocol first published: Issue 2, 2012

CONTRIBUTIONS OF AUTHORS

HvdR and JW: wrote the draft protocol.

HvdR: developed the search strategy.

RMD and MO: commented on the draft protocol.

DECLARATIONS OF INTEREST

No existing conflicts of interest.