Animal-assisted intervention as health promotion for elderly persons with dementia

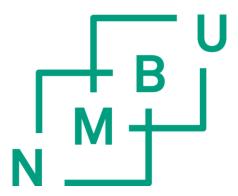
Dyreassistert intervensjon som helsefremmende tiltak for eldre personer med demens

Philosophiae Doctor (PhD) Thesis

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The Creation

When God had made the earth and sky the flowers and the trees, He then made all the animals the fish, the birds and bees.

And when at last He'd finished not one was quite the same. He said, 'I'll walk this world of mine and give each one a name'.

And so He traveled far and wide and everywhere He went, a little creature followed Him until its strength was spent.

When all were named upon the earth and in the sky and sea, the little creature said, 'Dear Lord, there's not one left for me.'

Kindly the Father said to him, 'I've left you to the end. I've turned my own name back to front and called you dog, My friend.'

Author unknown



Therapy-dog Veemtroppen's Qlara Photographer: Ida Kristin Myren

Table of Contents

SUMMARY	V
SAMMENDRAG	IX
LIST OF PAPERS	. XIII
ABBREVIATIONS	. XIV
1. INTRODUCTION	1
1.1. DEMENTIA	4
1.1.1. RISK FACTORS FOR DEMENTIA	4
1.1.2. DIAGNOSIS	5
1.1.3. DIFFERENT DEMENTIA DISORDERS	6
1.2. HOME-DWELLING PERSONS WITH DEMENTIA	7
1.3. Nursing home residents with dementia	9
1.4. CHALLANGES ASSOCIATED WITH DEMENTIA	9
1.4.1. NEUROPSYCHIATRIC SYMPTOMS	10
1.4.1.1. Agitation	11
1.4.1.2. Depression	12
1.4.1.3. Night-time behaviour disturbances	13
1.4.1.4. Apathy and activity	14
1.4.2. Medication	15
1.4.3. BALANCE	15
1.4.4. QUALITY OF LIFE	16
1.4.5. How the factors interact	17
1.4.6. MANAGEMENT OF DEMENTIA	17
1.5. Animal-assisted interventions	20
1.5.1. Definition	20
1.5.2. Previous findings	20
1.6. Theoretical framework	28
1.6.1. The biophilia hypothesis and the human-animal bond	29
1.6.1.1. Possible mechanisms explaining effect of animal-assisted interventions	s 2 9
1.6.2. Engagement theory	32
1.6.3. AIMS OF THE THESIS	33

2. MAT	ERIAL AND METHODS	37
2.1.	RESEARCH APPROACH	37
2.2.	RECRUITMENT AND PARTICIPANTS	37
	. Recruitment	
2.2.2	. Participants	38
2.3.	DESIGN AND RESEARCH METHODS	46
2.3.1	. RESEARCH SETTING AND INTERVENTION	46
2.3.2	. Intervention design	47
2.3.3	. Dogs and their handlers	49
2.3.4	. CONTROL GROUP	51
2.4.	ETHICAL CONSIDERATIONS	51
2.4.1	. Animal welfare	54
2.4.2	. POTENTIAL RISK FACTORS OF ANIMAL-ASSISTED INTERVENTIONS WITH DOGS	54
2.5.	Assessments and measurement points	55
2.5.1	. Cognitive function	56
2.5.2	. LEVEL OF DEMENTIA	57
2.5.3	. SYMPTOMS OF AGITATION	57
2.5.4	. Symptoms of depression	58
2.5.5	. QUALITY OF LIFE	58
2.5.6	. SLEEP PATTERN, LEVEL OF ACTIVITY, AND EXPOSURE TO LIGHT	58
2.5.7	. Balance	60
2.5.8	. Behavioural measurement	60
	2.5.8.1. Ethogram	61
2.5.9	. MEASUREMENT TIME POINTS	63
2.6.	STATISTICAL ANALYSES	64
2.6.1	. Power calculation	64
2.6.2	. Intraclass Correlation Coefficient	65
2.6.3	. Missing values	66
2.6.4	. Baseline analyses	66
2.6.5	Paper 1	67
2.6.6	. Papers 2 and 3	67
2.6.7	Paper 4	68
3. PRES	ENTATION OF PAPERS	69
3.1.	Paper 1	60
	Paper 2	
	Paper 3	
	Paper 4	
J.4.	I AFLIN T	/ 4

