

RESEARCH PAPER

The effectiveness and cost-effectiveness of assistive technology and telecare for independent living in dementia: a randomised controlled trial

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Abstract

Objectives: The use of assistive technology and telecare (ATT) has been promoted to manage risks associated with independent living in people with dementia but with little evidence for effectiveness.

Methods: Participants were randomly assigned to receive an ATT assessment followed by installation of all appropriate ATT devices or limited control of appropriate ATT. The primary outcomes were time to institutionalisation and cost-effectiveness. Key secondary outcomes were number of incidents involving risks to safety, burden and stress in family caregivers and quality of life.

Results: Participants were assigned to receive full ATT (248 participants) or the limited control (247 participants). After adjusting for baseline imbalance of activities of daily living score, HR for median pre-institutionalisation survival was 0.84;

95% CI, 0.63 to 1.12; $P = 0.20$. There were no significant differences between arms in health and social care (mean -£909; 95% CI, -£5,336 to £3,345, $P = 0.678$) and societal costs (mean -£3,545; 95% CI, -£13,914 to £6,581, $P = 0.499$). ATT group members had reduced participant-rated quality-adjusted life years (QALYs) at 104 weeks (mean -0.105; 95% CI, -0.204 to -0.007, $P = 0.037$) but did not differ in QALYs derived from proxy-reported EQ-5D.

Discussion: Fidelity of the intervention was low in terms of matching ATT assessment, recommendations and installation. This, however, reflects current practice within adult social care in England.

Conclusions: Time living independently outside a care home was not significantly longer in participants who received full ATT and ATT was not cost-effective. Participants with full ATT attained fewer QALYs based on participant-reported EQ-5D than controls at 104 weeks.

Keywords: assistive technology, telecare, dementia, social care, independent living, older people

Key Points

- There have been no large clinical trials of the clinical and cost-effectiveness and safety of assistive technology and telecare (ATT).
- In this randomised clinical trial (RCT) of 495 people comparing those with ATT to the control, the adjusted hazard ratio was 0.84, which was not significant.
- The study suggests that ATT does not enable people with dementia to maintain safe independent living for longer in their homes.

Introduction

Dementia represents a major and growing challenge for patients, their families, health and social care systems and society as a whole. In 2016, the global number of dementia cases was 43.8 million [1] and annual global costs of dementia (mostly from informal and social care) could grow to \$2 trillion by 2030 [2]. Dementia is also the most common single reason for care home entry [3], as progression of cognitive and functional impairment and the expression of risky behaviours undermine ability to live independently with safety. Quality of life for people with dementia worsens following care home placement [4]. Maximising the time people with dementia can spend in their own homes represents the most economically efficient long-term care model [5] and has become the stated policy in many care systems, including in the UK [6].

Assistive technology (AT) refers to electronic or mechanical devices that can support independence and improve quality of life by assisting with daily living activities, reducing harmful risks and improving communication. Devices used in dementia care can be broadly categorised as reminder or prompting devices, monitors and detectors to support safety, safer walking technologies, communication devices and devices to support use of leisure activities [7]. Telecare uses a combination of monitored alarms, sensors and other equipment to help people live independently [8]. Largely on the basis of data from uncontrolled project evaluations [9], assistive technology and telecare (ATT) has been promoted to support people with dementia to live independently [8]. The Whole Systems Demonstrator included a large randomised clinical trial (RCT) of telecare in the UK and found no overall reduction in people having to move into care homes, although people with dementia were not specifically

recruited to the trial [10]. Meta-analysis of two small and short randomised controlled trials in people with dementia found no significant delay of care home entry with ATT [11].

We carried out a pragmatic RCT, Assistive Technology and Telecare to maintain Independent Living At home in people with dementia (ATTILA trial), to test the clinical and cost-effectiveness of ATT in supporting people with dementia to continue to live safely within their own homes.

