RESEARCH ARTICLE

International Journal of Geriatric Psychiatry

Effect of animal-assisted interventions on depression, agitation and quality of life in nursing home residents suffering from cognitive impairment or dementia: a cluster randomized controlled trial

Christine Olsen[1], Ingeborg Pedersen[1], Astrid Bergland[2], Marie-José Enders-Slegers[3], Grete Patil[1] and Camilla Ihlebæk[1,4]

[1]Section for Public Health Science, Department of Landscape Architecture and Spatial Planning, Norwegian University of Life Sciences, Ås, Norway
[2]Faculty of Health Sciences, Oslo and Akershus University College, Oslo, Norway
[3]Psychology and Educational Sciences, Open University of the Netherlands, Heerlen, The Netherlands
[4]Faculty of Health and Social Work Studies, Østfold University College, Fredrikstad, Norway
Correspondence to: C. Olsen, E-mail: christine.olsen@nmbu.no

Objectives: The prevalence of neuropsychiatric symptoms in cognitively impaired nursing home residents is known to be very high, with depression and agitation being the most common symptoms. The possible effects of a 12-week intervention with animal-assisted activities (AAA) in nursing homes were studied. The primary outcomes related to depression, agitation and quality of life (QoL).

Method: A prospective, cluster randomized multicentre trial with a follow-up measurement 3 months after end of intervention was used. Inclusion criteria were men and women aged 65 years or older, with a diagnosis of dementia or having a cognitive deficit. Ten nursing homes were randomized to either AAA with a dog or a control group with treatment as usual. In total, 58 participants were recruited: 28 in the intervention group and 30 in the control group. The intervention consisted of a 30-min session with AAA twice weekly for 12 weeks in groups of three to six participants, led by a qualified dog handler. Norwegian versions of the Cornell Scale for Depression, the Brief Agitation Rating Scale and the Quality of Life in Late-stage Dementia scale were used.

Results: A significant effect on depression and QoL was found for participants with severe dementia at follow-up. For QoL, a significant effect of AAA was also found immediately after the intervention. No effects on agitation were found.

Conclusions: Animal-assisted activities may have a positive effect on symptoms of depression and QoL in older people with dementia, especially those in a late stage. Copyright © 2016 John Wiley & Sons, Ltd.

Key words: dementia; neuropsychiatric symptoms; depression; agitation; quality of life; non-pharmacological interventions; animal-assisted interventions

History: Received 06 July 2015; Accepted 23 December 2015; Published online 25 January 2016 in Wiley Online Library (wileyonlinelibrary.com)

DOI: 10.1002/gps.4436

Introduction

Dementia is among the leading causes of disability and death in the elderly (Lobo *et al*., 2000). Approximately 80% of nursing home residents in Norway suffer from dementia (Selbæk *et al*., 2007b), and dementia is the most common main diagnosis in the nursing home population in Norway (Nygaard, 2002). In older adults with a neurodegenerative form of dementia, ongoing degeneration of brain tissue eventually leads to a loss of cognitive and physical functions (McKhann *et al*., 1984; van Iersel *et al*., 2004). In addition to impaired cognition, neuropsychiatric symptoms (NPS) such as apathy, depressive symptoms, anxiety, agitation, restlessness

Copyright © 2016 John Wiley & Sons, Ltd.

and wandering are common symptoms (Selbæk, 2005; Selbæk *et al.*, 2007a).

The prevalence of NPS in patients with dementia has been reported as very high. For example, following a 2-year longitudinal study, Aalten *et al.* (2005) found that 95% of the patients developed one or more NPS. Lyketsos *et al.* (2002) found that 75% of the patients with dementia in their study population had experienced NPS in the preceding month and 55% reported having two or more symptoms. A recent Norwegian study found a 31% prevalence of depression among recently admitted long-term care patients (Iden *et al.*, 2014). NPS affect patients' quality of life (QoL) (Beerens *et al.*, 2013; Mjørud *et al.*, 2014b), and low QoL is associated with impaired mobility, lack of social activities and low performance in activities relating to daily living (Nagatomo *et al.*, 1997; Barca *et al.*, 2011; Telenius *et al.*, 2013; Mjørud *et al.*, 2014a).

As population ages, health care and social services face increased demands to provide services for older people with dementia or cognitive impairment. Because there is no cure for dementia (Geldmacher *et al.*, 2006), there is a need for new and innovative approaches to complement traditional health care. Medication for NPS is commonly used, but most of the medicines have major physical and mental side effects such as abnormal liver function, heart defects, gastrointestinal problems, apathy, ataxia, restlessness and insomnia (Tripathi and Vibha, 2010). The finding of Iden *et al.* (2014) that antidepressants had been prescribed for 44% of their study participants indicates extensive use. Little is known about the efficacy and safety of antidepressant medication when used to treat symptoms of agitation and psychosis (Seitz *et al.*, 2011). Therefore, it has been suggested that non-pharmacological interventions should be implemented on a larger scale in nursing homes (Douglas *et al.*, 2004; Iden *et al.*, 2014).

Several non-pharmacological alternatives and complementary treatments have evolved, including animal-assisted interventions (AAI). The International Association of Human–Animal Interaction Organizations (IAHAIO, 2014) defines AAI as 'a goal oriented and structured intervention that intentionally includes or incorporates animals in health, education and human service for the purpose of therapeutic gains in humans'. Animal-assisted activities (AAA) are a form of AAI whereby companion animals are taken by their human handlers to visit nursing homes for 'meet and greet' activities with residents.

Previous studies have shown mixed results regarding the effectiveness of AAI on depression, agitation and QoL for dementia patients (Richeson, 2003; Mossello *et al.*, 2011; Majic *et al.*, 2013; Nordgren and Engstrom, 2014a, 2014b; Friedmann *et al.*, 2015; Thodberg *et al.*, 2015). Further, much of the research on AAI and dementia to date has lacked adequate study designs for investigating the effects of interventions, and because of the limited use of control groups and follow-up measures, the conclusions are disputable. For this reason, the aim of this study was to examine the possible effects on depression, agitation and QoL in nursing home residents with dementia or cognitive impairment, through an intervention with AAA and a follow-up study.

