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Feature Article

Effect of animal-assisted activity on balance and quality of life in home-dwelling persons with dementia

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ABSTRACT

Purpose of the study was to examine if animal-assisted activity with a dog (AAA) in home-dwelling persons with dementia (PWDs) attending day-care centers would have an effect on factors related to risk of fall accidents, with balance (Berg balance scale) and quality of life (Quality of Life in Late-stage Dementia) as main outcome. The project was conducted as a prospective and cluster-randomized multicenter trial with a follow-up. 16 adapted day-care centers recruited respectively 42 (intervention group) and 38 (control group with treatment as usual) home-dwelling PWDs. The intervention consisted of 30 min sessions with AAA led by a qualified dog handler twice a week for 12 weeks in groups of 3–7 participants. The significant positive effect on balance indicates that AAA might work as a multifactorial intervention in dementia care and have useful clinical implication by affecting risk of fall.

Trial registrations: ClinicalTrials.gov; NCT02008630.

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Introduction

A World Health Organization (WHO) report on aging and health, published in 2015 (WHO^e), suggests there should be a shift in focus from diseases and morbidity to functional ability,¹ and therefore future studies of aging should be more specific when defining healthy aging and, in addition to describing patterns of morbidity and mortality, it is advisable to look at physical and cognitive function.^{1,2} Functional ability is the key for living good independent lives throughout the life course and obtaining a high quality of life (QoL).¹

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^e WHO – World Health Organization, PWDs – persons with dementia, QoL – quality of life, AAI – animal-assisted intervention, AAA – animal-assisted activity, MMSE – Mini-Mental State Examination, BBS – Berg Balance Scale, QUALID – Quality of Life in Late-stage Dementia, CDR – Clinical Dementia Rating (scale).

For many older people an independent life means living in their own place of residence. In Norway, about half of the total population of persons with dementia (PWDs) live in their own homes.³ People's ability to live at home as long as possible is a political goal in Norway and considered a human right.^{4,5} Part of reaching the political goal is the development of day-care centers for PWDs. Day-care centers have been described as offering respite care, with main aim to provide meaningful activities for home-dwelling PWDs.⁶

One type of activity that can be provided at day-care centers is animal-assisted interventions (AAIs), and these have become widely used among older people and especially dementia patients, as shown in several reviews.^{7–10} An AAI is defined 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.'¹¹ Animal-assisted activities (AAAs) are one type of AAI and include, for example, dogs and their handlers who visit for 'meet-and-greet' activities.¹¹ Most studies of AAIs have focused on the interventions' impacts on social outcomes,^{12–15} behavioral and psychological outcomes,^{16–20} and physiological outcomes,^{21–23} many of which are regarded as risk factors associated with falls. However, there are fewer studies of the effect of AAIs on performance-based physical outcomes and the results from these studies are inconsistent.^{19,24}

Balance is a central function in most activities of daily living²⁵ and is associated with QoL.²⁶ It has been shown that levels of physical activity decline with increasing age²⁷ and therefore in order to prevent falls it is important for people to maintain their physical performance as they age, particularly their strength and balance.²⁸ Complex interventions targeting several risk factors related to falls have been considered most effective for reducing the risk of falls and are therefore recommended.^{29,30} A model by Horak suggests that effective rehabilitation of balance requires an understanding of the many systems underlying postural control such as cognitive processing (attention and learning), biomechanical restraints (strength and limits of stability), sensory strategies, movement strategies, orientation in space, and control of dynamics.³¹

As stated by WHO, independent living and PWDs' QoL should be in focus. QoL has been a subject of great interest in assessments of the outcomes of medical and social interventions, and the need to improve PWDs' QoL is increasingly acknowledged.³² QoL is a multidimensional concept, which in older adults includes behavioral competence, the objective environment, psychological well-being, and perceived QoL.³³ QoL among elderly PWDs is often diminished³⁴ due to several factors such as low cognitive function, major depression, lack of social activities, impaired mobility, and low performance in activities of daily living.^{26,35–37} It is documented that older people consider good functioning to be of higher importance than the prevention of diseases,³⁸ and PWDs with higher physical capabilities, such as strength and balance, have scored higher on QoL.²⁶ Further, a study demonstrated that AAA had a positive effect on the QoL of PWDs living in nursing homes,²⁰ but it is not known whether the effect would be the same among home-dwelling PWDs.