4. DISC	CUSSION	77
4.1.	PERSON, STIMULI, AND ENVIRONMENTAL ATTRIBUTES THAT INFLUENCE ENGAGEMENT	78
4.2.	ENGAGEMENT	82
4.3.	AGITATION	84
4.4.	Depression	86
4.5.	BALANCE	88
4.6.	QUALITY OF LIFE	90
4.6.1	L. Environmental factors	90
	4.6.1.1. Person-centred and relationalship-centred care	92
4.6.2	2. BEHAVIOURAL COMPETENCE AND SOCIAL INTERACTIONS	94
4.6.3	3. WELL-BEING	94
4.6.4	4. Perceived quality of life	96
4.7.	EFFECT AT FOLLOW-UP	97
4.8.	METHODOLOGICAL ISSUES	98
4.8.1	1. DESIGN AND POWER CALCULATION	98
4.8.2	2. Recruitment	99
4.8.3	3. Implementation	100
4.8.4	4. Dropout	101
4.8.5	5. Proxy measurements	102
4.8.6	5. STATISTICAL ISSUES	103
4.8.7	7. QUANTITATIVE VERSUS QUALITATIVE METHODS	104
5. CON	ICLUSIONS AND IMPLICATIONS	105
5.1.	SUMMARY OF FINDINGS AND CONCLUSIONS	105
5.2.	THEORETICAL IMPLICATIONS.	106
5.3.	IMPLICATIONS FOR FURTHER RESEARCH	108
5.4.	CLINICAL IMPLICATIONS	109
6. REFE	ERENCES	111
APPENDI	X	127
PAPERS I	-IV	

Tables

Table 1. Criteria for dementia according to the International Classification of Diseases (ICD-10)
(WHO, 1993)5
Table 2. Overview of research in animal-assisted interventions with dogs for persons with
dementia divided into reviews, RCTs and single group studies22
Table 3. Demographic data, quality of life (QUALID), and ActiGraph data relating to persons with
dementia in nursing homes (PWD NH) and persons with dementia living at home (home-
dwelling persons with dementia)
Table 4. Demographic data for participants in control group and intervention group at nursing
homes41
Table 5. Demographic data for participants in control and intervention group in at day-care
centres
Table 6. Demographic data for participants at nursing homes and day-care centres present at
both video recorded sessions
Table 7. Ethogram – an overview of defined behaviours
Table 8. Time points of measure for all assessments used, divided into nursing homes and day-
care centres64
Figures
Figure 1. The Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009) 32
Figure 2. Flow diagram of nursing home participants40
Figure 3. Flow diagram of home-dwelling participants42
Figure 4. Number of participants extracted to each paper
Figure 5. Illustration of intervention setting
Figure 6. Intervention content and possible outcomes of interaction with the dog48
Figure 7. Illustration of the registration of behaviour
Figure 8. The Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009)79
Figure 9. Illustration of quality of life as a multidimensional concept in relation to the
Comprehensive Process Model of Engagement

Summary

Dementia is an increasing health concern for old people, their families, and their social and health care providers. A range of health care services is needed for persons with dementia, ranging from home-based services, respite care (e.g. attending a day-care centre), to residential care at a nursing home. An important goal in dementia care is to provide for and ensure a good quality of life. There is a great need for health promoting activities among persons with dementia, and animal-assisted interventions have become a widespread non-pharmacological alternative. Animal-assisted interventions have been found to have a positive influence on social behaviour, a beneficial effect on agitation and other behavioural disturbances, and indication of significant improvement in depression. However, the literature show mixed results, and the authors of reviews have called for further research. The first and main aim of the research for this thesis was therefore to investigate animal-assisted activity as a health promoting activity for homedwelling persons with dementia attending day-care centres and persons with dementia admitted to nursing home.