Methods

Design

The study was conducted in Norway as a prospective and cluster randomized multicentre 12-week trial with a 3-month follow-up. Computer-generated random numbers were used to randomize nursing home units to either an AAA group with a dog or to a control group with treatment as usual. The study was registered by ClinicalTrials.gov (identifier: NCT02008630).

Data collection was carried out at baseline before the intervention started (T_0), when finishing the intervention after 12 weeks (T_1), and at follow-up 3 months after the intervention had ended (T_2).

Participants and recruitment

Of 90 eligible nursing homes in three Norwegian counties, 10 adapted units for residents with dementia agreed to participate in the project (Figure 1). The nursing homes included in the study had to provide the facilities required to carry out the interventions. They also had to abstain from any dog-visiting activities for 3 months prior to the intervention, as well as during the whole intervention period from T_0 to T_2.

The health personnel in the nursing homes were asked to recruit between five and eight participants each. The inclusion criteria were as follows: aged 65 years or older and having dementia or a cognitive deficit score of less than 25 on the mini-mental state examination test (Folstein *et al.*, 1975; Strobel and Engedal, 2009). The exclusion criteria were nursing home residents with fear of dogs or with a dog allergy.

Of 130 eligible patients in the 10 units, 58 patients (45%) agreed to participate; seven patients (12%) died during the study period and were subsequently excluded from the study. Thus, the study population consisted of 51 participants. Three participants dropped out of the study after baseline data were

Copyright © 2016 John Wiley & Sons, Ltd.

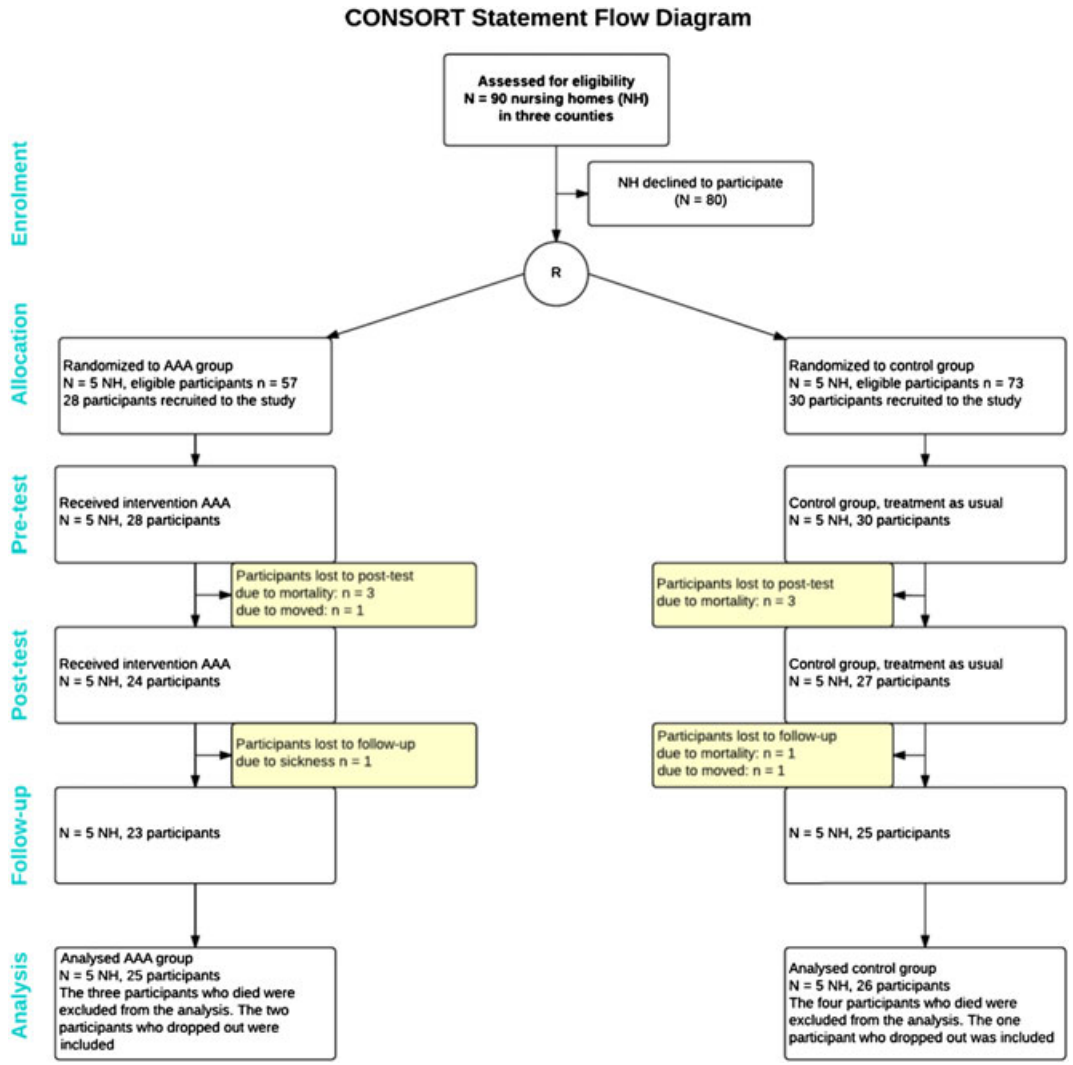


Figure 1 Consort flow diagram of participants.

collected but were included in the study population (Figure 1).

The study was conducted during winter–spring 2013 ($n = 12$), autumn–winter 2013 ($n = 22$) and spring–summer 2014 ($n = 24$).

Intervention and intervention content

A protocol was developed by the project group to standardize the AAA intervention across different units and dog handlers. The intervention consisted of a 30-min session with AAA twice weekly for 12 weeks in groups of three to six participants. The AAA sessions were led by a qualified dog handler.

For each session, the participants were randomly seated in a half-circle. Each session started with a greeting round, when each participant had the opportunity to pet the dog and feed it treats. Thereafter, the handler started the different activities, which included any of the following: petting the dog, feeding the dog a treat and throwing a toy for the dog to fetch. All activities were supposed to follow the protocol but should be individually tailored to each participant based on the health personnel's knowledge of the participant. However, no activities were mandatory, and the sessions therefore included activities that occurred between the participants and between each participant and the dog.

