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 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.

Keypoints:

- There have been no large clinical trials of the clinical and cost effectiveness and safety of Assistive Technology and Telecare.
- In this randomised clinical trial (RCT) of 495 people comparing those with assistive technology and telecare (ATT) to the control, the adjusted hazard ratio was 0.84, which was not significant.
- The study suggests that assistive technology and telecare (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 oflife 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 United Kingdom (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 with a diagnosis of 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). 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.

Table 1. ATT installations 12 wks-104 wks (for intervention arm only)

	12wks	24wks	52wks	104wks	Total (12wks–104wks)
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

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 quality of life measured with the EuroQol EQ-5D-5L[18] and unpaid caregiver outcome measures including the Zarit Burden Inventory,[19] the Centre for Epidemiological Studies Depression Scale,[20] the State Trait Anxiety Inventory,[21] the Short Form Health Survey[22] and the Carer Technology Acceptance Questionnaire.[23]

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 study. *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 two 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 three 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).[24] 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.[25] Costs and days in the community were discounted at 3.5% annually[26].Mixed effects linear difference-in-difference models compared the between-group difference in EQ-5D scors [27, 28] and average three-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 with a square-root link for costs, with inverse-probability weights derived from parametric models, Weibull accelerated failure time model for days in the community, group-mean utilities to calculate QALY by the integrated quality survival product method) [29]. Bootstrap standard errors of the estimates of costs, QALY and days in the community were produced (based on 25000 replications) and of costs and the EQ-5D index (based on 5000 replications). 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,[30] 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.

Results

Between August 14, 2013 and October 26, 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.[31] Appendix 1 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 v. 16.9) and lower BADLS scores (19.5 v. 20.4). A lower BADLS score indicates less impairment of activities of daily living.

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%)

		Intervention N=248	Control N=247
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

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 2), 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 3. The most common 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 vs 13; p=0.054).

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

(A)

(B)

Costs

Appendix 4 shows the flow of dyads participating in full cost assessments. Appendix 5 contains descriptive demographics for the sample participating in full baseline cost assessments. Appendix 6 and 7 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 (Appendix 6 and 7). Cumulative costs of the intervention and total health, social care and societal costs are presented in Appendix 8. 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 9).

Cost-effectiveness

Based on participant-rated EQ-5D (Appendix 10), 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 10). 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 (Appendix 10-16

Point incremental cost effectiveness ratios (ICER) 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 [32, 33]in participant-reported EQ-5D at 104 weeks were negative from either perspective because the outcome was (non-significantly) worse in the intervention group, with small positive differences in costs. Point ICER for a 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.

Cost-effectiveness acceptability curves (CEAC) for each outcome, where the point ICER was not the result of a worse outcome for the intervention group, are shown in Appendix 17-19. 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 20), but ICERs were in line with the results of the main cost-effectiveness analyses (Appendix 21).

Serious adverse events

Eighty-nine participants died whilst community resident, 41 in the intervention arm and 48 in the control arm (Appendix 22 and 23). There were no significant differences seen overall (p=0.14 Appendix 21) or in the grouped categories for causes of death (Appendix 23).

Serious adverse events (SAEs) were categorised and the number of participants reporting SAEs are summarised in Table 3. Appendix 24 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 behavioural 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).

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

Categorised SAE	Intervention, no. of participants	Control, no.

Safety concerns	13	5
Wandering	25	36
Falls	86	88
Dementia progression	37	43
Behaviour	5	16
Other medical condition	107	109
Carer related	11	10
Environmental/accident	13	15
Health deterioration	5	2
Other	2	1
Unknown	10	16
Total no. of participants	**195**	**201**

Discussion

ATTILA is the first randomised controlled trial of ATT in people with dementia, that 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, maintains higher quality of life,[4, 34] costs less[35] 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,[36] yet there are very little available data on the effectiveness, safety and costs of the technology.[37] 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 technologies to improve social participation are also being actively marketed.[36]

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 3), 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 eah 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 matching of technology to need[38] and assessor understanding of ATT and need can be suboptimal.[39] We have reported elsewhere the outcomes of the ATTILA 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 ATTILA needs assessment.[31] This finding is a potential major limitation and the trial's negative results need to be viewed in this light. ATTILA 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 costs data collection 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 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.[31]

Acknowledgements

submitted work; Peter Bentham reports personal fees from TauRx Therapeutics, outside the submitted work. John O'Brien 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; Alastair Burns is the registered Director of a Limited company (Memory Assessment Experts (MAE), receives 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

RH 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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ATTILA Supplementary Appendices

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Appendix 1

CONSORT flow chart

Appendix 2

Kaplan-Meier survival curve: Time to admission to care by baseline BADLS Score

Appendix 3

Reasons for admission to care categorised, p-value from Mantel-Haenszel test (ignoring time to event)

Categorised reason	Intervention N=248
Safety concern	12
Wandering	5
Falls	13
Loss of ADLs	14
Behaviour	8
Other medical condition	7
Deterioration (unspecified)	14
Caregiver health	9