Based on previous research on AAls and PWDs' need for meaningful activities,³⁹ research on the effect of AAls on the physical outcome 'balance' would be of great interest. Moreover, there has been a lack of research on the effect of AAls in home-dwelling PWDs in general.

The main aim of the study on which this article is based was therefore to examine whether, in the context of in home-dwelling PWDs attending day-care centers, AAAs would have an effect on factors related to the risk of fall accidents, with balance and QoL as main outcomes.

Material and methods

Design

The study was conducted as a prospective and cluster-randomized multicentre trial with a follow-up study. The project is registered in ClinicalTrials.gov, a service of the USA's National Institutes of Health (identifier: NCT02008630).

A total of 16 adapted day-care centers for home-dwelling PWDs in the Norwegian counties of Østfold, Vestfold, Oslo, and Akershus were recruited to the project. After recruitment, each day-care center was randomized, by computerized random numbers at Uni Helse in Bergen, to either animal-assisted activity with a dog (AAA) or to a control group with treatment as usual, which means they continued routine care in their respective settings.

The day-care centers included in the study all provided the facilities required to carry out the interventions. They also abstained from any activities involving dog visits for three months prior to the intervention, as well as during the whole intervention and follow-up.

After randomization, each day-care center was asked to recruit between 5 and 8 home-dwelling participants.

Data were collected at pre-test before the intervention started (T_0), when the intervention finished (T_1), and at follow-up three months after the end of the intervention (T_2).

Participants and recruitment

The recruited participants were at the age of 65 years or older and had either a diagnosis of dementia or a cognitive deficit measured as a score of less than 25 on the Mini-Mental State Examination (MMSE).^{40,41} Participants with a fear of dogs or with a dog allergy were not included.

A total of 80 participants were included in the study: 42 in the intervention group and 38 in the control group (Fig. 1). One of the participants in the intervention group withdrew and was therefore excluded from the analysis. The study was conducted during three periods: winter–spring 2013 ($n = 17$), autumn–winter 2013 ($n = 30$), and spring–summer 2014 ($n = 32$).

Procedure

The testers were health-care personnel working at the day-care centers. Prior to the start of the study they received mandatory lectures on how to use the Quality of Life in Late-stage Dementia (QUALID) questionnaire, and 2.5 h course in the theory relating to the Berg Balance Scale (BBS) and practical training in the use of the scale. The testers were encouraged to continue their training by putting it into practice in the day-care centers prior to the start of the study. In order to avoid bias, the BBS tests were always performed in the same room at each center.

Dogs and their handlers

Both dogs and their handlers were well educated regarding AAAs and were considered suited for such tasks. All dog handlers were females. Prior to the study, the dogs were subjected to a screening test that contained different elements intended to assess personality traits, such as boldness, aggressiveness, sociability, and exploration, in addition to assessing each dog's behavior when being handled and petted. The tests were conducted by dog trainers and ethologists at the Norwegian Centre of Anthrozoology. Both the dogs and their handlers then completed at least one course in AAls for visiting dogs. In addition, most handlers had either a bachelor degree or prior experiential learning within biology or social care.

Intervention and intervention content

The intervention consisted of 30-min sessions of AAAs in groups of 3–7 participants twice per week for 12 weeks. The AAAs sessions were led by a qualified dog handler. A protocol for conducting AAAs was followed to ensure consistency between the intervention sessions held in the day-care centers. The intervention had a relatively strict design and was standardized as far as possible, despite the fact that one of the study objectives was to see whether it was possible to measure effects when AAAs occurred in a realistic setting with a representative sample of participants and different dog teams.