Methods

Patients and procedures

Participants were people diagnosed with dementia or cognitive difficulties sufficient to suggest dementia, who met English Social Services' eligibility criteria for Fair Access to Care Services and were consequently entitled to receive services [12], were living in the community (including sheltered/supported and very sheltered/supported accommodation) within 11 local authority areas in England, and had a working telephone line. Exclusion criteria were: current receipt of an ATT intervention, previous unsuccessful installation of ATT and an identified urgent need for a home care package. Informed written consent was obtained from participants and from caregivers who provided data.

Trial design

The trial compared outcomes in participants randomised, on a one-to-one allocation, to receive: (1) an ATT needs assessment, followed by installation of indicated ATT devices and response services (ATT Intervention), or (2) ATT needs assessment, followed by installation restricted to only smoke

and carbon monoxide detectors and a pendant alarm, if indicated (ATT Control) Table 1. Co-primary outcomes were time to residential care entry and cost-effectiveness [13]. Secondary outcome measures included burden and quality of life in unpaid carers, the number and severity of serious adverse events and data on acceptability, applicability and reliability of ATT packages.

The study was approved by the UK National Health Service Health Research Authority National Research Ethics Committee (Reference 12/LO/186) and was registered (ISRCTN86537017).

Trial end-points and assessments

Time in days from randomisation to institutionalisation was defined as time to permanent transition from living in participant's own home to a nursing or residential care home or admission to an acute care facility that resulted in permanent move into a residential care or nursing home. *Cost-effectiveness*: We examined the incremental cost of community-based support: per institutional day avoided (days to institutionalisation), per quality-adjusted life year (QALY) lived in the community and per minimum clinically important difference (of 0.074) in the EQ-5D index [14]. EQ-5D index scores (utilities) were available from both participant and caregivers. Analyses took a health and social care perspective and a societal perspective (costs to participant and caregiver, including out-of-pocket payments for home adaptations, ADL equipment, travel to appointments and opportunity costs of providing unpaid care).

Secondary trial outcome assessments included the Bristol Activities of Daily Living Scale (BADLS) [15], Standardised Mini-Mental State Examination (SMMSE) [16] and Model of Human Occupation Screening Tool (MOHOST) [17] at baseline. Additional outcome measures were participant's quality of life measured with the EuroQol EQ-5D-5L [14] and unpaid caregiver outcome measures including the Zarit Burden Inventory [18], the Centre for Epidemiological Studies Depression Scale [19], the State Trait Anxiety Inventory [20], the Short Form Health Survey [21] and the Carer Technology Acceptance Questionnaire [22].

Statistical analyses

Analyses were by intention to treat, with all randomised participants included in the comparison and analysed according to their randomised allocation, including those who discontinued the trial. *Time to institutionalisation* was compared between intervention and control arms using survival analysis methods. Kaplan–Meier survival curves were created for graphical representation of the time to event comparisons. Statistical significance was determined by the log rank test. Analyses included all events, even those occurring after 2 years. Participants who died, withdrew from follow-up or were lost to follow-up were censored at the date of withdrawal from the study. Continuous outcome measures

were analysed using repeated measures regression techniques to maximise statistical power.

Costs and cost-effectiveness analyses

Costs were calculated on the basis of caregiver-reported service use over the prior 3 months at baseline, 12, 24, 52 and 104 weeks, attaching nationally applicable unit cost measures to health and social care use for each participant using the Client Service Receipt Inventory (CSRI) [23]. The costs of the intervention were calculated drawing on information from key informant interviews, nationally applicable unit costs and price information from procurement frameworks provided by the Northern Housing Consortium [24]. Costs and days in the community were discounted at 3.5% annually [25]. Mixed effects linear difference-in-difference models compared the between-group difference in EQ-5D scores [26, 27] and average 3-month costs over the follow-up relative to baseline. Analyses of days lived in the community, QALY, total health and social care costs and total societal costs combined group-level estimates from different models (gamma generalised linear model with a square root link for costs, with inverse-probability weights derived from parametric models, [28, 29, 30] Weibull accelerated failure time model for days in the community, group-mean utilities to calculate QALY by the integrated quality survival product method) [30,31]. Bootstrap standard errors of the estimates of costs, QALY and days in the community (based on 25,000 replications) and of costs and the EQ-5D index (based on 5,000 replications) were produced. Cost-effectiveness acceptability curves (CEACs) were constructed from bootstrapped estimates to depict the probability of cost-effectiveness at a series of threshold willingness to pay for an incremental effect, ranging from £0 to £50,000. This range included the National Institute for Health and Care Excellence (NICE) threshold of between £20,000 and £30,000 per QALY.