Other	6
Unknown	5
Any cause	**93**

Appendix 4

Flow of full assessment completion

Appendix 5

Baseline demographic characteristics of the sample with dyads participating in full baseline assessments

Characteristic	Intervention N
Female	131
Age bands	
<65	11
65 to 79	83
80 and older	135
Mean age (SD)	80.9
Risk of wandering	
Low	164
Moderate	48
High	17
Safety risk within the home	
Low	116
Moderate	95
High	18
Caregiver involvement	
Live-in	114
Visits at least once/day	51
Visits less than once/day	64
Caregiver-participant relationship	
Spouse/partner	88
Sibling/child/child-in-law	119
Other relatives and non-familial	22

Appendix 6

Use of health, social and unpaid care over prior three months, intervention and control, for observations with data available at baseline, 12, 24, 52 and 104 week follow-ups

Service/Item	Units	Valid N	Intervention No. users (%)
Baseline		**Expected=229**	
Community health			
GP	Visits	229	159 (69)
Practice nurse	Visits	229	88 (38)
Community nurse	Visits	229	52 (23)
Physiotherapist	Visits	229	33 (14)
OT	Visits	229	61 (27)
Dietician	Visits	229	3 (1)
Paramedic	Visits	228	24 (11)
Specialist nurse	Visits	229	22 (10)
Dentist	Visits	229	55 (24)
Optician	Visits	229	46 (20)
Chiropodist	Visits	229	84 (37)
Mental health			
Mental health nurse	Visits	229	78 (34)
Psychiatrist	Visits	229	52 (23)
Psychologist	Visits	229	4 (2)
Mental health team	Visits	229	17 (7)
Community care			
Home care	Visits	229	91 (40)
Home care	Hours	229	91 (40)
Social worker	Visits	229	75 (33)
Cleaner	Visits	229	59 (26)
Meals on Wheels	Visits	229	9 (4)
Laundry service	Visits	229	7 (3)
Sitting service	Visits	229	6 (3)
Carer support worker	Visits	229	11 (5)
Day services			
Day centre	Attendances	229	38 (17)
Lunch club	Attendances	229	19 (8)
Patient education	Attendances	229	11 (5)
Hospital care			
ED	Attendances	229	29 (13)
Inpatients services	Days	229	24 (10)
Day hospital services	Days	229	2 (1)
Outpatients services	Visits	229	100 (44)
Residential respite			
Residential home	Days	228	1 (0)
Nursing home	Days	228	5 (2)
Medications			

Service/Item	Units	Valid N	Intervention No. users (%)	
Any medications	Units	225	144 (64)	
Dementia	Units	226	116 (51)	
Mental health	Units	225	71 (32)	
Equip. & adaptations				
Equip. (HSC)	Items	217	48 (22)	
Unpaid care; out-of-pocket				
Equipment (private)	Items	217	9 (4)	
Travel to appoint.	Trips	219	111 (51)	
Unpaid care	Hours	214	212 (99)	5
Carer cut down work	Hours	205	3 (1)	
Carer stopped work	Weeks	207	1 (0)	
Unpaid care oth. carers	Hours	216	124 (57)	1
Time off work oth. carers	Days	215	15 (7)	
ATT				
ATT devices (inc. basic)	Items	223	217 (97)	
12 weeks		**Expected=189**		
Community health				
GP	Visits	188	118 (63)	
Practice nurse	Visits	188	72 (38)	
Community/District Nurse	Visits	188	36 (19)	
Physiotherapist	Visits	188	21 (11)	
OT	Visits	188	24 (13)	
Dietician	Visits	188	3 (2)	
Paramedic	Visits	188	18 (10)	
Specialist nurse	Visits	188	18 (10)	
Dentist	Visits	189	33 (17)	
Optician	Visits	189	39 (21)	
Chiropodist	Visits	189	77 (41)	
Mental health				
Mental health nurse	Visits	188	34 (18)	
Psychiatrist	Visits	188	24 (13)	
Psychologist	Visits	187	2 (1)	
Mental health team	Visits	188	7 (4)	
Community care				
Home care	Visits	189	81 (43)	
Home care	Hours	189	81 (43)	
Social worker	Visits	188	41 (22)	
Cleaner	Visits	189	54 (29)	
Meals on Wheels	Visits	189	11 (6)	
Laundry service	Visits	189	4 (2)	
Sitting service	Visits	189	8 (4)	
Carer support worker	Visits	189	10 (5)	
Day services				
Day centre	Attendances	189	42 (22)	