Since the main aim of the study was to see whether interventions with a dog would have an impact on participants' balance, the protocol was designed with that in mind. For each session, the participants were randomly seated in a half-circle, and the dog handler moved around the group so that each participant was able to greet the dog and feed it treats. Next, the handler organized different activities such as petting the dog, brushing the dog, feeding the dog a treat, or throwing a toy for the dog to fetch. The dog was kept both off and on its leash during the session, but

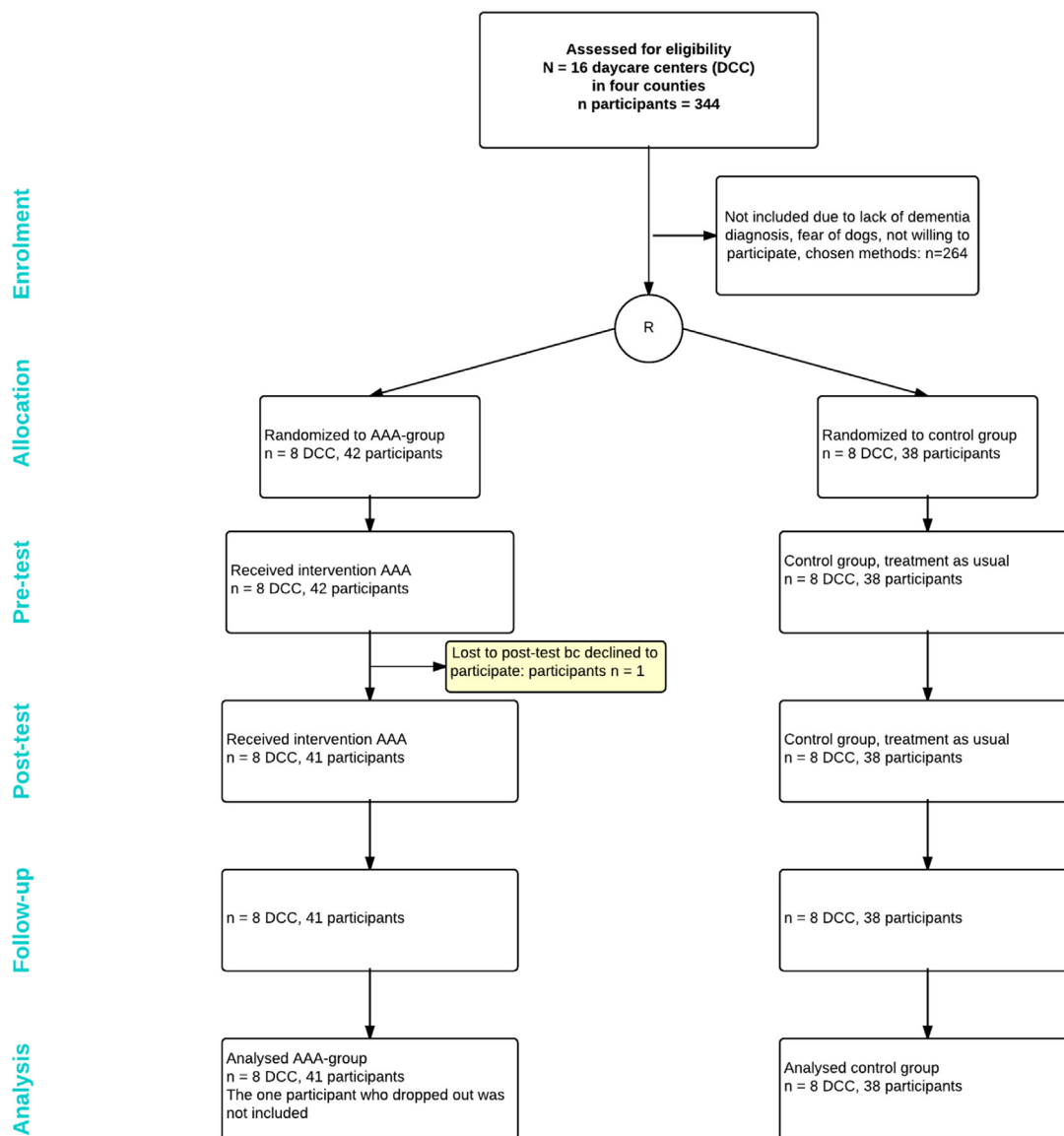


Fig. 1. Consort flow diagram of participants.

always remained under the control of the owner. The dog was never allowed to wander around the room and risk standing in the way of the participants, which would have increased their risk of a fall.