Sample size estimations were based on the observation that 50% of participants with a BADLS score of >15 would be expected to have entered residential care after 24 months [32], so that a 30% reduction in the institutionalisation rate from 50% to 35% would require involvement of 500 participants, allowing for 10% attrition due to death whilst still community resident. This would equate to an average of 55 days of longer independent home life for participants receiving the intervention.

Patient and public involvement

The study was supported by Alzheimer's Society Research Network volunteers, who were past or current family caregivers of a person with dementia, and who partnered with us in the study design, the wording of information materials and consent documentation and were members of the Trial Steering Group. At the end of the trial they commented on the findings and contributed to dissemination.

Table 1. ATT installations 12–104 weeks (for intervention arm only)

	12 weeks	24 weeks	52 weeks	104 weeks	Total (12–104 weeks)
Intervention technology installed					
Reminder/Prompting	116/580 (20%)	18/124 (15%)	9/87 (10%)	17/97 (18%)	160/888 (18%)
Safety	220/580 (38%)	45/124 (36%)	30/87 (35%)	43/97 (44%)	338/888 (38%)
Communication	8/580 (1%)	1/124 (0%)	2/87 (2%)	1/97 (1%)	12/888 (2%)
Support leisure time	1/580 (0%)	2/124 (2%)	1/87 (1%)	0/97 (0%)	4/888 (0%)
Any other devices	0/580 (0%)	0/124 (0%)	0/87 (0%)	0/97 (0%)	0/888 (0%)
Total installed	580	124	87	97	888
Total installed	580	124	87	97	888

Table 2. Baseline characteristics

		Intervention N = 248	Control N = 247
Age	<65	11 (4%)	4 (2%)
	65–80	89 (36%)	93 (38%)
	80+	148 (60%)	150 (61%)
Age	Mean (SD)	81.0 (8.2)	80.8 (7.4)
Gender	Male	102 (41%)	103 (42%)
	Female	146 (59%)	144 (58%)
Risk of wandering/leaving home inappropriately	Low	178 (72%)	180 (73%)
	Medium	52 (21%)	48 (19%)
	High	18 (7%)	19 (8%)
Safety risks within home identified	Low	125 (50%)	124 (50%)
	Medium	104 (42%)	101 (41%)
	High	19 (8%)	22 (9%)
Level of caregiver support	Live in	119 (48%)	121 (49%)
	Once daily	60 (24%)	61 (25%)
	Less than once daily	69 (28%)	65 (26%)
SMMSE Score*	0–9	23 (10%)	34 (15%)
	10–19	79 (36%)	96 (43%)
	20–25	87 (39%)	74 (33%)
	26–30	32 (14%)	19 (9%)
SMMSE Score	Mean (SD)	18.7 (6.6)	16.9 (6.9)
BADLS Score**	0–4	17 (7%)	10 (4%)
	5–14	72 (31%)	64 (28%)
	15–29	95 (41%)	102 (45%)
	30+	46 (20%)	49 (22%)
BADLS Score	Mean (SD)	19.5 (11.3)	20.4 (10.9)

*51 participants did not have a baseline SMMSE Score. **40 participants did not have a baseline BADLS Score.

Results

Between 14 August 2013 and 26 October 2016, 495 participants were randomised from 11 recruiting sites (listed in online supplement) in England. Outcomes of Baseline structured ATT needs assessments and details of the individual ATT components that were installed in participants' homes have been previously reported [33]. Appendix A1 is the Consort diagram of the flow of participants through the trial. During follow-up, 200 participants were admitted to care, 89 died, 42 withdrew from follow-up and 18 were lost to follow-up. Once a participant had entered residential care, no further outcome assessments took place.