Service/Item	Units	Valid N	Intervention No. users (%)	
Lunch club	Attendances	189	17 (9)	
Patient education	Attendances	189	11 (6)	
Hospital care				
Emergency department	Attendances	189	30 (16)	
Inpatients services	Days	189	20 (11)	
Day hospital services	Days	189	1 (1)	
Outpatients services	Visits	189	74 (39)	
Residential respite				
Residential home	Days	188	0 (0)	
Nursing home	Days	188	5 (3)	
Medications				
Medications	Units	187	122 (65)	
Dementia	Units	189	104 (55)	
Mental health	Units	187	58 (31)	
Equip. & adaptations				
Equipment (HSC)	Items	184	27 (15)	
Unpaid care; out-of-pocket				
Equipment (private)	Items	185	6 (3)	
Travel to appointments	Trips	188	85 (45)	
Unpaid care	Hours	186	186 (100)	6
Carer cut down work	Hours	174	1 (1)	
Carer stopped work	Weeks	175	3 (2)	
Unpaid care oth. carers	Hours	186	99 (53)	
Time off work oth. carers	Days	184	9 (5)	
ATT				
ATT devices (inc. basic)	Items	188	164 (87)	
Week 24		**Expected=178**		
Community health				
GP	Visits	176	101 (57)	
Practice nurse	Visits	177	69 (39)	
Community/District Nurse	Visits	177	30 (17)	
Physiotherapist	Visits	177	20 (11)	
OT	Visits	177	18 (10)	
Dietician	Visits	177	4 (2)	
Paramedic	Visits	177	12 (7)	
Specialist nurse	Visits	176	11 (6)	
Dentist	Visits	177	38 (21)	
Optician	Visits	177	37 (21)	
Chiropodist	Visits	177	65 (37)	
Mental health				
Mental health nurse	Visits	177	24 (14)	
Psychiatrist	Visits	177	13 (7)	
Psychologist	Visits	177	1 (1)	
Mental health team	Visits	177	7 (4)	

Service/Item	Units	Valid N	Intervention No. users (%)	
Community care				
Home care	Visits	177	79 (45)	
Home care	Hours	177	79 (45)	
Social worker	Visits	177	29 (16)	
Cleaner	Visits	177	47 (27)	
Meals on Wheels	Visits	177	10 (6)	
Laundry service	Visits	177	2 (1)	
Sitting service	Visits	177	8 (5)	
Carer support worker	Visits	177	3 (2)	
Day services				
Day centre	Attendances	177	36 (20)	
Lunch club	Attendances	177	15 (8)	
Patient education	Attendances	177	10 (6)	
Hospital care				
Emergency department	Attendances	177	23 (13)	
Inpatients services	Days	177	10 (6)	
Day hospital services	Days	177	3 (2)	
Outpatients services	Visits	177	62 (35)	
Residential respite				
Residential home	Days	175	1 (1)	
Nursing home	Days	175	4 (2)	
Medications				
Any medications	Units	175	122 (70)	
Dementia	Units	177	105 (59)	
Mental health	Units	175	57 (33)	
Equipment (HSC)	Items	175	28 (16)	
Unpaid care; out-of-pocket				
Equipment (private)	Items	175	8 (5)	
Travel to appointments	Trips	177	58 (33)	
Unpaid care	Hours	175	173 (99)	6
Carer cut down work	Hours	171	2 (1)	
Carer stopped work	Weeks	169	1 (1)	
Unpaid care oth. carers	Hours	175	102 (58)	1
Time off work oth. carers	Days	175	20 (11)	
ATT				
ATT devices (inc. basic)	Items	176	148 (84)	
Week 52		**Expected=150**		
Community health				
GP	Visits	148	96 (65)	
Practice nurse	Visits	148	64 (43)	
Community Nurse	Visits	148	31 (21)	
Physiotherapist	Visits	148	9 (6)	
OT	Visits	148	17 (11)	
Dietician	Visits	148	4 (3)	

Service/Item	Units	Valid N	Intervention No. users (%)	
Paramedic	Visits	148	15 (10)	
Specialist nurse	Visits	148	17 (11)	
Dentist	Visits	148	33 (22)	
Optician	Visits	148	25 (17)	
Chiropodist	Visits	148	61 (41)	
Mental health				
Mental health nurse	Visits	148	12 (8)	
Psychiatrist	Visits	148	7 (5)	
Psychologist	Visits	148	1 (1)	
Mental health team	Visits	148	4 (3)	
Community care				
Home care	Visits	148	77 (52)	
Home care	Hours	148	77 (52)	1
Social worker	Visits	148	29 (20)	
Cleaner	Visits	148	38 (26)	
Meals on Wheels	Visits	148	5 (3)	
Laundry service	Visits	148	4 (3)	
Sitting service	Visits	148	5 (3)	
Carer support worker	Visits	148	1 (1)	
Day services				
Day centre	Attendances	148	35 (24)	
Lunch club	Attendances	148	12 (8)	
Patient education	Attendances	148	7 (5)	
Hospital care				
Emergency department	Attendances	148	25 (17)	
Inpatients services	Days	148	17 (11)	
Day hospital services	Days	148	0 (0)	
Outpatients services	Visits	148	52 (35)	
Residential respite				
Residential home	Days	148	1 (1)	
Nursing home	Days	148	5 (3)	
Medications				
Any medications	Units	145	101 (70)	
Dementia	Units	147	85 (58)	
Mental health	Units	145	45 (31)	
Equipment (HSC)	Items	147	22 (15)	
Unpaid care; out-of-pocket				
Equipment (private)	Items	147	14 (10)	
Travel to appointments	Trips	147	49 (33)	
Unpaid care	Hours	145	145 (100)	6
Carer cut down work	Hours	146	1 (1)	
Carer stopped work	Weeks	144	0 (0)	
Unpaid care oth. carers	Hours	147	84 (57)	1
Time off work oth. carers	Days	146	7 (5)	