To gain more knowledge of the quality of life and known associated risk factors in persons with dementia living at home and persons with dementia living in nursing homes, a cross-sectional study was done. Data relating to demography, degree of dementia, use of walking aids, social encounters, use of psychotropic medications, sleep patterns, physical activity levels, exposure to light, and quality of life were collected from 193 persons with dementia (78 nursing home residents and 115 home-dwellers). Significant differences were found, even when stratified by the degree of dementia. Walking aids were used by a significantly higher number of persons with dementia living in nursing homes than home-dwelling persons with dementia. Home-dwelling persons with dementia had significantly more social contact with their family members and friends than persons with dementia living in nursing home. They also had significantly better sleep patterns, higher activity levels, had more exposure to light, used fewer psychotropic medications, and appeared to have a significantly higher quality of life than persons with dementia in nursing homes. A multiple regression analysis was used to test the association between residency and quality of life. The regression model explained 28% of the variance in

quality of life in persons with moderate dementia. However, only residency contributed significantly in the model. Residency also significantly predicted negative change in quality of life over time.

The second aim of the research was to investigate whether animal-assisted group activity could reduce symptoms of agitation and depression and enhance quality of life among persons with dementia living in nursing homes, and whether the degree of their dementia would impact any possible effects. The study was conducted as a prospective cluster-randomized multicentre trial with a follow-up measurement three months after end of the intervention. A total of 10 nursing home units for persons with dementia were randomized to control with treatment as usual (N = 30) or to animal-assisted group activity with a dog (N = 28). The animal-assisted activity was conducted for 30 minutes two times per week for 12 weeks. The sessions included activities such as petting the dog, talking to it, brushing its hair, feeding the dog a treat, or throwing a ball for the dog to fetch. Psychometric assessments for depression, agitation, and quality of life were used as outcome measures. The intervention group had a continual decrease in symptoms of depression, while the control group had a continual increase, and a significant effect of the intervention was found from pre-test to follow-up. Stratified by the degree of dementia, an almost significant effect on depression from pre-test to post-test (p = 0.054) and a significant effect from pre-test to follow-up (p = 0.001) among participants with severe dementia was found. No effect was found on symptoms of agitation, but for quality of life a significant effect of the animal-assisted activity was found both at post-test (p = 0.035) and follow-up (p = 0.003) among persons with severe dementia.

Falls and fractures are common among home-dwelling older persons. Norwegian society's health care costs due to fall injuries is substantial, but more importantly fall accidents are a major cause of disability, immobility, and mortality among the elderly, and have a huge impact on the affected individual's quality of life. Accordingly, the third aim of the research was to investigate whether animal-assisted group activity would improve balance function and enhance quality of life among home-dwelling persons with dementia attending day-care centres. This study, too, was conducted as a prospective cluster-randomized multicentre trial with a follow-up measurement three months after end of the intervention. A total of 16 day-care centres for persons with

dementia were randomized to control with treatment as usual (N = 38) or to animal-assisted group activity with a dog (N = 42).

Balance and quality of life were defined as main outcomes of the study. There was a significant positive effect of the animal-assisted activity on balance from baseline to post-test (p = 0.03). The positive effect on balance also showed clinical significance. In addition, the average increase in balance in the animal-assisted activity group suggests a c.20% reduction in fall risk. No effect of the intervention was found on quality of life, which in this study population was found to already be quite high. However, we found a strong association between clinical improvement on balance and improvement in quality of life from pre-test to post-test.

One session of animal-assisted activity early and one session late in the intervention period were video recorded at both nursing homes and at day-care centres in order to analyse behaviours that occurred during the animal-assisted activity. A total of 49 persons with dementia (21 nursing home residents and 28 home-dwellers attending a day-care centre) were included. Behaviours seen in the video recordings were categorized using an ethogram and their frequency and duration was registered. A theoretical framework for assessing engagement was used to analyse the ethogram. The results showed a high level of involvement as well as indications of a positive attitude, which implies that the intervention created engagement and a positive affect among all participants.