The control groups were not offered any new activities, and their treatment continued as usual, including diverse group activities such as reminiscence, music therapy, sensory garden, singing, exercise, cooking and handicrafts.

Copyright © 2016 John Wiley & Sons, Ltd.

Dogs and their handlers

Both dogs and their handlers were carefully selected for their suitability to work with AAIs. The dogs had to take and pass a mentality test containing different elements with respect to, for example, aggressiveness, sociability, anxiety and handling. Similarly, their handlers completed at least one course in AAIs for visiting dogs. To enhance the similarity between the 10 units, all handlers were informed about the protocol for the sessions both verbally and in writing.

All handlers, except one, had either a theoretical or practical background in health care or biological science.

Assessments and procedures for data collection

The instruments used in the study have all been tested for their validity and reliability and have been designed and/or are commonly used for older people with dementia. Prior to the start of the project, two health professionals from each nursing home unit attended lectures with instructions on how to use the instruments. They later scored all assessments at all three time points (T_0, T_1 and T_2).

Depression was measured using the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos *et al*., 1988; Barca *et al*., 2010); a validated Norwegian version was used (Korner *et al*., 2006). The scale contains 19 symptoms of depression in five domains (mood-related signs, behavioural disturbance, physical signs, cyclic functions and ideational disturbance). Each item is rated on a scale from absent, mild/intermittent to severe, with a sum score ranging from 0 to 38 (Cronbach's alpha = 0.74). A sum score below 6 indicates the absence of depressive symptoms, scores above 10 indicate probable major depression and scores above 18 indicate definite major depression (Alexopoulus *et al*., 1988).

Agitation and restlessness were measured using the Brief Agitation Rating Scale (BARS) (Finkel *et al*., 1993), derived from the 29-item Cohen-Mansfield Agitation Inventory (Cohen-Mansfield *et al*., 1989). The BARS is used to assess the presence and severity of physically aggressive, physically non-aggressive and verbally agitated behaviours in older nursing home residents. It is a seven-level scale of frequency from 1 (*never*) to 7 (*a few times per hour or continuously for half an hour or more*). The validated Norwegian version of the instrument (Swift *et al*., 2002; Sommer and Engedal, 2011) is a nine-item inventory with a sum score ranging from 9 to 63 (Cronbach's alpha = 0.76), where a high score indicates higher frequency of agitated behaviour.

Quality of life was measured using the validated Norwegian version of Quality of Life in Late-stage Dementia (QUALID) (Weiner *et al*., 2000; Røen *et al*., 2015). The scale consists of 11 items with a possible score of 1–5 on each item. The items are rated by frequency of occurrence, comprising both positive and negative dimensions of concrete and observable mood and performance. Scores are summed to range from 11 to 55 (Cronbach's alpha = 0.79). A low score indicates a high QoL.

The Clinical Dementia Rating Scale (CDR) is a 5-point scale used to assess six domains of cognitive and functional performance-applicable dementia (Hughes *et al*., 1982; Engedal and Haugen, 1993; Nygaard and Ruths, 2003). CDR staging is a valid substitute for a dementia assessment among nursing home residents to determine the severity of dementia (Engedal and Haugen, 1993; Nygaard and Ruths, 2003). A CDR of 0 implies *no cognitive impairment*, 0.5 *very mild dementia*, 1 *mild dementia*, 2 *moderate dementia* and 3 *severe dementia*.

The study participants' sociodemographic characteristics on age, gender, education, use of walking aids, social contact, hobbies and animal contact were collected at baseline (Table 1).

Ethics

The project was performed in accordance with the Helsinki Declaration and the Regional Committee for Medical and Health Research Ethics approved the project. Nursing staff at each participating nursing home allocated eligible participants, provided information about the study and obtained written consent. Written and verbal information about the study was given to the patients and their relatives by the primary caregiver. A procedure was developed for health personnel to evaluate the participants' cognitive capacity to give informed written consent. Those with sufficient cognitive capacity were informed about the project and gave written consent to participate. For those with reduced capacity, health personnel and/or the next of kin took this decision on their behalf and gave written consent. All participants were informed that they could withdraw from the study at any stage.

Statistical analyses

Prior to commencing the study, a power calculation was made using statistical software JMP version 12 (SAS Institute, Cary, SC, USA) with BARS as the

Copyright © 2016 John Wiley & Sons, Ltd.

Table 1 Demographic data for control and animal-assisted activity (AAA)

	Control ($n = 26$)	AAA ($n = 25$)	*p*-value
Gender, women (%)	17 (65.4)	15 (60.0)	0.69
Missing	0	0	
Age, mean (SD)	84.1 (6.7)	82.9 (8.5)	0.60
Missing	1	1	
Enjoy animal contact (%)	24 (92.3)	18 (72.0)	0.78
Missing	0	5 (20.0)	
Clinical Dementia Rating Scale (%)			0.72
0	0	0	
0.5	1 (3.9)	0	
1	1 (3.9)	2 (8.0)	
2	12 (46.2)	11 (44.0)	
3	12 (46.2)	12 (48.0)	
Missing	0	0	
Education (%)			0.20
Primary school	17 (65.4)	9 (36.0)	
Secondary school	4 (15.4)	3 (12.0)	
Higher education	3 (11.5)	2 (8.0)	
Other	2 (7.7)	3 (12.0)	
Missing	0	8 (32.0)	
Walking aids (%)			0.16
None	8 (30.8)	10 (40.0)	
Walking sticks	0	0	
Cane	3 (11.5)	1 (4.0)	
Crutches	0	0	
Rollator	8 (30.8)	12 (48.0)	
High walker	4 (15.4)	0	
Wheelchair	3 (11.5)	1 (4.0)	
Supported walking	0	1 (4.0)	
Missing	0	0	
Social contact (%)			0.10
Daily	0	2 (8.0)	
Several times per week	9 (34.6)	7 (28.0)	
Once per week	10 (38.5)	14 (56.0)	
Every other week	4 (15.4)	0	
Rare	3 (11.5)	1 (4.0)	
Missing	0	1 (4.0)	
Hobbies (%)			0.30
Cognitive activities	7 (26.9)	3 (12.0)	
Physical activities	11 (42.3)	8 (32.0)	
Other	1 (3.85)	2 (8.0)	
Combination	4 (15.4)	8 (32.0)	
Missing	3 (11.5)	4 (16.0)	

SD, standard deviation.

primary outcome measure. A power calculation for change of means in BARS with 80% probability of detecting differences between groups, alpha 0.05, and a least significant difference of 7.0 points ($SD = 8.4$) between the intervention group and the control group indicated a necessary total of 30 participants in each group at the respective units. The power calculation took into account a 20% dropout rate.