Participant baseline demographic characteristics were balanced across arms (Table 2). Participants in the ATT intervention arm, however, had higher mean sMMSE scores (18.7 versus 16.9) and lower BADLS scores (19.5 versus 20.4). A lower BADLS score indicates less impairment of activities of daily living.

Time to entering care

Comparing ATT to control, the unadjusted hazard ratio (HR) was 0.75 (95% confidence interval (CI) 0.58 to 1.01; $P = 0.054$) (Figure 1A). Rates of entry to care, however, were significantly affected by participants' baseline BADLS scores. Participants with a higher baseline BADLS score (indicating greater impairment of activities of daily living) were more likely to be admitted to care ($P < 0.0001$) (Appendix A2), and there were more participants in the intervention group with a lower baseline score (Table 2). Figure 1B is a forest plot of time to admission to care between intervention groups, split by baseline BADLS scores. When we adjusted for baseline BADLS score, there was no significant difference in time to entry to care (HR 0.84 (95% CI 0.63 to 1.12, $P = 0.20$)).

To determine whether ATT might have helped prevent individual entries to care, the reasons for institutionalisation have been categorised in Appendix A3. The most common

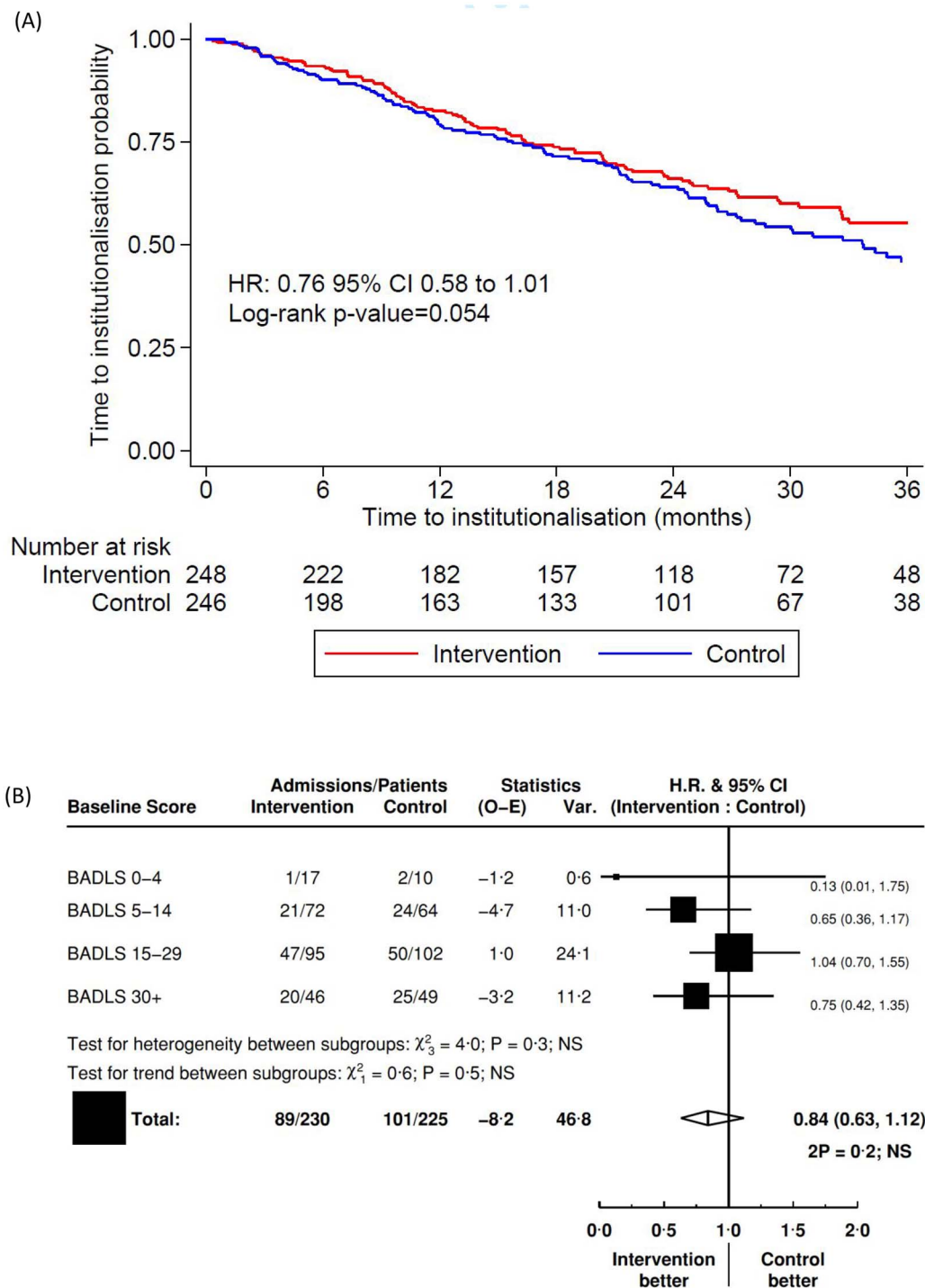


Figure 1. (A) Kaplan–Meier survival curve of time to admission to care by randomised intervention unstratified. (B) Forest plot of time to admission to care by randomised intervention adjusted for baseline BADLS score.

reason for entering care was inability to perform activities of daily living, and this was reduced in the intervention group (14 versus 29; $P = 0.016$). Moving to a care home because of safety concerns, which might have been expected to be reduced by ATT, was actually more common in the

intervention group (12 versus 4, $P = 0.043$). Wandering, a behaviour whose associated risks might be mitigated by appropriate ATT, was non-significantly reduced as a reason for entering care in the intervention group (5 versus 13; $P = 0.054$).

Costs