The overall conclusion of this thesis is that a 30-minute session with a dog enabled persons with dementia to engage, and after doing this two times per week for 12 weeks, the intervention seemed to have an effect on their depression, balance, and quality of life. The findings contribute further knowledge of animal-assisted interventions for persons with dementia, and provided valuable experience in how to incorporate animal-assisted intervention into traditional care and treatment for nursing home residents and participants at day-care centres. Activities should be tailored to their needs and interests, and their degree of dementia should be considered when planning individual or group-based animal-assisted activity. Animal-assisted intervention with dogs should be considered for use as a health promoting activity in the future.

Sammendrag

Demens er en økende utfordring for eldre personer, for deres pårørende, og for helse- og sosialtjenestene. Personer med demens har et stort behov for helsetjenester, fra hjemmetjenester, plass på dagsenter og til behov for sykehjemsplass. Et viktig mål i demensomsorgen er å legge til rette for, samt sikre god livskvalitet, og det er derfor stort behov for helsefremmende aktiviteter for personer med demens. Dyreassisterte intervensjoner er blitt et relativt utbredt og populært tiltak, og tidligere forskning antyder at slike tiltak kan ha en positiv effekt på sosial atferd, på agitasjon og andre atferdsforstyrrelser og at det kan ha en positiv effekt på depresjon. Det etterspørres imidlertid ytterligere forskning for å understøtte dette, og hovedformålet med dette forskningsprosjektet var derfor å undersøke dyreassisterte aktiviteter med hund som helsefremmende tiltak for eldre personer med demens, både hjemmeboende og sykehjemsbeboere.

Først gjennomførte vi en tverrsnittsundersøkelse blant 193 personer med demens (78 sykehjemsbeboere og 115 hjemmeboende) for å få mer kunnskap om deres livskvalitet og kjente risikofaktorer hos personer med demens. Demografiske data, grad av demens, bruk av ganghjelpemiddel, sosial kontakt, bruk av psykotrope medisiner, søvnmønster, fysisk aktivitetsnivå, eksponering for lys og livskvalitet ble innhentet og analysert. Det var signifikante forskjeller mellom hjemmeboende og sykehjemsbeboere, også når vi stratifiserte på grad av demens. Sykehjemsbeboere brukte i større grad ganghjelpemidler, og brukte flere psykotrope medisiner enn hjemmeboende. Hjemmeboende hadde oftere kontakt med familie og venner, de hadde bedre søvnmønster, høyere aktivitetsnivå, var mer eksponert for lys, og hadde høyere livskvalitet enn sykehjemsbeboere. Videre analyser viste at det å bo på sykehjem ga dårligere livskvalitet, også over tid.

Det neste målet var å undersøke om gruppeaktivitet med hund kunne redusere symptomer på depresjon og agitasjon, og øke livskvalitet hos sykehjemsbeboere. Studien ble gjennomført som en cluster-randomisert kontrollert studie, med målinger før intervensjonsstart (pre-test), etter intervensjonens slutt (post-test), og tre måneder etter intervensjonens slutt (follow-up). 10 sykehjem ble randomisert til kontroll, hvor de fortsatte med sitt ordinære tilbud (N = 30), eller

gruppeaktivitet med hund (N = 28). Aktiviteten med hund bestod av sesjoner på 30 minutter, to ganger i uken i 12 uker. Innholdet i aktiviteten bestod av å kose med hunden, snakke med den, børste den, gi godbit og kaste ball. Psykometriske tester for å måle depresjon, agitasjon og livskvalitet ble benyttet for å kunne analysere effekt. Intervensjonsgruppen hadde en kontinuerlig nedgang i symptomer på depresjon, mens kontrollgruppen hadde en kontinuerlig forverring. Vi fant en signifikant effekt av intervensjonen fra pre-test til follow-up. Når vi stratifiserte på grad av demens, fant vi en nesten signifikant effekt fra pre-test til post-test (p = 0.054) og en signifikant effekt fra pre-test til follow-up (p = 0.001) hos pasienter med alvorlig grad av demens. Denne effekten viste seg også å være klinisk signifikant. Det ble ikke funnet noen effekt av intervensjonen på agitasjon, men på livskvalitet var effekten signifikant både fra pretest til post-test (p = 0.035) og fra pre-test til follow-up (p = 0.003) hos personer med alvorlig demens.