The idea behind the sessions was that the participants' physical functions would be enhanced by doing different physical tasks such as bending down, reaching out, lifting their arms, and throwing a ball. It was assumed that if the participants were to give the dog commands and reward it with treats that might stimulate the participants' cognitive function, increase their self-efficacy, and improve their fine motor skills, and petting the dog would result in sensory stimulation. The intervention was in many ways comparable with a seated, group-based program limited to range of motion exercises of a standard type for elderly people.⁴² Range of motion exercise programs usually consist of 30–45 min sessions consisting of the following elements: introduction/discussions, vocal exercises, word/memory games, range of motion exercises (using fingers, hands, arms, knees, and ankles), and finally relaxation exercises.

All sessions followed the main protocol, but they were individually tailored to each participant based on the care workers' knowledge of the participant. Hence, none of the AAAs was mandatory during the sessions, and the sessions included activities that naturally occurred between the participants, and between each participant and the dog.

Ethics

The Regional Committee for Medical Research Ethics approved the project, which was conducted in accordance with the Helsinki Declaration. Since the randomization was done on an institutional level, the participants were aware of the conditions under which they would participate. A procedure was developed for evaluating the participants' capacity to give informed written consent. Health care workers performed the evaluations. Participants with sufficient capacity were informed about the project both in writing and orally, and were asked to give written consent. For those with reduced capacity, either their health-care workers and/or their

next-of-kin took the decision on whether to give written consent on their behalf. Participants were informed that they could withdraw from the study at any time.

Assessments

All instruments used in the study have been tested for their validity and reliability and have been designed for use with elderly persons with dementia.

To measure balance, we used the Norwegian version of the BBS.^{43,44} The BBS is a performance-based measure of balance consisting of 14 observable tasks frequently encountered in everyday life. Scoring is based on participants' ability to perform the 14 tasks or movements independently and meet certain time and distance requirements. The test is simple and easy to administer and is safe for the elderly to perform. The test rates performance on a 5-level scale from 0 (cannot perform) to 4 (normal performance) for 14 different tasks involving functional balance control, including transfer, turning, and stepping. The total score ranges from 0 to 56.

Quality of life was measured using the validated Norwegian version of QUALID.^{45,46} The scale consists of 11 items with a possible score of 1–5 on each item. The items are proxy-rated by frequency of occurrence, comprising both positive and negative dimensions of concrete and observable mood and performance, such as to what degree the participant enjoys touching or being touched, eating and interacting with others, frequency of smiling, whether the participant appears sad or is in discomfort, irritable, or emotionally calm. Scores are summed to range from 11 to 55. A low score indicates a high QoL.

To measure cognitive and functional level, the Clinical Dementia Rating (CDR) scale was used. The CDR is a 5-point scale that assesses six domains of cognitive and functional performance applicable to dementia.^{47–49} CDR staging is a valid substitute for a dementia assessment to determine the severity of dementia.^{48,49} A CDR of 0 implies no cognitive impairment, 0.5 = very mild dementia, 1 = mild dementia, 2 = moderate dementia, and 3 = severe dementia.

CDR and sociodemographic characteristics on age, gender, education, use of walking aids, social contact, hobbies and animal contact were collected at baseline (T_0) by the pre-trained health-care workers working at the day-care centers. MMSE were also assessed at baseline for participants without a diagnosis of dementia. BBS and QUALID were assessed at T_0 , T_1 , and T_2 by the same health-care workers.

Statistical analyses

A power calculation was made using statistical software JMP Version 12 with BBS as the primary outcome measure prior to commencing the study. This was done with regard to the necessary number of participants in the intervention group and control group. A power calculation (80%) on BBS prior to the study ($\alpha = 0.05$, LSD = 5.0, SD = 14.1), estimated number of participants in each groups to 50. The dropout rate was set at 20% for both the control group as well as intervention group.