Appendix A4 shows the flow of dyads participating in full cost assessments. Appendix A5 contains descriptive demographics for the sample participating in full baseline cost assessments. Appendices A6 and A7 present service use and costs at each assessment point. Participants were high users of health and social care services. Use and costs increased during follow-up (Appendices A6 and A7). Cumulative costs of the intervention and total health, social care and societal costs are presented in Appendix A8. ATT costs over the follow-up were modest (Intervention: £322 (SE £18); Control: £214 (SE £16)).

Health-related quality of life

Raw mean participant-rated EQ-5D index scores were lower in the intervention than the control group at 52 (mean difference -0.079 , 95% CI -0.139 to -0.018 , $P=0.011$) and 104 weeks (mean difference -0.088 , 95% CI -0.169 to -0.008 , $P=0.032$) (Appendix A9).

Cost-effectiveness

Based on participant-rated EQ-5D (Appendix A10), individuals in the intervention arm had significantly lower QALY at weeks 52 (mean difference -0.044 (95% CI -0.088 to 0.000 , $P=0.05$)) and 104 (mean difference -0.105 (95% CI -0.204 to -0.007 , $P=0.037$)). Allocation groups did not differ significantly in QALYs derived from proxy-reported EQ-5D at any point. There were no significant differences in 24-week, 52-week and 104-week censor-adjusted health and social care and societal costs between intervention and control participants (Appendix A10). Change in EQ-5D-participant and EQ-5D-proxy index scores did not differ between groups at 24, 52 or 104-weeks, nor did change in follow-up costs from baseline (Appendices A10–A16).

Point incremental cost-effectiveness ratios (ICERs) for institutionalisation-free days and for proxy-reported QALY at 104 weeks were negative. The 104-week ICER for participant-reported QALY was positive because, while costs were non-significantly lower in the intervention group, QALY were significantly lower in the intervention group. Point ICER for a minimal clinically important difference (MCID) of 0.074 [34,35] in participant-reported EQ-5D at 104 weeks was negative from either perspective because the outcome was (non-significantly) worse in the intervention group, with small positive differences in costs. Point ICER for an MCID in proxy-reported EQ-5D at 104 weeks was positive (small positive differences in outcomes and costs) from the health and social care services perspective, but negative (small positive differences in outcomes and small negative differences in costs) from the societal perspective.