Fall og bruddskader er vanlig hos hjemmeboende. Helsevesenets utgifter til fallskader er store, men det som er viktigere, er at fallulykker fører til funksjonshemming, immobilitet og dødelighet blant eldre, og har en stor innvirkning på den enkeltes livskvalitet. I den tredje studien ville vi derfor undersøke om gruppebasert aktivitet med hund kunne bedre balansen og øke livskvaliteten hos hjemmeboende personer med demens. Denne studien ble også gjennomført som en cluster-randomisert kontrollert studie, med målinger pre-test, post-test, og ved follow-up. Totalt 16 dagsenter for personer med demens ble randomisert til kontroll, hvor de fortsatte med sitt ordinære tilbud (N = 38), eller gruppeaktivitet med hund (N = 42).

Måleverktøy for å evaluere balanse og livskvalitet ble brukt for å teste effekt. Det var en signifikant klinisk og statistisk effekt av intervensjonen fra pre-test til post-test (p = 0.03). Denne forbedringen i balanse tilsier ca. 20 % redusert sjanse for fall. Det ble ikke funnet noen effekt på livskvalitet, som for øvrig ble funnet å være relativt god blant de hjemmeboende Vi fant imidlertid en sterk sammenheng mellom klinisk bedring i balanse og bedring i livskvalitet.

For å kunne kartlegge hvilke atferder som oppstod under sesjonene, ble én av sesjonene i uke to og én av sesjonene i uke 10 filmet. Totalt ble 49 deltakere inkludert (21 sykehjemsbeboere og 28 hjemmeboende). Vi brukte etogram for å registrere atferder, mens et etablert teoretisk

rammeverk ble brukt for å evaluere engasjement. Det at deltakerne brukte mesteparten av tiden på å observere hunden, snakke til den og gjøre aktiviteter med den, samt at de viste mye smil og latter, indikerer at aktiviteten med hund skapte engasjement og positive følelser hos både hjemmeboende og sykehjemsbeboere.

Den overordnede konklusjonen i denne avhandlingen må sies å være at 30 minutter gruppeaktivitet med hund skapte engasjement blant personer med demens, og at man ved å tilby dette to ganger i uken i 12 uker ser ut til å kunne minske symptomer på depresjon, gi bedre balanse og høyere livskvalitet. Studien har bidratt til å gi økt kunnskap om dyreassisterte intervensjoner for personer med demens, samt hvordan man kan inkorporere et slikt tiltak i tillegg til tradisjonell omsorg og behandling for sykehjemsbeboere og hjemmeboende med dagsentertilbud. Aktiviteten bør være individuelt tilrettelagt i forhold til deltakerens interesse og behov, og grad av demens bør tas med i vurderingen når man planlegger tiltaket. Dyreassisterte intervensjoner med hund bør heretter vurderes som et helsefremmende tiltak for eldre personer med demens.

List of papers

- Olsen, Pedersen, Bergland, Enders-Slegers, Jøranson, Calogiuri, & Ihlebæk. (2016).
 Differences in quality of life in home-dwelling persons and nursing home residents with dementia a cross-sectional study. BMC Geriatrics, 16(1), 1-11. DOI: 10.1186/s12877-016-0312-4
- Olsen, Pedersen, Bergland, Enders-Slegers, Patil, & Ihlebæk. (2016). Effect of animalassisted interventions on depression, agitation and quality of life in nursing home residents suffering from cognitive impairment or dementia: A cluster randomized controlled trial. International Journal of Geriatric Psychiatry, Epub ahead of print. DOI: 10.1002/gps.4436
- 3. Olsen, Pedersen, Bergland, Enders-Slegers, & Ihlebæk. (2016). Effect of animal-assisted activity on balance and quality of life in home-dwelling persons with dementia. Geriatric Nursing, Epub 2016 May 4. DOI: http://dx.doi.org/10.1016/j.gerinurse.2016.04.002
- 4. Olsen, Pedersen, Bergland, Enders-Slegers, & Ihlebæk. (2016). Engagement in elderly persons with dementia attending animal-assisted group activity. Dementia (London). DOI: 10.1177/1471301216667320