Intraclass correlation coefficient

To test the level of agreement between the different raters, two persons from the same day-care center ($N = 16$: 2 raters from each of 8 institutions) with the same training in BBS scored the same participants ($N = 42$) without conferring with each other. This resulted in an Intraclass Correlation Coefficient (ICC) for the BBS, ICC = 0.879 (single measures) (average measures = 0.936).

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

	Control ($n = 38$)	AAA ($n = 41$)	<i>p</i> -value
Women (%)	23 (60.5)	21 (51.2)	
Men (%)	14 (36.8)	18 (43.9)	
Missing	1 (2.6)	2 (4.9)	0.47
Enjoy animal-contact (%)	25 (75.8)	30/4 (88.2)	0.19
Missing	5	7	
Clinical Dementia Rating Scale (%)			0.89
0	1 (3)	2 (4.9)	
0.5	0 (0)	2 (4.9)	
1	16 (48.5)	16 (39.0)	
2	15 (45.5)	20 (48.8)	
3	1 (3)	1 (2.4)	
Missing	5	0	
Education (%)			0.48
Primary school	19 (57.6)	15 (50.0)	
Secondary school	5 (15.2)	5 (16.7)	
Higher education	8 (24.2)	8 (26.7)	
Other	1 (3)	2 (6.7)	
Missing	5	11	
Walking aids (%)			0.01
None	25 (69.4)	18 (47.4)	
Walking sticks	4 (11.1)	2 (5.3)	
Cane	2 (5.6)	3 (7.9)	
Crutches	0 (0)	1 (2.6)	
Rollator	5 (13.9)	14 (36.8)	
High walker	0	0	
Wheelchair	0	0	
Supported walking	0	0	
Missing	2	3	
Living conditions (%)			0.06
Private residence	35 (94.6)	35 (87.5)	
Sheltered housing	1 (2.7)	5 (12.5)	
Other facilities	1 (2.7)	0	
Missing	1	1	
Live together with (%)			0.99
None	19 (51.4)	22 (53.7)	
Spouse	18 (48.6)	18 (43.9)	
Other relatives	0	1 (2.4)	
Missing	1		
Social contact (%)			0.56
Daily	13 (37.1)	13 (33.3)	
Several times per week	15 (42.9)	16 (41.0)	
Once per week	5 (14.3)	7 (17.9)	
Every other week	1 (2.9)	1 (2.6)	
Rare	1 (2.9)	2 (5.1)	
Missing	3	2	
Hobbies (%)			0.80
Cognitive activities	10 (32.3)	8 (22.9)	
Physical activities	12 (38.7)	19 (54.3)	
Other	3 (9.7)	0	
Combination	6 (19.4)	8 (22.9)	
Missing	7	6	

Missing data

In some cases, one or a few items in the instruments BBS ($N = 21$) and QUALID ($N = 2$) were missing. To evaluate the missing data, we consulted clinical practice and arranged for a well-qualified physiotherapist with 15 years of experience to use the BBS to fill in the missing items so that it would be possible to calculate a plausible sum score. For missing data on item level in QUALID, we used the person mean substitution method.

The Multiple Imputation procedure in SPSS Version 23.0 was used to handle missing sum scores for the whole scales of BBS and QUALID.

Analyses of effects

All analyses were computed using statistical software IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corp.).

Table 2
Scores in Berg Balance Scale (BBS) and Quality of life in Late-Stage Dementia (QUALID) for control and animal-assisted activity (AAA) (mean \pm SD),^a estimates of fixed effects.^b

