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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], 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, Netherlands

[4] Faculty of Health and Social Work Studies, Østfold University College, Fredrikstad, Norway

Running head: Animal-assisted interventions for dementia patients

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

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 was found in persons with severe dementia in the animal-assisted intervention group compared to the control group
- Animal-assisted activity may be effective in dementia care

Corresponding author: Christine Olsen, Section for Public Health Science, Department of Landscape, Architecture and Spatial Planning, PO Box 5003, NO-1432 Ås, Norway, Telephone: +47 90682983, E-mail: christine.olsen@nmbu.no

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Abstract

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 three months after end of intervention. 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 recruited: 28 in the intervention group and 30 in the control group. The intervention consisted of a 30-minute session with AAA twice weekly for 12 weeks in groups of 5–7 participants, led by a qualified dog handler. Norwegian versions of the Cornell Scale for Depression (CSDD), The Brief Agitation Rating Scale (BARS) and the Quality of Life in Late-stage Dementia (QUALID) scale.

Results: 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: AAA may have a positive effect on symptoms of depression and QoL in elderly people with dementia, especially those in a late stage.

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 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 two-year longitudinal study, Aalten *et al.* (2005) found that 95% of the patients developed one or more NPS. Lyketsos *et al.* 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 (Lyketsos*, et al.* 2002). 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 (Barca*, et al.* 2011; Mjørud*, et al.* 2014a; Nagatomo*, et al.* 1997; Telenius*, et al.* 2013).

As population ages, health care and social services face increased demands to provide services for elderly people with dementia or cognitive impairment. Since 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). Iden *et al.*'s finding that antidepressants had been prescribed for 44% of their study participants, indicates extensive use (Iden *et al.* 2014). 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 (Friedmann*, et al.* 2015; Majic*, et al.* 2013; Mossello*, et al.* 2011; Nordgren and Engstrom 2014a, b; Richeson 2003; 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 due 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 three-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 three 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 three 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 5 and 8 participants each. The inclusion criteria were: 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; 7 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 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-minute session with AAA twice weekly for 12 weeks in groups of 3–7 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.

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 elderly 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 probable major depression, and scores above 18 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 (CMAI) (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 elderly nursing home residents. It is a 7-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 (Sommer and Engedal 2011; Swift*, et al.* 2002) is a 9-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) (Røen*, et al.* 2015; Weiner*, et al.* 2000). 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 (Engedal and Haugen 1993; Hughes*, et al.* 1982; 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, 2 = moderate, 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 with BARS as the 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 (ICC) 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), 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 Version 22.0. 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 (Alexopoulos 2002). Subjects with 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 (MMSE) 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 8 (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 to 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 (Friedmann *et al.* 2015; Majic *et al.* 2013). 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 (DMAS), 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 NPS to manage in dementia patients. The lack of a significant effect on agitation is in line with findings from other AAI studies (Friedmann *et al.* 2015; Nordgren and Engstrom 2014a; Thodberg *et al.* 2015), although some early research have reported positive effects (McCabe*, et al.* 2002; Richeson 2003; Sellers 2006). Elderly 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). Being part of a group intervention where a dog is the centre of attention might not only reduce the pressure in social interaction, but also the dog might serve as a 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.

The instruments used to measure the outcomes were standardized, validated and reliable (Barca *et al.* 2010; Korner *et al.* 2006; Sommer and Engedal 2011; Swift *et al.* 2002); 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 toward 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 drop-out rate (17%) was as expected, due to the population's age and progressive decease.

There is a need for high-quality research in non-pharmacological interventions for elderly 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 elderly 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.

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Tables

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)	

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

	Estimates of main effects[1]					
	Control – Intervention		$T_1 - T_0$[3]		$T_2 - T_0$	
Variables[2]	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

Notes: [1]A mixed model was used to estimate main effects; [2]Dependent variables: Cornell Scale for Depression in Dementia (CSDD), Brief Agitation Rating Scale (BARS), and Quality of Life in Late-stage Dementia (QUALID); [3]T_0 = pre-test, T_1 = post-test, T_2 = follow-up

Table 3 CSDD, BARS and QUALID for control and animal-assisted activity (AAA) (mean ± SD), and estimates of fixed effects.

				Estimates of fixed effects[1]							
				$T_1 - T_0$				$T_2 - T_0$			
Variables[2]	Pre-test (T_0)	Post-test (T_1)	Follow-up (T_2)	Estimate	*t*	*P*[3]	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)								

Notes: [1]A mixed model was used to estimate time trends between the groups; [2]Dependent Variables: Cornell Scale for Depression in Dementia (CSDD), Brief Agitation Rating Scale (BARS), and Quality of life in Late-stage Dementia (QUALID); [3]Significance level 0.05

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

				Estimates of fixed effects[1]							
				$T_1 - T_0$				$T_2 - T_0$			
Variables[2]	Pre-test (T_0)	Post-test (T_1)	Follow-up (T_2)	Estimate	*t*	*P*[3]	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)								