Intraclass correlation coefficient

To test the level of agreement between the different raters, health personnel from five units with the same training in BARS scored the same participants ($n = 28$), intraclass correlation (ICC) = 0.84 (single measures). Values between 0.75 and 1.0 are considered to indicate excellent interrater reliability (Hallgren, 2012). ICC was also used to test for cluster effect of facilities (ICC BARS = 0.02; ICC CSDD = -0.04; ICC QUALID = 0.28).

Missing data

The person mean substitution method was used to impute missing data on item level for CSDD, BARS and QUALID if three or fewer items were missing.

Analyses

All analyses were computed using statistical software IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. To assess the internal consistency of CSDD, BARS and QUALID, Cronbach's alpha was calculated for the sum scores, all of which showed acceptable consistency. One-way ANOVA for continuous data and chi-square for categorical data were used to test the differences in means between the intervention and control groups at T_0.

A mixed model was used to investigate changes over time and differences between the intervention group and the control group (West, 2009). The dependent variables were the three main types of assessment: CSDD, BARS and QUALID. Time was modelled as a repeated variable, and an autoregressive covariance structure (AR1) was used to accommodate dependencies between the three points in time. The type of intervention was included as fixed effect; nursing home within group was included as random effect. T_0 was used as reference point for time. The control group was set as the reference group. To accommodate different time trends between the groups, an interaction term was included between the intervention group and control group and points of time—the effect of interest in the study.

As severity of dementia is known to affect main assessments (Beerens *et al.*, 2013; Mjørud *et al.*, 2014a), also stratified analyses of cognitive and functional performance (CDR) were conducted. Before the analyses, CDR was dichotomized into either mild/moderate or severe dementia.

To test the clinically significant change in depression, a modified method developed by Teri *et al.* (1997) was used. The participants' sum scores for T_0, T_1 and T_2 were categorized into four levels according the administration and scoring guidelines for the CSDD by George S. Alexopoulos (2002). Subjects with

Copyright © 2016 John Wiley & Sons, Ltd.

a score that showed improvement on at least two levels from T_0 to T_1 or from T_0 to T_2 were considered as having a clinically significant improvement in their depression symptoms. A subanalysis using mixed models was used to test for the effect of attendance at the AAA sessions. Attendance was grouped into high (>90%) and low (<90%).

Results

No significant differences were found between the intervention group and the control group at baseline (Table 1). All of the participants in the control group had a dementia diagnosis, but five did not in the AAA group. For the latter participants, the mean mini-mental state examination was 13.80 ($SD = 6.61$, range: 7–23). There were 26 complete cases in the control group (65.4% women) and 25 in the intervention group (60% women). The mean age was 84.1 years in the control group and 82.9 years in the intervention group. Regarding CDR, 92% of the participants in each of the two groups scored moderate or severe on the rating scale. The majority of the participants reported that they enjoyed contact with animals.

The main effects of intervention and time are listed in Table 2. No significant effects of the intervention were found from T_0 to T_1 for depression in the total sample (Table 3). However, the intervention group had a continual decrease in the CSDD score, while the control group had a continual increase in the CSDD score, and a significant effect of the intervention was found from T_0 to T_2 (Table 3). When stratified on CDR, there was a close to and significant effect on depression from T_0 to T_1 ($p = 0.054$) and T_0 to T_2 ($p = 0.001$) among participants with severe dementia (Table 4). For participants with mild to moderate dementia, the intervention showed no significant effects.

Also the significant difference between the groups with regard to depression from T_0 to T_2 showed clinical significance. More participants in the AAA group improved than in the control group ($p = 0.03$) (Table 5). A total of eight (17%) participants in the intervention group improved by two levels on the CSDD score, from T_0 to T_2, but none in the control group. Three participants (6.4%) from both the AAA group and the control improved one level (Table 5).

There were no significant effects of the intervention on change in agitation from either T_0 to T_1 or T_0 to T_2 (Table 3) or when stratified on cognitive level (Table 4).

Significant effects of the intervention were found on QoL for persons with severe dementia from both T_0 to T_1 and T_0 to T_2 (Table 4). The control group showed an increase in the QUALID score over the study period, indicating a decline in QoL, whereas the AAA group showed a decrease in the QUALID score. There were no significant effects on QoL in the total sample (Table 3) or in persons with mild to moderate dementia (Table 4).

The number of sessions attended did not affect the outcome of the CSDD, BARS or QUALID scores (data not shown). The participation rate was high: 16 (64%) of the participants attended 90% or more of the group sessions.

Discussion

The main finding in the study was significant statistical and clinical improvement in symptoms of depression from baseline (T_0) to follow-up 12 weeks after end of the intervention (T_2) in the AAA group compared with the control group. The intervention effect on depression was found to be associated with severe dementia. For patients with severe dementia, the intervention also showed significant effects on QoL in the change from T_0 to T_1 and T_2. In the control group, the symptoms gradually worsened during the study period. The intervention showed no significant effects on agitation.

Although there have been inconsistent findings regarding the effect of AAI on depression in patients with dementia (Moretti *et al.*, 2011; Mossello *et al.*, 2011), the decline in symptoms found in the AAA group is in line with findings from earlier studies (Majic *et al.*, 2013; Friedmann *et al.*, 2015). In a similar study with AAI group intervention, Friedmann *et al.* (2015) found that depression decreased during the intervention period, while the reminiscing group, used for comparison, did not experience a decrease in depression. However, in contrast to the study reported in the present article, no significant effect was found between groups (Friedmann *et al.*, 2015). Majic *et al.* (2013) studied the effect of individual-based AAI on depression in nursing home residents. When using the Dementia Mood Assessment Scale, they found that while the control group worsened during the intervention period, the intervention group showed constant frequency and severity in symptoms of depression (Majic *et al.*, 2013).