Variables	Pre-test (T ₀)	Post-test (T ₁)	Follow-up (T ₂)	Estimates of fixed effects							
				T ₁ – T ₀				T ₂ – T ₀			
				Estimate	t	p ^g	95% CI	Estimate	t	p ^g	95% CI
BBS											
Control	45.31 \pm 4.56 (n = 35)	45.50 \pm 6.72 (n = 28)	46.57 \pm 4.78 (n = 23)								
AAA	41.55 \pm 7.84 (n = 40)	44.71 \pm 8.05 (n = 34)	44.28 \pm 7.55 (n = 29)								
				^c 3.17	–2.27	0.03	0.40, 5.95	^d 1.63	–0.87	0.39	–2.08, 5.35
				^e 3.15	–2.21	0.03	0.30, 6.00	^f 0.92	–0.55	0.59	–2.39, 4.23
QUALID											
Control	15.94 \pm 4.06 (n = 36)	16.52 \pm 6.90 (n = 27)	15.23 \pm 4.06 (n = 22)								
AAA	15.89 \pm 4.17 (n = 37)	16.28 \pm 4.28 (n = 29)	16.65 \pm 3.98 (n = 26)								
				^c –0.19	0.02	0.99	–2.43, 2.40	^d 0.89	–0.59	0.56	–2.11, 3.88
				^e 0.08	–0.06	1.00	–2.50, 2.65	^f 0.39	0.30	0.76	–2.90, 2.13

^a Analysis of variance (ANOVA) is used to test the differences in means between registration times and groups.

^b A mixed model was used to estimate time trends between the groups. Dependent variables: Berg Balance Scale (BBS) and Quality of Life in Late-stage Dementia (QUALID).

^c Original data AAA vs Control Post-test – Pre-test.

^d Original data AAA vs Control Follow-up – Pre-test.

^e Pooled data AAA vs Control Post-test – Pre-test.

^f Pooled data AAA vs Control Follow-up – Pre-test.

^g Significance level 0.05.

Analysis of variance (ANOVA) was used to test the differences in means between groups at baseline (T₀).

A mixed model was used to investigate changes over time (T₀, T₁ and T₂) and differences between the groups (intervention and control group).⁵⁰ The dependent variables were BBS and QUALID. Time was modeled as a repeated variable, and an autoregressive covariance structure (AR1) was used to accommodate dependencies between the three time points. ‘Groups’ was included as fixed effect, and day-care center within group was included as random effect. T₀ was used as reference point for time, and the control group was set as the reference group. To accommodate different time trends between the groups, which was the effect of interest in this study, an interaction term between groups and points of time was included in the model.

When using multiple imputations, possible values for missing values are generated into five datasets. The Linear Mixed Models procedure produces output for each complete dataset, including a pooled output that estimates what the results would have been if the dataset had not had any missing values. Table 2 shows the results from pooled data (b) in addition to the original data (a).

Results

The group characteristics of the participants are listed in Table 1. In the control group, 60.5% were women, and the mean age was 81.7 years. In the AAA group, 51.2% were women, and the mean age was 84.0 years. The majority of participants in both groups reported that they enjoyed contact with animals. About half of the participants had mild dementia (CDR 1), and almost half were assessed as having moderate dementia (CDR 2). Only 1 participant in the control group and 4 participants in the AAA group were assessed as 0 or 0.5 on CDR, and 1 in each group had severe dementia (CDR 3). Most of the participants in both groups had a low educational level. Almost half of the participants in the AAA group used walking aids, and 36.8% used a rollator. The majority of the participants in both groups lived in a private residence, and more than half of them lived alone. However, most participants had frequent social contact, as over 90% of participants in both groups met with family members or friends at least once per week. The participants were quite actively engaged in hobbies and in both cognitive and physical activities.

We found a significant difference between the groups in the pre-test regarding BBS score, as participants in the AAA group scored

significantly lower than those in the control group ($p = 0.01$). The mean score on the BBS for the AAA group was 41.55 at T₀, with an increase to 44.71 at T₁, and a score of 44.28 at T₂. The control group scored 45.31 at T₀, 45.50 at T₁, and 46.57 at T₂. On balance, the AAA intervention was a significant positive effect from T₀ to T₁ ($p = 0.03$) (Table 2). No effect was found at follow-up, even though the improvement experienced by the intervention group remained constant after T₁.