Service/Item	Units	Valid N	Intervention No. users (%)	
ATT				
ATT devices (inc. basic)	Items	146	131 (90)	
Week 104		**Expected=96**		
Community health				
GP	Visits	93	66 (71)	
Practice nurse	Visits	92	28 (30)	
Community/District Nurse	Visits	93	20 (22)	
Physiotherapist	Visits	93	7 (8)	
OT	Visits	93	8 (9)	
diet	Visits	93	2 (2)	
Paramedic	Visits	93	10 (11)	
Specialist nurse	Visits	93	11 (12)	
Dentist	Visits	93	16 (17)	
Optician	Visits	93	21 (23)	
Chiropodist	Visits	93	37 (40)	
Mental health				
Mental health nurse	Visits	93	6 (6)	
Psychiatrist	Visits	93	1 (1)	
Psychologist	Visits	93	0 (0)	
Mental health team	Visits	93	0 (0)	
Community care				
Home care	Visits	93	46 (49)	
Home care	Hours	93	46 (49)	1
Social worker	Visits	93	11 (12)	
Cleaner	Visits	93	32 (34)	
Meals on Wheels	Visits	93	2 (2)	
Laundry service	Visits	93	1 (1)	
Sitting service	Visits	93	6 (6)	
Carer support worker	Visits	93	2 (2)	
Day services				
Day centre	Attendances	93	20 (22)	
Lunch club	Attendances	93	5 (5)	
Patient education group	Attendances	93	3 (3)	
Hospital care				
Emergency department	Attendances	93	8 (9)	
Inpatients services	Days	93	6 (6)	
Day hospital services	Days	93	1 (1)	
Outpatients services	Visits	93	35 (38)	
Residential respite				
Residential home	Days	93	0 (0)	
Nursing home	Days	93	1 (1)	
Medications				
Any medications	Units	92	61 (66)	
Dementia	Units	93	50 (54)	

Service/Item	Units	Valid N	Intervention No. users (%)	
Mental health	Units	92	29 (32)	
Equipment (HSC)	Items	92	10 (11)	
Unpaid care; out-of-pocket				
Equipment (private)	Items	92	5 (5)	
Travel to appointments	Trips	93	35 (38)	
Unpaid care	Hours	91	88 (97)	6
Carer cut down work	Hours	90	1 (1)	
Carer stopped work	Weeks	89	0 (0)	
Unpaid care oth. carers	Hours	93	53 (57)	1
Time off work oth. carers	Days	93	3 (3)	
ATT				
ATT devices (inc. basic)	Items	93	85 (91)	

Note: OT= Occupational therapist; HSC=health and social care providers; oth. carers=other relatives and friends who provide care; ATT (inc. basic) =all ATT devices recorded on ATT checklist including "basic" ATT (e.g. key safes, standard smoke alarms).

Appendix 7

Mean costs (standard errors) and between-group difference (95% confidence intervals): health and social care services for participant, unpaid carer costs, out-of-pocket costs, total health and social care and societal costs over prior three months, at baseline, 12, 24, 52 and 104 week assessments (£, 2016-17)

		Intervention		
Cost	**N**	**Mean**	**SE**	**N**
Baseline		**Expected=229**		
Hospital	229	619	130	223
Primary and community health	229	253	18	223
Community mental health	227	62	7	223
Respite residential/nursing	228	35	19	223
Community care	224	1433	299	220
Day care (any provider)	229	153	36	223
Equipment & adaptations[a]	218	4	1	203
Medications	226	23	5	222
Unpaid care[b]	217	5928	488	202
Equipment & adaptations - self[c]	218	2	1	203
Out-of-pocket[d]	219	8	2	202
Health & social care	210	2231	228	201
Intervention	223	85	2	203