The level of agitation observed at baseline was in line with a reliability study of the Norwegian version of BARS (mean 24.2, SD 12.6) (Sommer *et al.*, 2009) and indicate observed agitated behaviour once or twice per week. Agitation is one of the most difficult

Copyright © 2016 John Wiley & Sons, Ltd.

Table 2 Estimates of main effects of intervention and time for CSDD, BARS and QUALID

Estimates of main effects[1]						
Dependent variables	Control–intervention		$T_1 - T_0$		$T_2 - T_0$	
	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
CSDD	1.78	−2.88, 6.44	1.16	−1.38, 3.70	0.89	−1.29, 3.08
BARS	0.67	−9.65, 10.99	−1.25	−5.35, 2.86	−0.03	−3.24, 3.17
QUALID	1.00	−5.05, 7.06	−0.33	−3.74, 3.08	−0.63	−3.27, 2.00

CSDD, Cornell Scale for Depression in Dementia; BARS, Brief Agitation Rating Scale; QUALID, Quality of Life in Late-stage Dementia; T_0, pre-test; T_1, post-test; T_2, follow-up; CI, confidence interval..
[1]A mixed model was used to estimate main effects.

Table 3 CSDD, BARS and QUALID for control and AAA (mean ± SD) and estimates of fixed effects

				Estimates of fixed effects[1]							
				$T_1 - T_0$				$T_2 - T_0$			
Dependent variables	Pre-test (T_0)	Post-test (T_1)	Follow-up (T_2)	Estimate	t	p^2	95% CI	Estimate	t	p	95% CI
CSDD											
Control	6.88 ± 4.70 ($n = 26$)	8.28 ± 5.62 ($n = 25$)	9.58 ± 6.61 ($n = 24$)	−2.09	1.38	0.171	−5.09, 0.92	−3.73	2.11	0.037	−7.23, −0.23
AAA	8.35 ± 4.65 ($n = 23$)	7.86 ± 4.42 ($n = 22$)	7.41 ± 5.01 ($n = 22$)								
BARS											
Control	23.19 ± 11.39 ($n = 26$)	24.65 ± 13.95 ($n = 26$)	24.00 ± 13.20 ($n = 25$)	−1.43	0.64	0.525	−5.88, 3.02	0.50	0.17	0.864	−6.20, 5.21
AAA	23.44 ± 7.64 ($n = 25$)	23.75 ± 7.13 ($n = 24$)	24.87 ± 8.34 ($n = 23$)								
QUALID											
Control	22.92 ± 8.50 ($n = 26$)	25.31 ± 10.26 ($n = 26$)	26.48 ± 10.05 ($n = 25$)	−1.75	0.95	0.344	−5.41, 1.92	3.60	1.50	0.136	−8.34, 1.15
AAA	23.92 ± 6.99 ($n = 25$)	24.80 ± 5.79 ($n = 24$)	24.57 ± 6.58 ($n = 23$)								

CSDD, Cornell Scale for Depression in Dementia; BARS, Brief Agitation Rating Scale; QUALID, Quality of Life in Late-stage Dementia; AAS, animal-assisted activity; CI, confidence interval.
[1]A mixed model was used to estimate time trends between the groups.
[2]Significance level 0.05.

NPS to manage in dementia patients. The lack of a significant effect on agitation is in line with findings from other AAI studies (Nordgren and Engstrom, 2014a; Friedmann *et al.*, 2015; Thodberg *et al.*, 2015), although some early research have reported positive effects (McCabe *et al.*, 2002; Richeson, 2003; Sellers, 2006).

Older persons with dementia often have a diminished QoL (Bárrios *et al.*, 2012). This was confirmed in the results of the study as there was a substantial decrease in QoL over time in participants with severe dementia in the control group. AAA was found to have an effect on both QoL and depression in the group of patients with severe dementia. It is possible that the AAA intervention might have been of particular value for this group, as patients with severe dementia have been found to have a high prevalence of unmet needs regarding meaningful activities and social contact (Cohen-Mansfield *et al.*, 2015). Not only might being part of a group intervention where a dog is the centre of attention reduce the pressure in social interaction, but also the dog might serve as a

Copyright © 2016 John Wiley & Sons, Ltd.

Table 4 CSDD, BARS, QUALID stratified on CDR for control and AAA (mean ± SD) and estimates of fixed effects

Dependent variables	Pre-test (T_0)	Post-test (T_1)	Follow-up (T_2)	Estimates of fixed effects[1]							
				$T_1 - T_0$				$T_2 - T_0$			
				Estimate	t	p^2	95% CI	Estimate	t	p	95% CI
CSDD mild/moderate dementia											
Control	6.36 ± 5.56 ($n = 14$)	8.15 ± 6.09 ($n = 13$)	10.50 ± 8.18 ($n = 14$)	−1.81	0.66	0.513	−7.35, 3.73	−4.46	1.45	0.151	−10.58, 1.67
AAA	8.77 ± 6.39 ($n = 13$)	9.36 ± 6.02 ($n = 11$)	8.55 ± 6.64 ($n = 11$)								
CSDD severe dementia											
Control	11.25 ± 6.74 ($n = 12$)	12.92 ± 8.08 ($n = 12$)	16.70 ± 11.72 ($n = 10$)	−5.04	1.99	0.054	−10.17, 0.09	−11.00	3.67	0.001	−17.01,−5.00
AAA	13.50 ± 5.28 ($n = 10$)	11.00 ± 6.91 ($n = 11$)	7.91 ± 5.43 ($n = 11$)								
BARS mild/moderate dementia											
Control	21.43 ± 10.09 ($n = 14$)	21.71 ± 12.63 ($n = 14$)	21.79 ± 11.40 ($n = 14$)	0.48	−.017	0.866	−5.23, 6.20	−0.09	0.03	0.980	−7.40, 7.21
AAA	21.92 ± 6.13 ($n = 13$)	22.69 ± 5.92 ($n = 13$)	21.92 ± 8.80 ($n = 12$)								
BARS severe dementia											
Control	25.25 ± 12.88 ($n = 12$)	28.08 ± 15.17 ($n = 12$)	26.82 ± 15.27 ($n = 11$)	−3.68	1.02	0.317	−11.04, 3.67	−0.95	0.24	0.811	−8.89, 6.99
AAA	25.08 ± 8.99 ($n = 12$)	25.00 ± 8.47 ($n = 11$)	28.09 ± 6.77 ($n = 11$)								
QUALID mild/moderate dementia											
Control	20.36 ± 5.96 ($n = 14$)	23.07 ± 9.50 ($n = 14$)	23.00 ± 6.56 ($n = 14$)	1.05	−0.40	0.692	−4.27, 6.38	1.47	−0.47	0.643	−4.85, 7.79
AAA	21.46 ± 7.00 ($n = 13$)	25.23 ± 5.10 ($n = 13$)	25.83 ± 8.08 ($n = 12$)								
QUALID severe dementia											
Control	25.91 ± 10.21 ($n = 12$)	27.92 ± 10.90 ($n = 12$)	30.91 ± 12.15 ($n = 11$)	−5.08	2.33	0.035	−9.79, −0.37	−9.79	3.15	0.003	−16.03,−3.54
AAA	26.58 ± 6.17 ($n = 12$)	24.27 ± 6.72 ($n = 11$)	23.18 ± 4.40 ($n = 11$)								