Abbreviations

ANOVA Analysis of variance

BARS Brief Agitation Rating Scale

BBS Berg Balance Scale

CDR Clinical Dementia Rating scale

CDR 0, 0.5 and 1 Mild degree of dementia

CDR 2 Moderate degree of dementia

CDR 3 Severe degree of dementia

cpm Counts per minute

CSDD Cornell Scale for Depression in Dementia

IAHAIO International Association of Human-Animal Interaction Organizations

ICC Intraclass Correlation Coefficient

ICD-10 International Classification of Diseases

MMSE Mini-Mental State Examination

N Number

NH Nursing home

p Significance level

QoL Quality of life

QUALID Quality of Life in late-stage Dementia

R² Proportion of the variance

RCT Randomized controlled trial

SD Standard deviation

T₀ Pre-test

 T_1 Post-test

T₂ Follow-up

TST Total sleep time

WASO Wake after sleep onset

WHO World Health Organization

1. Introduction

This thesis focuses on animal-assisted intervention as health promotion for persons with dementia. Advances in medical care, healthier lifestyles and increased access to family planning causes the world population to age rapidly (OECD & EU., 2014). There has been a substantial increase in average life expectancy during the 20th century (WHO, 2011), and life expectancy in Norway is above the EU28 average (OECD & EU., 2014). This will lead to an increase in number of elderly in the coming years, and The Norwegian Ministry of Health and Care Services estimates that the amount of elderly will be twice the amount of children and young people by 2050 (Norwegian Ministry of Health and Care Services, 2015b). A consequence of the world population rapidly aging, is an increase in age-related diseases (Norwegian institute of Public Health, 2011). High age is the most important risk factor for poor health, functional decline, and use of health care resources (Christensen et al., 2009), including the risk of dementia (Khanahmadi et al., 2015). Worldwide estimates in 2015 counted 46.8 million persons with dementia today, and due to the ageing population an increase in dementia prevalence is expected in the coming years both in the developed and in developing countries (Prince et al., 2015). For Norway, the latest estimated number is 78.000 persons in 2015, with an expected increase to 112.000 in 2030 (Vossius et al., 2015). Although dementia is a key predictor for admission to nursing-home (Hajek et al., 2015), most people with dementia live at home (Lystrup et al., 2006). There is no cure for dementia (Geldmacher et al., 2006), and dementia is a rapidly increasing health concern for old people, their families, and their social and health care providers. No pharmacologic treatment is available to slow or stop the malfunction and death of neurons in the brain that cause mild cognitive impairment and dementia (Reitz & Mayeux, 2014), therefore, strategies for preventing dementia and identifying treatments to alter the course of disease will be important in the future (Prince et al., 2015).

Persons with dementia often express that they lose their sense of belonging when they get the dementia diagnosis (Norwegian Ministry of Health and Care Services, 2015a). They experience prejudgments from the society, they get insecure, and self-efficacy decrease (Norwegian Ministry of Health and Care Services, 2015a). Living with dementia will also affect the relatives, and may

cause a tremendous burden for them, both social, psychological and physical (Norwegian Ministry of Health and Care Services, 2015a). A range of health care services is needed for persons with dementia, from home-based services, respite care such as attending a day-care centre, or residential care at a nursing home. Dementia is a leading cause for disability and institutionalization, and represents a substantial financial burden on the society. In 2010 the estimated cost of dementia in the United States was between 157 and 215 billion dollars (Hurd et al., 2013). The average annual cost of dementia in Norway is estimated to 358.000 NOK per person (Vossius et al., 2015). The average survival time for people diagnosed with dementia was found to be 8.1 years in the same report, which gives a total cost of health and care-services throughout the course to be 2.9 million NOK per person (Vossius et al., 2015). Health care and long-term care costs for dementia patients is three times as great as for others in the same age group (Alzheimer's Association, 2012).