It has been found that a change of 6.5 points on the BBS is required to reveal a genuine change in balance function (i.e. minimal detectable change, MDC) in community-dwelling elderly.⁵¹ No participants in the control group had an increase of 6.5 points or more, but 13 (39.4%) participants in the AAA group improved at least 6.5 points on the BBS (Chi-square <0.001).

No significant difference at pre-test was found in QUALID. For QUALID, the mean score of the control group was 15.94 at T₀, 16.52 at T₁, and 15.23 at T₂, while for the AAA group the scores were 15.89, 16.28, and 16.65 respectively. No effect of the intervention was found on QoL from T₀ to T₁ or from T₀ to T₂ (Table 2).

For the subgroup of participants with a clinically significant change in BBS and a post-score in QUALID ($n = 9$), a correlation with QUALID ($r = -0.61$) was found ($p = 0.08$).

Discussion

The results showed that AAA had a statistically significant and clinically positive effect on balance measured by the BBS for participants in the intervention group compared to the control group from pre-test (T₀) to post-test (T₁), but not from pre-test to follow-up (T₂). No effect was found on QoL. However, a strong favorable association with QUALID was found, with a tendency toward statistical significance in the subgroup of participants with a clinical improvement on the BBS.

One explanation for our findings might be connected directly to the mechanisms involved in maintenance of balance during different position and mobility. The current dominant theory of balance control is the systems theory approach.^{31,52–54} In this approach, balance is seen as a result of complex integration and coordination of several underlying systems covering sensory/perceptual processes, cognitive influences (such as attention, motivation, and intention), and motor processes.^{53,54} In Horak’s model, significant components required to maintain good balance are: cognitive processing (attention and learning), biomechanical

restraints (strength and limits of stability), sensory strategies, movement strategies, orientation in space, and control of dynamics.³¹ These multiple mechanisms are important in order to remain good balance and to prevent falls, and it might be that AAA affects several mechanisms due to the complexity of the intervention. AAI has been found to increase cognition,⁵⁵ and in our intervention, the participants were encouraged, for example, to remember the dog's name, different commands, and how to perform different tasks, in order to enhance cognitive processing. During their interaction with the dog, participants constantly moved with both frontal and lateral body weight shifts; they bent down to pick up the ball, they turned around to see the dog, and they leaned forward to pet the dog – all movements that require good postural control. Their sensory system would have been activated by touching the dog and feeling the differences in the texture of its hair. Moreover, dogs have slightly higher temperatures than humans and this can trigger the human somatosensory system. Part of the intervention involved the dog placing his head on each participant's lap and putting slight pressure on the participant's feet.

Balance and mobility impairments are associated with decreased balance confidence. Within the context of balance and falls, self-efficacy may be related to either falls self-efficacy (defined as a person's level of confidence in avoiding falling during daily activities) or balance self-efficacy (a person's confidence in performing tasks without losing balance or becoming unsteady).⁵⁶ According to social cognitive theory – which postulates that a person's perceived level of ability predicts behavior better than their actual physical ability⁵⁷ – mastery experience (offering opportunities for successful performance), verbal persuasion (positive feedback from instructors or therapists), change in physiological or affective states, or vicarious experience (observing others' successes) are important aspects of self-efficacy. Accordingly, the participants might have increased their experiences of, for example, mastering new tasks by feeding the dog a treat, giving the dog a command and seeing that the dog did what they were asking, and being able to throw the ball. The dog handler gave positive feedback and the dog was able to give positive feedback through its behavior. Touching the dog might have led to changes in each participant's physiological state, which has been reported as an important outcome of AAI.^{21–23,58} Moreover, the group design allowed the participants to observe others' successes (vicarious experience). Importantly, it is anticipated that strategies that are effective in improving balance self-efficacy are also associated with meaningful clinical endpoints, particularly reduction in the risk and rate of falls. AAI with farm animals has been shown to improve participants' self-efficacy through mastering work tasks related to the animals.⁵⁹