Cornell Scale for Depression in Dementia (CSDD), Brief Agitation Rating Scale (BARS), and Quality of Life in Late-stage Dementia (QUALID); AAS, animal-assisted activity; CI, confidence interval.
[1]A mixed model was used to estimate time trends between the groups.
[2]Significance level 0.05.

mediator for conversation and lead to social cohesion within the group (Beetz *et al.*, 2012). The effect found at T_2 for both depression and QoL may indicate that the intervention initiated a process that continued beyond the end of intervention period. The intervention may have contributed to an increase in social interaction in general between the participants and staff. Earlier research has shown that AAI might improve social behaviour (Filan and Llewellyn-Jones, 2006), increase social interactions and conversations (Bernstein *et al.*, 2000; Kramer *et al.*, 2009) and reduce loneliness (Banks and Banks, 2002).

The study had several weaknesses that should be considered when interpreting the results. Generalization of the results should be done with caution because both the recruitment of the nursing homes and participants might have been biased towards those who regarded AAA as a positive activity.

Copyright © 2016 John Wiley & Sons, Ltd.

Table 5 Clinically significant change on subject level in Cornell Scale for Depression in Dementia (chi-square and *p*-value)

		$T_1 - T_0$		$T_2 - T_0$	
		Control group ($n = 26$) N (%)	AAA group ($n = 23$) N (%)	Control group ($n = 25$) N (%)	AAA group ($n = 22$) N (%)
Improved	−3.00	0 (0)	1 (2.0)	0 (0)	0 (0)
	−2.00	2 (4.1)	2 (4.1)	0 (0)	8 (17.0)
	−1.00	4 (8.2)	4 (8.2)	3 (6.4)	3 (6.4)
No change	0.00	11 (22.4)	11 (22.4)	13 (68.4)	6 (31.6)
Worse	1.00	7 (14.3)	5 (10.2)	5 (10.6)	3 (6.4)
	2.00	1 (2.0)	0 (0)	3 (12)	2 (4.3)
	3.00	1 (2.0)	0 (0)	1 (2.1)	0 (0)
		$\chi^2 = 3.16$, $p = 0.79$		$\chi^2 = 12.14$, $p = 0.03$	

T_0, pre-test; T_1, post-test; T_2, follow-up; AAS, animal-assisted activity.

The instruments used to measure the outcomes were standardized, validated and reliable (Swift *et al.*, 2002; Korner *et al.*, 2006; Barca *et al.*, 2010; Sommer and Engedal, 2011); moreover, an excellent interrater reliability was found. However, the raters were not blind to whether the participants were part of an AAA group or a control group. Although this might have influenced the positive change seen for depression and QoL, the trend towards increased agitation indicates that raters were not biased.

When using treatment as usual as a control condition, there is always a possibility that any observed effect of the intervention is merely a novelty effect. However, all participants in the study were offered a range of regular activities, and the AAA were additional to these. Using another activity as control condition would therefore be both difficult in practice and imply a wish to compare different interventions' effectiveness, which was not within the scope of the study. Furthermore, it could be argued that the dog handler, not the dog, is the decisive factor in AAIs. By definition, AAA implies a human and animal team, and using a control condition without a dog was therefore not considered.

A strength of the study lies in its design, as randomized controlled trials are the most robust evaluative method (Puffer *et al.*, 2005). Methodological issues in cluster randomized trials are straightforward and manageable (Murphy *et al.*, 2006), and we considered these issues carefully. The assessment of the long-term effects is a further strength of our study. The moderate dropout rate (17%) was as expected, because of the population's age and progressive decease.

There is a need for high-quality research in non-pharmacological interventions for older people with dementia (Iden *et al.*, 2014), and the present results contribute to a better understanding of the feasibility and effect of AAA programmes for older people with dementia. The fact that the statistical difference in the CSDD also showed significant clinical relevance renders the results valuable for clinical practice.

Conclusion

The significant improvements in depression and QoL show that complementary treatment such as AAA may be useful in dementia care. The effects were found for persons with severe dementia, which supports the importance of individually tailored interventions where participants' cognitive and functional levels are taken into account.

Conflict of interest

The first-named author owns a share in the Norwegian Centre of Anthrozoology, which was a partner in the study project.

Key points

- The prevalence of neuropsychiatric symptoms in cognitively impaired nursing home residents is high.
- Non-pharmacological treatment is recommended.
- Significant improvements to both the severity of depression and quality of life were found in persons with severe dementia in the animal-assisted intervention group compared with the control group.
- Animal-assisted activity may be effective in dementia care.

Acknowledgements

The project was funded by grant no. 217516 from Oslofjordfondet and RFF Hovedstaden, NMBU, and cooperating partners (the Norwegian Centre of Anthrozoology, Buskerud, and Vestfold University College, Centre for Development of Institutional and Home Care Services, Vestfold). Cooperating partners supported the project through internal funding.

The authors also thank the participants, the nursing homes and health workers, the dogs and their handlers and the cooperating partners.