| | Intervention | | | |
Cost	N	Mean	SE	N
Intervn.+Health & social care	205	2276	228	189
Societal[e]	208	8162	540	200
Intervn.+Societal[e]	203	8262	546	188
Week 12		**Expected=189**		
Hospital	189	467	121	186
Primary and community health	188	223	21	185
Community mental health	186	36	8	186
Respite residential/nursing	188	45	26	185
Community care	188	1857	377	185
Day care	189	229	45	186
Equipment & adaptations[a]	186	4	1	184
Medications	189	34	9	186
Unpaid care[b]	186	6214	470	183
Equipment & adaptations - self[c]	186	2	1	184
Out-of-pocket[d]	188	7	2	184
Health & social care	182	2930	416	181
Intervention	188	61	3	166
Intervn.+Health & social care	181	2978	418	161
Societal[e]	182	9202	620	180
Intervn.+Societal[e]	181	9283	624	160
Week 24		**Expected=178**		
Hospital	177	296	73	168
Primary and community health	177	193	20	168
Community mental health	177	21	4	168
Respite residential/nursing	175	35	21	166
Community care	176	2 475	537	165
Day care	177	230	48	167
Equipment & adaptations[a]	176	7	2	168
Medications	177	26	5	168
Unpaid care[b]	175	6 843	575	168
Equipment & adaptations - self[c]	176	3	2	168
Out-of-pocket[d]	177	6	2	168
Health & social care	173	3 298	560	162
Intervention	176	55	3	157
Intervn.+Health & social care	171	3382	566	151
Societal[e]	172	9 954	769	162
Intervn.+Societal[e]	170	10 032	778	151
Week 52		**Expected=150**		
Hospital	148	470	149	137
Primary and community health	148	195	18	137
Community mental health	148	28	18	137
Respite residential/nursing	148	60	37	137
Community care	148	3 377	747	137
Day care	148	361	72	137

		Intervention		
Cost	**N**	**Mean**	**SE**	**N**
Equipment & adaptations[a]	148	8	2	137
Medications	147	25	5	137
Unpaid care[b]	147	6 851	560	136
Equipment & adaptations - self[c]	148	6	2	137
Out-of-pocket[d]	147	6	2	136
Health & social care	147	4 510	777	137
Intervention	146	64	3	129
Intervn.+Health & social care	143	4 613	797	129
Societal[e]	146	11 442	927	136
Intervn.+Societal[e]	143	11 492	947	128
Week 104		**Expected=96**		
Hospital	93	430	186	89
Primary and community health	93	227	26	89
Community mental health	93	4	2	89
Respite residential/nursing	93	3	3	89
Community care	93	4 537	1 264	87
Day care	93	365	98	89
Equipment & adaptations[a]	93	9	3	89
Medications	93	21	6	89
Unpaid care[b]	93	7 308	781	89
Equipment & adaptations - self[c]	93	3	2	89
Out-of-pocket[d]	93	6	3	89
Health & social care	93	5 693	1 300	87
Intervention	93	63	4	87
Intervn.+Health & social care	92	5 808	1 314	84
Societal[e]	93	12 961	1 599	87
Intervn.+Societal[e]	92	13 117	1 614	84

Note: Intervn.=Intervention costs
*p<0.05 **p<0.01 ***p<0.001
a Funded by NHS or Social Services
b Unpaid carers' time in care and support to participant
c Expenditure by self or family on equipment purchases
d Expenditure by self or family on travel to appointments
e Societal costs: participant's health and social care costs; unpaid carers' time in care and support to participant; expenditure by self or family on travel to appointments, equipment purchases

Appendix 8

Mean cumulative costs (standard errors): intervention costs, total health and social care and societal costs (at opportunity and replacement cost valuation of unpaid carer time) from baseline to 104 weeks (£, 2016-17)

	Cost	Intervention			
		n	Mean	SE	n
		Expected=229			
	Intervn: ATT inc. baseline ATT cost[a]	223	408	18	203
	Intervn: ATT over 104 weeks follow-up	223	322	18	203
	Health & social care	210	19 232	3 086	201
	Intervn.+Health & social care	205	19 649	3 206	189
	Societal[b]	208	55 209	4 404	200
	Intervn.+Societal[b]	203	56 000	4 579	188
	Sensitivity analysis				
	Societal[c]	208	12 8935	8 862	200
	Intervn.+Societal[c]	203	12 9845	9 163	188

Note: Sample includes any participant that had participated in a baseline assessment and whose data for that cost at baseline was not missing; Intervn.=Intervention costs

*p<0.05; **p<0.01; ***p<0.001

a ATT costs: includes the costs of the ATT assessment and ATT package installed prior to baseline assessment

b societal costs: participant's health and social care costs; unpaid carers' time in care and support to participant (opportunity cost valuation); expenditure by self or family on travel to appointments, equipment purchases

c societal costs: participant's health and social care costs; unpaid carers' time in care and support to participant (replacement cost valuation); expenditure by self or family on travel to appointments, equipment purchases

Appendix 9

Mean EQ-5D index scores and standard errors and between-group difference and 95% confidence intervals: at baseline, 12, 24, 52 and 104 week assessment points

Outcome measure	Intervention			Contro	
	N	Mean	SE	N	Mea
Baseline	**Expected=229**			**Expected=224**	
EQ-5D - Participant	208	0.748	0.016	199	0.77
EQ-5D - Proxy	208	0.539	0.015	197	0.52
Week 12	**Expected=189**			**Expected=188**	
EQ-5D - Participant	175	0.734	0.019	161	0.76
EQ-5D - Proxy	178	0.551	0.017	178	0.51
Week 24	**Expected=178**			**Expected=168**	
EQ-5D - Participant	157	0.731	0.02	143	0.78
EQ-5D - Proxy	172	0.512	0.019	158	0.51
Week 52	**Expected=150**			**Expected=139**	
EQ-5D - Participant	120	0.709	0.023	104	0.78
EQ-5D - Proxy	144	0.482	0.023	129	0.4
Week 104	**Expected=96**			**Expected=90**	
EQ-5D - Participant	75	0.73	0.03	59	0.81
EQ-5D - Proxy	92	0.462	0.029	84	0.42