CEACs for each outcome, where the point ICER was not the result of a worse outcome for the intervention group, are shown in Appendices A17–A19. CEACs for change in the EQ-5D-proxy (24, 52 and 104 weeks), QALYs derived from the EQ-5D-proxy (24, 52 and 104 weeks), and for days in

the community (104 weeks) reflect the sampling uncertainty in the cost and outcomes analyses and indicate that we cannot be confident at the 95% level that the ATTILA intervention was cost-effective.

Sensitivity analysis of the cost of unpaid care: valuing unpaid caregivers' time at replacement cost, more than doubled societal costs in both groups (Appendix A20), but ICERs were in line with the results of the main cost-effectiveness analyses (Appendix A21).

Serious adverse events

A total of 89 participants died whilst community resident, 41 in the intervention arm and 48 in the control arm (Appendices A22 and A23). There were no significant differences seen overall ($P=0.14$ Appendix A21) or in the grouped categories for causes of death (Appendix A23).

Serious adverse events (SAEs) were categorised and the number of participants reporting SAEs are summarised in Table 3. Appendix A24 plots the number of participants experiencing each SAE type with a test of significance for differences between intervention and control arms. There was a significant reduction in participants experiencing behaviour-related SAEs in the intervention group when compared to the control group ($P=0.01$). More participants experienced SAEs related to safety concerns in the intervention group than in the control group ($P=0.06$).

Discussion

ATTILA is the first randomised controlled trial of ATT in people with dementia, which was powered to detect moderate benefits associated with the use of the technology. We found provision of home-based technology, installed following an individual needs assessment within current practice in England, had no significant effect on the time that people with dementia were able to continue to live independently in their own homes. There was no evidence of cost-effectiveness in terms of days lived in the community, impact on health-related quality of life or QALY based on proxy-reported EQ-5D, from the health and social care or societal perspective. The ATT intervention group attained fewer QALY, based on participant-reported EQ-5D over 104 weeks, than the control group.

Optimising the care of people with dementia within their own homes, to delay or reduce transition to alternative care settings, is preferred by people with dementia; this maintains higher quality of life [4, 36], costs less [37] and is a public health imperative [5]. A major role for ATT and robotics in augmenting human care provision in the homes of people with dementia is anticipated [38], yet there are very little available data on the effectiveness, safety and costs of the technology [39]. Currently available technologies have focussed on monitoring well-being, safety, physical activity and social participation, but robotic devices to assist with physical care, social support and mobility, and therapeutic

Table 3. SAEs categorised, *P*-value from Mantel–Haenszel test (ignoring time to event)

Categorised SAE	Intervention, no. of participants	Control, no. of participants	Total no. of participants	<i>P</i> -value
Safety concerns	13	5	18	0.06
Wandering	25	36	61	0.13
Falls	86	88	174	0.83
Dementia progression	37	43	80	0.45
Behaviour	5	16	21	0.01
Other medical condition	107	109	216	0.83
Carer related	11	10	21	0.83
Environmental/accident	13	15	28	0.69
Health deterioration	5	2	7	0.26
Other	2	1	3	0.57
Unknown	10	16	26	0.22
Total no. of participants	195	201	396	0.45

technologies to improve social participation are also being actively marketed [38].

ATTILA aimed to answer a simple but important question: would the provision of a full package of ATT increase the length of time that people with dementia were able to live safely and independently in their own homes, compared to provision of a very basic package? Whilst the results indicate that a full ATT package did not extend the time lived in the community, the planned survival analyses could not control for all the factors that might underlie the difficult decision to enter residential care. When the reasons for moving into care were compared between trial arms (Appendix A3), participants allocated to the full ATT package were less likely to move because of wandering or loss of activities of daily living function, but more likely to move because of concerns about safety at home. Although the number of participants moving for each of these reasons was small within the overall trial, differences between trial arms provide evidence that ATT may be able to reduce the risks associated with some of the common reasons for a move to care in a small number of people. It is also possible that the provision of a full ATT package leads to an increased awareness of safety concerns with consequent shortening of independent living. This could also underlie reductions in QALY based on participants' own ratings in the intervention group. Qualitative work, undertaken as part of the study, found that people with dementia and their caregivers sometimes experienced the technology as disruptive to their daily lives.