Copyright © 2016 John Wiley & Sons, Ltd.

References

Aalten P, de Vugt ME, Jaspers N, Jolles J, Verhey FR. 2005. The course of neuropsychiatric symptoms in dementia. Part I: findings from the two-year longitudinal Maasbed study. *Int J Geriatr Psychiatry* **20**: 523–530.

Alexopoulos GS. 2002. The Cornell Scale for Depression in Dementia: Administration and Scoring Guidelines, WMCoCU Cornell Institute of Geriatric Psychiatry (ed.)(ed.).. Weill Medical College of Cornell University: White Plains, NY; 10.

Alexopoulos GA, Abrams RC, Young RC, Shamoian CA. 1988. Cornell scale for depression in dementia. *Biol Psychiatry* **23**: 271–284. Til norsk ved Dag Årsland.

Alexopoulus GS, Abrams RC, Young RC. 1988. Cornell scale for depression in dementia. *Biol Psychiatry* **23**: 271–284.

Banks MR, Banks WA. 2002. The effects of animal-assisted therapy on loneliness in an elderly population in long-term care facilities. *J Gerontol A Biol Sci Med Sci* **57**: 428–432.

Barca ML, Engedal K, Selbæk G. 2010. A reliability and validity study of the Cornell scale among elderly inpatients, using various clinical criteria. *Dement Geriatr Cogn Disord* **29**: 438–447.

Barca ML, Engedal K, Laks J, Selbæk G. 2011. Quality of life among elderly patients with dementia in institutions. *Dement Geriatr Cogn Disord* **31**: 435–442.

Bárrios H, Narciso S, Guerreiro M, *et al.* 2012. Quality of life in patients with mild cognitive impairment. *Aging Ment Health* **17**: 287–292.

Beerens HC, Zwakhalen SM, Verbeek H, Ruwaard D, Hamers JP. 2013. Factors associated with quality of life of people with dementia in long-term care facilities: a systematic review. *Int J Nurs Stud* **50**: 1259–1270.

Beetz A, Uvnas-Moberg K, Julius H, Kotrschal K. 2012. Psychosocial and psychophysiological effects of human-animal interactions: the possible role of oxytocin. *Front Psychol* **3**: 234.

Bernstein PL, Friedmann E, Malaspina A. 2000. Animal-assisted therapy enhances resident social interaction and initiation in long-term care facilities. *Anthrozoös* **13**: 213–224.

Cohen-Mansfield J, Marx MS, Rosenthal AS. 1989. A description of agitation in a nursing home. *J Gerontol Biol Med Sci* **44**: M77–M84.

Cohen-Mansfield J, Dakheel-Ali M, Marx MS, Thein K, Regier NG. 2015. Which unmet needs contribute to behavior problems in persons with advanced dementia? *Psychiatry Res* **228**: 59–64.

Douglas S, James I, Ballard C. 2004. Non-pharmacological interventions in dementia. *Adv Psychiatr Treat* **10**: 171–177.

Engedal K, Haugen PK. 1993. The prevalence of dementia in a sample of elderly Norwegians. *Int J Geriatr Psychiatry* **8**: 565–570.

Filan SL, Llewellyn-Jones RH. 2006. Animal-assisted therapy for dementia: a review of the literature. *Int Psychogeriatr/IPA* **18**: 597–611.

Finkel SI, Lyons JS, Anderson RL. 1993. A brief agitation rating scale (BARS) for nursing home elderly. *J Am Geriatr Soc* **41**: 50–52.

Folstein MF, Folstein SE, McHugh PR. 1975. 'Mini-mental state'. A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* **12**: 189–198.

Friedmann E, Galik E, Thomas SA, *et al.* 2015. Evaluation of a pet-assisted living intervention for improving functional status in assisted living residents with mild to moderate cognitive impairment: a pilot study. *Am J Alzheimers Dis Other Demen* **30**: 276–289.

Geldmacher DS, Frolich L, Doody RS, *et al.* 2006. Realistic expectations for treatment success in Alzheimer's disease. *J Nutr Health Aging* **10**: 417–429.

Hallgren KA. 2012. Computing inter-rater reliability for observational data: an overview and tutorial. *Tutor Quant Methods Psychol* **8**: 23–34.

Hughes CP, Berg L, Danziger WL, Coben LA, Martin RL. 1982. A new clinical scale for the staging of dementia. *Br J Psychiatry* **140**: 566–572.

IAHAIO. 2014. IAHAIO White Paper. In The IAHAIO Definitions for Animal Assisted Intervention and Guidelines for Wellness of Animals Involved. Amsterdam: International Association of Human-Animal Interaction Organizations.

Iden KR, Engedal K, Hjorleifsson S, Ruths S. 2014. Prevalence of depression among recently admitted long-term care patients in Norwegian nursing homes: associations with diagnostic workup and use of antidepressants. *Dement Geriatr Cogn Disord* **37**: 154–162.

van Iersel MB, Hoefsloot W, Munneke M, Bloem BR, Olde Rikkert MG. 2004. Systematic review of quantitative clinical gait analysis in patients with dementia. *Z Gerontol Geriatr* **37**: 27–32.

Korner A, Lauritzen L, Abelskov K, *et al.* 2006. The Geriatric Depression Scale and the Cornell Scale for Depression in Dementia. A validity study. *Nord J Psychiatry* **60**: 360–364.

Kramer SC, Friedmann E, Bernstein PL. 2009. Comparison of the effect of human interaction, animal-assisted therapy, and AIBO-assisted therapy on long-term care residents with dementia. *Anthrozoös* **22**: 43–57.

Lobo A, Launer LJ, Fratiglioni L, *et al.* 2000. Prevalence of dementia and major subtypes in Europe: a collaborative study of population-based cohorts. Neurologic diseases in the elderly research group. *Neurology* **54**: S4–S9.

Lyketsos CG, Lopez O, Jones B, *et al.* 2002. Prevalence of neuropsychiatric symptoms in dementia and mild cognitive impairment: results from the cardiovascular health study. *JAMA* **288**: 1475–1483.

Majic T, Gutzmann H, Heinz A, Lang UE, Rapp MA. 2013. Animal-assisted therapy and agitation and depression in nursing home residents with dementia: a matched case–control trial. *Am J Geriatr Psychiatr* **21**: 1052–1059.