Appendix 10

Adjusted Results from Regression Analyses of Outcomes, Costs (£, 2016-17) and cost-effectiveness

Outcome	Number of cases, between-group difference or ICER	Assessment point	
		Week 24	Week 52
Health and social care (HSC) total costs			
	Number of cases	N=450[a]	N=450[a]
	Mean (95% CI)[b] : Intervention	4 449 (3425, 5896)	9 366 (7 301, 12 069
	Mean (95% CI)[b] : Control	4 960 (3669, 6998)	10 051 (7 794, 13 250
	Difference: Intervention-Control Mean (95% CI)[b]	-511 (-2008, 600) p=0.438	-685 (-2 992, 1 546) p=0.554
Societal total costs			
	Number of cases	N=450[a]	N=450[a]
	Mean (95% CI)[b] : Intervention	14 084 (12 226, 15 710)	28 174 (24 470, 31 84
	Mean (95% CI)[b] : Control	15 386 (13 075, 18 278)	29 277 (25 621, 33 39
	Difference: Intervention-Control Mean (95% CI)[b]	-1 302 (-4 801, 1 460) p=0.412	-1103 (-6 216, 3737) p=0.665
QALY – EQ-5D – participant			
	Number of cases	N=450[a]	N=450[a]
	Mean (95% CI)[b] : Intervention	0.334 (0.319, 0.348)	0.680 (0.646, 0.712)
	Mean (95% CI)[b] : Control	0.350 (0.336, 0.364)	0.724 (0.692, 0.754)
	Difference: Intervention-Control Mean (95% CI)[b]	-0.016 (-0.036, 0.003) p=0.109	-0.044* (-0.088, 0.000) p=0.05
	ICER (cost per QALY, HSC[c])	-511/-0.016=31 668	-685/-0.044=1
	ICER (cost per QALY, societal[c])	-1 302/-0.016=80 697	-1103/-0.044=2
QALY – EQ-5D – proxy			
	Number of cases	N=450[a]	N=450[a]
	Mean (95% CI)[b] : Intervention	0.245 (0.231, 0.258)	0.485 (0.453,0.516)
	Mean (95% CI)[b] : Control	0.234 (0.220, 0.248)	0.470 (0.439, 0.499)

	Difference: Intervention-Control Mean (95% CI)[b]	0.010 (-0.009, 0.029) p=0.292	0.016 (-0.026, 0.057) p=0.467
	ICER (cost per QALY, HSC[c])	-511/0.010=-49 825	-685/0.016 =-4
	ICER (cost per QALY, societal[c])	-1 302/0.010=-126 964	-1103/0.016 =- 957
Institutionalisation-free days			
	Number of cases		
	Mean (95% CI)[b] : Intervention		
	Mean (95% CI)[b] : Control		
	Difference: Intervention-Control Mean (95% CI)[b]		
	ICER (cost per institutionalisation-free day, HSC[c])		
	ICER (cost per institutionalisation-free day, societal[c])		
EQ-5D– participant and HSC costs		Available cases[df]	Available case
	Number of cases	N=287	N=229
	Difference-in-difference: Mean (95% CI)[g] outcome	-0.011 (-0.052, 0.028) p=0.593	-0.004 (-0.046, 0.037) p=0.845
	Difference-in-difference: Mean (95% CI)[h] costs	367 (-850, 1 474) p=0.593	534 (-748, 2 082) p=0.462
	ICER (difference in costs/MCID[j])	367/-0.148 =-2 475	534/-0.056=-9
EQ-5D– participant, Societal costs			
	Number of cases	N=284	N=227
	Difference-in-difference: Mean (95% CI)[g] outcome	-0.015 (-0.056, 0.024) p=0.458	-0.008 (-0.050, 0.033) p=0.709
	Difference-in-difference: Mean (95% CI)[h] costs	251 (-1164, 2 005) p=0.756	-116 (-1 765, 2 185) p=0.907
	ICER (difference in costs/MCID[j])	251/-0.204=-1 231	-116/-0.105=1
EQ-5D– proxy, HSC costs			
	Number of cases	N=309	N=257
	Difference-in-difference: Mean (95% CI)[g] outcome	0.034	0.027

		(-0.007, 0.074) p=0.098	(-0.015, 0.068) p=0.205
	Difference-in-difference: Mean (95% CI)[h] costs	313 (-949, 1 313) p=0.584	442 (-926, 1 502) p=0.481
	ICER (difference in costs/MCID[i])	313/0.463=677	442/0.36=1226
EQ-5D– proxy, Societal costs			
	Number of cases	N=308	N=257
	Difference-in-difference: Mean (95% CI)[g] outcome	0.033 (-0.008, 0.073) p=0.892	0.027 (-0.015, 0.068) p=0.812
	Difference-in-difference: Mean (95% CI)[g] costs	110 (-1 569, 1 630) p=0.115	-220 (-2 175, 1 443) p=0.812
	ICER (difference in costs/MCID[i])	110/0.448=246	-220/0.36=-61