Rates of admission to care in people with Alzheimer's disease are influenced by functional ability. In our analyses, we found a highly significant effect of Baseline BADLS score on time to admission to care. Participants with a higher Baseline BADLS (indicating more impairment of function) were more likely to be admitted to care ($P < 0.0001$). Unfortunately and by chance, there was an imbalance in Baseline BADLS scores between participants in the intervention and control arms. More participants in the intervention arm had lower BADLS scores (indicating less impairment of

function). Consequently, we adjusted for this difference at Baseline in the primary analysis.

ATT installation to meet imposed performance targets can reduce accurate matching of technology to need, [40] and the assessor's understanding of technology and need can be suboptimal [41]. We have reported elsewhere the outcomes of the ATTLA standardised needs assessments in terms of the ATT components that were recommended for participants, and that there was limited fidelity of technology recommendation to the ATTLA needs assessment [33]. This finding is a potential major limitation and the trial's negative results need to be viewed in this light. ATTLA was, however, a large and pragmatic trial, which examined the effectiveness of ATT in a real-world setting within which technology is currently deployed to support people with dementia living in their own homes. Our results are likely to be generalisable to real world settings within which ATT is used.

We recognise several limitations to generalisability of results from this study. Blinding to allocation of participants and assessors was not undertaken as this would not have been feasible and would have been a potential source of bias. Although we obtained data from caregivers, recall bias could have affected the precision and size of cost estimates. Estimation of costs in intervals not covered by the cost collection instrument assumed constant use of most services between intervals (although ED and hospital admission costs reflected use during those intervals). Participant-reported EQ-5D ratings were missing in substantial numbers at follow-up. The analyses of QALY drew on group mean utilities at each time point and did not adjust for baseline characteristics. The finding that the ATT intervention group had lower QALYs on the participant-reported EQ-5D-5L must be interpreted with caution, given the substantial rates of attrition on that measure.

Our data suggest that it would be premature to conclude that more extensive ATT systems to support independent home living for people with dementia are clinically important or cost-effective compared to more basic systems. This may be because basic ATT such as carbon monoxide and

pendant alarms are themselves effective in preventing harms, or because more extensive ATT systems are inadequately supported by providers, or inadequately tailored to the needs of people with dementia and their caregivers [33].

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Acknowledgements: The authors thank those who participated in the trial, and their unpaid carers, for their contribution to this research, which would not have been possible without them.

Declaration of Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form and declare the following: all authors had financial support from NIHR HTA (Grant 10/50/02) for the submitted work; P.B. reports personal fees from TauRx Therapeutics, outside the submitted work. J.O'B. reports personal fees from TauRx, personal fees from Axon, personal fees from GE Healthcare, grants and personal fees from Avid/Lilly, personal fees from Eisai, grants from Alliance Medical, outside the submitted work; A.B. is the registered Director of a Limited company (Memory Assessment Experts (MAE), who received an honorarium for being a Consultant Editor on the International Journal of Geriatric Psychiatry, John Wiley & Sons, Inc, and reports personal fees for various lectures for occasional medical legal reports and private practice, and report writing for the DVLA; there are no other relationships or activities that could appear to have influenced the submitted work.

Ethical Approval: The study was approved by the NHS Health Research Authority National Research Ethics Committee (REC reference number 12/LO/1816) and is registered with the ISRCTN (<http://www.controlled-trials.com/ISRCTN86537017>).

Data Sharing: Further information on the trial design and data are available from the corresponding author on request.

Transparency Statement: R.H. affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health and Social Care.

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Received 11 May 2020; editorial decision 5 October 2020