To ensure effectiveness, multifactorial and individual-tailored interventions are necessary to improve balance.³¹ An individual's balance is fundamental to their independent living and QoL. However, balance is an integral component of daily activities and balance control is complex and multifactorial.^{60,61} It could be speculated that AAA, in addition to affecting psychological, cognitive processing, the strength and limits of stability, and sensory strategies, contains so many different elements of balance stimulation that individuals could benefit from it some way or another even though individually they would have a unique combination of constraints affecting their balance control.³¹ Seated group-based exercise programs comparable to our intervention have previously been found to improve functional capability.⁶²

Earlier studies have shown the effect of AAI on social, behavioral, psychological, and physiological outcomes, such as increased social behavior,^{12–15} decreased depression,^{19,20,63} increased mood,⁶⁴ decreased agitation,^{10,17} and physiological outcomes that

might reduce restlessness (for other studies, see the review by Beetz et al.⁵⁸). These factors are all linked to fall prevention.⁶⁵ In a small study conducted by Herbert & Greene, it was found that elderly adults walked significantly farther when a dog was present than when they walked alone.²⁴ It is open to speculation as to whether the AAA made our participants more confident and motivated them to become more physically active in the everyday life and thereby improve their performance in the BBS test.

Even though we found a statistically significant clinical effect on balance, which is known to affect QoL,²⁶ no effect of the intervention was found on the QoL assessment for the whole group. This finding contrasts with the previously reported positive effect of AAA on QoL.²⁰ This might be due to the fact that the QoL of the participants in our study was generally quite high, while the participants in our previous study of the effect of AAA on PWDs in nursing homes had a much more diminished QoL.²⁰ However, we found a strong association between improvement in balance and improvement in QoL for the subgroup of participants with clinical change in the BBS. This finding is in line with that reported by Telenius et al., who found a significant correlation between the BBS and QUALID in a group of 168 participants.²⁶

It has been emphasized that findings on home-dwelling PWDs should be implemented in applied dementia care,⁶⁶ and the clinically significant results of our study demonstrate the value of implementation in clinical care. The average increase of 3.16 points in the BBS in the AAA group suggests 20% reduction in the risk of falls.⁶⁷ Even though no significant effects of the AAA were found at follow-up, the intervention group retained their level of score in the BBS, indicating a potential long-term establishing effect.

The study had several weaknesses that should be considered. The randomization process was handled before the recruitment of participants. This was done for ethical reasons, since it would have been unethical to recruit participants who might have been motivated by a potentially beneficial intervention but then found themselves randomized to a control group. Our method might thus have caused bias regarding who attended the AAA. Despite randomization, differences at pre-test were found in the BBS. This was accommodated within the mixed model framework in which differences in time trends was the effect of interest. The method we used is considered to be the most robust evaluative method,⁶⁸ and methodological issues regarding cluster randomization were deliberately cautious.⁶⁹

The control group received treatment as usual, which included activities such as excursions, walking, dancing, physiotherapy, reading aloud, handicrafts, and music therapy. Even though we cannot completely preclude that the effect of the intervention was due to a novelty effect, the broad spectrum of activities in the day-care centers would have reduced this risk.

Possible unreliability of the measures we used should be considered, as reliability issues can arise especially with longitudinal studies.⁷⁰ However, all measurements used were reliable and validated.^{43–46}

The assessments were not blind, which with QUALID is impossible because of the required profound knowledge of the person. Even though QUALID is a validated assessment for PWDs, it is not much used in home-dwelling PWDs. It could be that the assessment does not capture dimensions regarding QoL among home-dwelling PWDs, and it might have been the case that the raters did not have profound knowledge of the participants' daily life because of limitations as to how much time the care workers had to spend with the persons. However, the same primary caretaker filled out the questionnaire throughout the study period, thus ensuring consistency. Furthermore, this possible limitation would have been the same for both groups. For the BBS, blind assessment would have been possible, but because of the design, it would have been very

difficult and expensive to manage. Since the raters were not blind as to whether the participants were part of the AAA group or the control group, they might have had certain expectations and thus biased the study results to some extent.

Conclusion

The results of the study indicate that AAA might have useful clinical implications by leading to improvements in balance and thereby preventing risks of falls. However, in our study, AAA in a group setting did not affect the QoL of the study population.

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