Note: *p<0.05

a Estimates of multiple analyses combined: data from 450 observations analysed in survival analysis; cumulative mean costs per group; data from cases available at each assessment point (where baseline BADLS score was also available) summarised to give mean utilities per group per assessment point

b Bias-corrected bootstrapped 95% confidence intervals, bootstrapped estimates (25000 replications)

c Outcome difference rounded to the third decimal place.

d Cost and outcome data available from baseline and at least one follow-up point.

e Cost and outcome data available from baseline and at least two follow-up points.

f 95% confidence intervals, bootstrapped estimates (5000 replications); estimates of group means at baseline and over follow-up and within-group baseline-follow up differences from difference-in-difference models are provided in Appendices 10 to 15.

g Estimates from outcome equation, where covariates are allocation to ATT, BADLS categories, stratification variables.

h Estimates from cost equation, where covariates are allocation to ATT, BADLS categories, stratification variables.

i Cost per gain of 0.074 in EQ-5D (Fang et al 2016; Walters and Brazier 2005); outcome difference rounded to the third decimal place.

Appendix 11

Difference-in-difference model estimates: average three-month costs at baseline and across 24-week follow-up period. Sample: available cases for EQ-5D-participant.

	Baseline	SE	Follow-up period
Health & social care[d]			
Intervention	2295	250	2 785
Control	2541	356	2665
Societal			
Intervention	8152	545	8978
Control	8558	614	9133

Appendix 12

Difference-in-difference model estimates: average three-month costs at baseline and across 24-week follow-up period. Available cases for EQ-5D outcomes and health and social care costs.

	Baseline	SE	Follow-up period	
EQ-5D-participant				
Intervention	0.746	0.017	0.747	
Control	0.792	0.020	0.804	
EQ-5D-Proxy				
Intervention	0.546	0.014	0.546	
Control	0.565	0.016	0.531	

Appendix 13

Difference-in-difference model estimates: average three-month costs at baseline and across 52-week follow-up period. Sample: available cases for EQ-5D-participant.

	Baseline	SE	Follow-up period	
Health & social care[d]				
Intervention	2 250	291	3 239	
Control	2 504	447	2 959	
Societal				
Intervention	7 961	584	9 665	
Control	8 450	709	10 038	

Appendix 14

Difference-in-difference model estimates: average three-month costs at baseline and across 52-week follow-up period. Available cases for EQ-5D outcomes and Health and social care costs.

	Baseline	SE	Follow-up period	
EQ-5D-5L-participant				
Intervention	0.774	0.016	0.766	
Control	0.813	0.019	0.809	
EQ-5D-5L-Proxy				
Intervention	0.569	0.013	0.539	
Control	0.575	0.018	0.517	

Appendix 15

Difference-in-difference model estimates: average three-month costs at baseline and across 104-week follow-up period. Available cases for EQ-5D-participant.

	Baseline	SE	Follow-up period	
Health & social care[d]				
Intervention	2257	295	3639	
Control	2502	40	3185	
Societal				
Intervention	8037	600	10051	
Control	8536	691	10397	

Appendix 16

Difference-in-difference model estimates: average three-month costs at baseline and across 104-week follow-up period. Available cases for EQ-5D outcomes and Health and social care costs.

	Baseline	SE	Follow-up period	
EQ-5D-5L-participant				
Intervention	0.767	0.016	0.752	
Control	0.807	0.018	0.808	
EQ-5D-5L-Proxy				
Intervention	0.567	0.014	0.524	
Control	0.573	0.018	0.509	

Appendix 17

Cost-effectiveness acceptability curve: person with dementia QALY derived from the EQ-5D-Proxy and total costs at 24, 52 and 104-week follow-up

Appendix 18

Cost-effectiveness acceptability curve at 24, 52 and 104-week follow-up: EQ-5D-Proxy index scores and health and social care costs

Notes: MCID=minimal clinically important difference; MCID=0.074

Appendix 19

Cost-effectiveness acceptability curve: institutionalisation-free days and total costs at 104-week follow-up

Appendix 20

Sensitivity analysis: Adjusted Results from Regression Analyses of Outcomes, Societal costs (£, 2016-17) and cost-effectiveness (unpaid care valued at replacement cost)