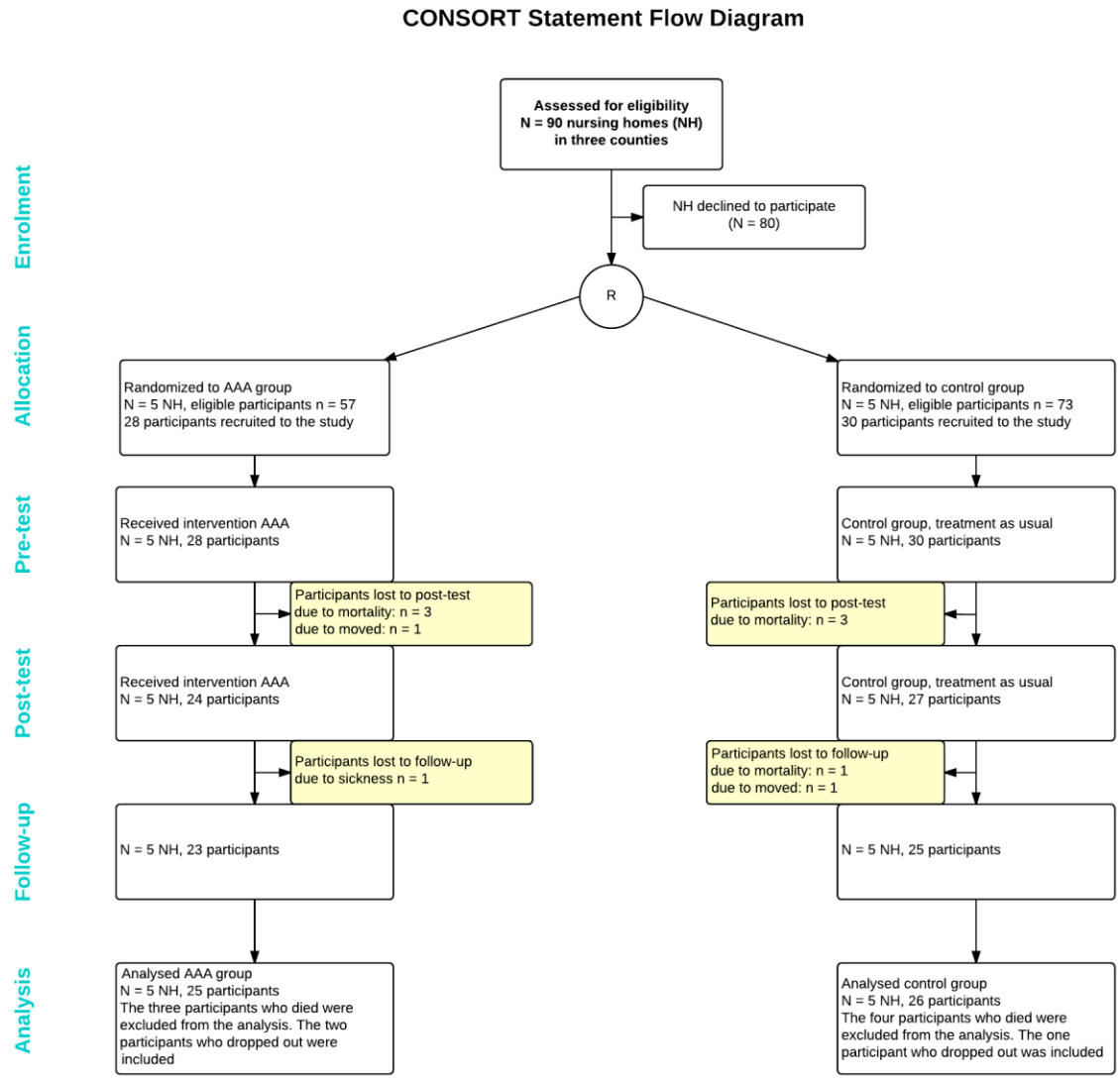
Notes: [1] A mixed model was used to estimate time trends between the groups; [2]Dependent variables: Cornell Scale for Depression in Dementia (CSDD), Brief Agitation Rating Scale (BARS), and Quality of Life in Late-stage Dementia (QUALID); [3]Significance level 0.05

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

		$T_1 - T_0$[1]		$T_2 - T_0$	
		Control group (n=26)	AAA group (n=23)	Control group (n=25)	AAA group (n=22)
		N (%)	N (%)	N (%)	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)
		$x^2 = 3.16$, p = 0.79		$x^2 = 12.14$, p = 0.03	

Notes: [1]T_0 = pre-test, T_1 = post-test, T_2 = follow-up

Figures


CONSORT Statement Flow Diagram
Enrolment
Allocation
Pre-test
Post-test
Follow-up
Analysis
Assessed for eligibility
N = 90 nursing homes (NH)
in three counties
NH declined to participate
(N = 80)
R
Randomized to AAA group
N = 5 NH, eligible participants n = 57
28 participants recruited to the study
Randomized to control group
N = 5 NH, eligible participants n = 73
30 participants recruited to the study
Received intervention AAA
N = 5 NH, 28 participants
Control group, treatment as usual
N = 5 NH, 30 participants
Participants lost to post-test
due to mortality: n = 3
due to moved: n = 1
Participants lost to post-test
due to mortality: n = 3
Received intervention AAA
N = 5 NH, 24 participants
Control group, treatment as usual
N = 5 NH, 27 participants
Participants lost to follow-up
due to sickness n = 1
Participants lost to follow-up
due to mortality: n = 1
due to moved: n = 1
N = 5 NH, 23 participants
N = 5 NH, 25 participants
Analysed AAA group
N = 5 NH, 25 participants
The three participants who died were
excluded from the analysis. The two
participants who dropped out were
included
Analysed control group
N = 5 NH, 26 participants
The four participants who died were
excluded from the analysis. The one
participant who dropped out was included