McCabe BW, Baun MM, Speich D, Agrawal S. 2002. Resident dog in the Alzheimer's special care unit. *West J Nurs Res* **24**: 684–696.

McKhann G, Drachman D, Folstein M, *et al.* 1984. Clinical diagnosis of Alzheimer's disease: report of the NINCDS-ADRDA work group under the auspices of Department of Health and Human Services Task Force on Alzheimer's Disease. *Neurology* **34**: 939–944.

Mjørud M, Kirkevold M, Rosvik J, Selbæk G, Engedal K. 2014a. Variables associated to quality of life among nursing home patients with dementia. *Aging Ment Health* **18**: 1013–1021.

Mjørud M, Røsvik J, Rokstad AMM, Kirkevold M, Engedal K. 2014b. Variables associated with change in quality of life among persons with dementia in nursing homes: a 10 months follow-up study. *PLoS One* **9**: e115248: .

Moretti F, De Ronchi D, Bernabei V, *et al.* 2011. Pet therapy in elderly patients with mental illness. *Psychogeriatrics* **11**: 125–129.

Mossello E, Ridolfi A, Mello AM, *et al.* 2011. Animal-assisted activity and emotional status of patients with Alzheimer's disease in day care. *Int Psychogeriatr/IPA* **23**: 899–905.

Murphy AW, Esterman A, Pilotto LS. 2006. Cluster randomized controlled trials in primary care: an introduction. *Eur J Gen Pract* **12**: 70–73.

Nagatomo I, Kita K, Takigawa M, Nomaguchi M, Sameshima K. 1997. A study of the quality of life in elderly people using psychological testing. *Int J Geriatr Psychiatry* **12**: 599–608.

Nordgren L, Engstrom G. 2014a. Animal-assisted intervention in dementia: effects on quality of life. *Clin Nurs Res* **23**: 7–19.

Nordgren L, Engstrom G. 2014b. Effects of dog-assisted intervention on behavioural and psychological symptoms of dementia. *Nurs Older People* **26**: 31–38.

Nygaard HA. 2002. Sykehjemmet som medisinsk institusjon—et fatamorgana? *Tidsskr Nor Laegeforen* **122**: 823–825.

Nygaard HA, Ruths S. 2003. Missing the diagnosis: senile dementia in patients admitted to nursing homes. *Scand J Prim Health Care* **21**: 148–152.

Puffer S, Torgerson DJ, Watson J. 2005. Cluster randomized controlled trials. *J Eval Clin Pract* **11**: 479–483.

Richeson NE. 2003. Effects of animal-assisted therapy on agitated behaviors and social interactions of older adults with dementia. *Am J Alzheimers Dis Other Demen* **18**: 353–358.

Røen I, Selbæk G, Kirkevold O, *et al.* 2015. The reliability and validity of the Norwegian version of the quality of life in late-stage dementia scale. *Dement Geriatr Cogn Disord* **40**: 233–242.

Seitz DP, Adunuri N, Gill SS, *et al.* 2011. Antidepressants for agitation and psychosis in dementia. *Cochrane Database Syst Rev*. DOI: 10.1002/14651858.CD008191.pub2 Alternate journal: The Cochrane database of systematic reviews, ISSN: 1361-6137.

Selbæk G. 2005. Atferdsforstyrrelser og psykologiske symptomer ved demens. *Tidsskr Norske Lægeforening* **125**: 1500–1502.

Selbæk G, Kirkevold Ø, Engedal K. 2007a. The prevalence of psychiatric symptoms and behavioural disturbances and the use of psychotropic drugs in Norwegian nursing homes. *Int J Geriatr Psychiatry* **22**: 843–849.

Selbæk G, Kirkevold Ø, Engedal K. 2007b. The prevalence of psychiatric symptoms and behavioural disturbances and the use of psychotropic drugs in Norwegian nursing homes. *Int J Geriatr Psychiatry* **22**: 843–849.

Sellers DM. 2006. The evaluation of an animal assisted therapy intervention for elders with dementia in long-term care. *Activities, Adaptation & Aging* **30**: 61–77.

Sommer OH, Engedal K. 2011. Reliability and validity of the Norwegian version of the Brief Agitation Rating Scale (BARS) in dementia. *Aging Ment Health* **15**: 252–258.

Sommer OH, Aga O, Cvancarova M, *et al.* 2009. Effect of oxcarbazepine in the treatment of agitation and aggression in severe dementia. *Dement Geriatr Cogn Disord* **27**: 155–163.

Strobel C, Engedal K. 2009. Norsk Revidert Mini Mental Status Evaluering (MMSE-NR).

Swift RH, Harrigan EP, Cappelleri JC, Kramer D, Chandler LP. 2002. Validation of the behavioural activity rating scale (BARS)™: a novel measure of activity in agitated patients. *J Psychiatr Res* **36**: 87–95.

Telenius EW, Engedal K, Bergland A. 2013. Physical performance and quality of life of nursing-home residents with mild and moderate dementia. *Int J Environ Res Public Health* **10**: 6672–6686.

Teri L, Logsdon RG, Uomoto J, McCurry SM. 1997. Behavioral treatment of depression in dementia patients: a controlled clinical trial. *J Gerontol B Psychol Sci Soc Sci* **52B**: P159–P166.

Thodberg K, Sorensen LU, Christensen JW, *et al.* 2015. Therapeutic effects of dog visits in nursing homes for the elderly. *Psychogeriatrics*. DOI: 10.1111/psyg.12159 ISSN: 1346-3500.

Tripathi M, Vibha D. 2010. An approach to and the rationale for the pharmacological management of behavioral and psychological symptoms of dementia. *Ann Indian Acad Neurol* **13**: S94–S98.

Weiner MF, Martin-Cook K, Svetlik DA, *et al.* 2000. The quality of life in late-stage dementia (QUALID) scale. *J Am Med Dir Assoc* **1**: 114–116.

West BT. 2009. Analyzing longitudinal data with the linear mixed models procedure in SPSS. *Eval Health Prof* **32**: 207–228.

Copyright © 2016 John Wiley & Sons, Ltd.