Outcome	Number of cases, between-group difference or ICER	
		Week 104
Societal total costs[a]		
	Number of cases	N=450[b]
	Mean (95% CI)[c] : Intervention	131 847 (119 111, 146 973)
	Mean (95% CI)[c] : Control	133 781 (119 333, 149 963)
	Difference: Intervention-Control Mean (95% CI)[c]	-1 934 (-19 986, 16 892) p=0.838
QALY – EQ-5D – participant		
	Number of cases	N=450[b]
	Mean (95% CI)[c] : Intervention	1.201 (1.127, 1.271)
	Mean (95% CI)[c] : Control	1.306 (1.23s4, 1.376)
	Difference: Intervention-Control Mean (95% CI)[c]	-0.105* (-0.204, -0.007) P=0.037
	ICER (cost[a] per QALY)[d]	-1 934/-0.105=18 371
QALY – EQ-5D – proxy		
	Number of cases	N=450[b]
	Mean (95% CI)[c] : Intervention	0.828 (0.762, 0.894)
	Mean (95% CI)[c] : Control	0.798 (0.733, 0.861)
	Difference: Intervention-Control Mean (95% CI)[c]	0.030 (-0.058, 0.117) p=0.497
	ICER (cost[a] per QALY)[d]	-1 934/0.030=-63 587
Institutionalisation-free days		
	Number of cases	N=450[b]
	Mean (95% CI)[c] : Intervention	597.075 (572.464, 620.939)

	Mean (95% CI)[c] : Control	589.177 (563.373, 614.062)
	Difference: Intervention-Control Mean (95% CI)[c]	7.898 (-26.438, 42.425) P=0.653
	ICER (cost[a] per institutionalisation-free day)[d]	-1 934/7.898=-245
EQ-5D– participant, Societal costs[a]		Available cases[ef]
	Number of cases	N=241
	Difference-in-difference: Mean (95% CI)[g] outcome	-0.019 (-0.06, 0.017) p=0.323
	Difference-in-difference: Mean (95% CI)[h] costs	316 (-3 457, 3 978) P=0.867
	ICER (difference in costs/MCID[i])	316/-0.262=-1 209
EQ-5D– proxy, Societal costs[a]		
	Number of cases	N=266
	Difference-in-difference: Mean (95% CI)[g] outcome	0.021 (-0.022, 0.06) p=0.324
	Difference-in-difference: Mean (95% CI)[h] costs	-288 (-3 930, 3 249) p=0.875
	ICER (difference in costs/MCID[i])	-288/0.281=-1 024

a unpaid carers' time in care and support to participant valued at the cost of a homecare worker
b estimates of multiple analyses combined: data from 450 observations analysed in survival analysis; cumulative mean costs per group; data from cases available at each assessment point (where baseline BADLS score was also available) summarised to give mean utilities per group per assessment point
c Bias-corrected bootstrapped 95% confidence intervals, bootstrapped estimates (25000 replications)
d Outcome difference rounded to the third decimal place.
e cost and outcome data available from baseline and at least two follow-up points
f 95% confidence intervals, bootstrapped estimates (5000 replications)
g Estimates from outcome equation, where covariates are allocation to ATT, BADLS categories, stratification variables.
h Estimates from cost equation, where covariates are allocation to ATT, BADLS categories, stratification variables.
i Cost per gain of 0.074 in EQ-5D (Fang et al 2016; Walters and Brazier 2005); difference in outcome rounded to the third decimal place.

Appendix 21

Mean costs (standard errors): unpaid care and total costs from the societal perspective with unpaid care valued at replacement cost over prior three months, at baseline, 12, 24, 52 and 104 week assessments (£, 2016-17)

		Intervention			
Cost	N	Mean	SE	N	
Baseline		**Expected=229**			**Expecte**
Unpaid care[a]	217	18 270	1 240	202	
Intervn.+Societal[b]	203	20 502	1285	188	
Week 12		**Expected=189**			**Expecte**
Unpaid care[a]	186	19 802	1332	183	
Intervn.+Societal[b]	181	22 569	1371	160	

Cost	N	Mean	SE	N	
Week 24		**Expected=178**			**Expecte**
Unpaid care[a]	175	21 685	1528	168	
Intervn.+Societal[b]	170	24 769	1575	151	
Week 52		**Expected=150**			**Expecte**
Unpaid care[a]	147	20 117	1517	136	
Intervn.+Societal[b]	143	24 582	1633	128	
Week 104		**Expected=96**			**Expect**
Unpaid care[a]	93	21 337	2035	89	
Intervn.+Societal[b]	92	27 125	2527	84	

Note: Intervn.=Intervention costs
a unpaid carers' time in care and support to participant valued at the cost of a homecare worker
b societal costs: participant's health and social care costs; unpaid caregivers' time in care and support to participant valued at the cost of a homecare worker; expenditure by self or family on travel to appointments, equipment purchases

Appendix 22

Kaplan-Meier survival curve: Time to death whilst community resident by randomised arm

Appendix 23

Causes of death categorised, p-value from Mantel-Haenszel test (ignoring time to event)

Cause of death	Intervention N=248
Health/dementia deterioration	8
Pneumonia/respiratory failure	4
Heart attack/heart failure	3
Stroke	7
Cancer	7
Infection	6
Other	2
Unknown	4
Total	41

Appendix 24

Forest plot for the incidence of SAEs, p-value from Mantel-Haenszel test (ignoring time to event)