Public health has a great focus both nationwide, as well as global. In 2015, Norwegian Ministry of Health and Care Services, made a report of public health 2014-2015. In this report, The Norwegian government states that they want to strengthen services for persons with dementia and their relatives, and public health should be promoted in all sectors (Norwegian Ministry of Health and Care Services, 2015b). Furthermore, to handle the rising number of older people with dementia who is dependent on help from other persons and to ensure good quality of life and promote health, we need more evidence-based knowledge about modifiable factors related to physical functioning and mental health in this population.

Health promotion is 'the process of enabling people to increase control over, and to improve, their health' (WHO, 1986). A World Health Organization (WHO) report on ageing and health suggests that the focus should be on functional ability rather than diseases and morbidity (Beard et al., 2015). Functional ability is the key for living good independent lives throughout their life course and obtaining a high quality of life (Beard et al., 2015). The Ottawa Charter for Health Promotion emphasizes that all people should be able to achieve their fullest health potential, but enabling people to cope with chronic illness is also essential (WHO, 1986). This is the focus of the Norwegian Care Plan 2020 too (Norwegian Ministry of Health and Care Services, 2015a). Person centred approach is essential in order to able persons with dementia to utilizing their resources

as far as possible and to feel safe and sense of mastery (Norwegian Ministry of Health and Care Services, 2015a).

An important factor in the person centred approach is meaningful activities. However, several studies have shown that persons with dementia's need for meaningful activities are often unmet (Cohen-Mansfield et al., 2015; Hancock et al., 2006; van der Ploeg et al., 2013). Persons with dementia are frequently reported to participate in few activities and to be unoccupied most of the day (Smit et al., 2015), and high prevalence of inactivity, apathy and sedentary behaviour is commonly reported (Bates-Jensen et al., 2004; MacRae et al., 1996). Having the possibility to participate in activities and activities that amount to something is important for improving a sense of independence and positive self-image (Allen, 2011). During times of activity persons with dementia express positive affect much more often than during unoccupied time (Schreiner et al., 2005).

For many older people an independent life means living in their own place of residence. People's ability to live at home as long as possible is a political goal in Norway and considered a human right (Ministry of Health and Care Services, 2003; WHO, 2010). Part of reaching the political goal is the development of day-care centres for persons with dementia. Day-care centres have been described as offering respite care, with main aim to provide meaningful activities for home-dwelling persons with dementia (Norwegian Ministry of Health and Care Services, 2015a). However, the progress of dementia will often lead to total dependency on others and finally to residential care (Hajek et al., 2015). Residential care can ensure necessary care and safety when a person with dementia is dependent on help. Nevertheless, living in a nursing home will affect life. Many studies have investigated the effect of nursing home environments on different health and behavioural factors (Anderiesen et al., 2014; Cohen-Mansfield et al., 2015; van der Ploeg et al., 2013; Willemse et al., 2015), and dependency in itself and institutionalization might be negatively related to poorer quality of life (Beerens et al., 2013; Nikmat et al., 2015). Nursing home residents with dementia are one of the most functionally disabled groups living in nursing homes today, and their care needs are significant (Galik et al., 2014; Samus et al., 2009).

Based on this knowledge, the main aim of this thesis was to investigate animal-assisted activity as a health promoting activity for home-dwelling persons with dementia attending a day-care centre and persons with dementia admitted to nursing home.

1.1.Dementia

Dementia is a syndrome due to disease of the brain, usually affecting people as they are getting older, and is a major cause of disability and dependency among older people (WHO, 2012). Dementia has a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement (WHO, 2016). Decline in memory is a key characteristic of dementia. Memory is divided in different subtypes, where short-term memory refers to the ability to remember limited amounts of information for a very brief (seconds) period of time (Atkinson & Shiffrin, 1968). Long-term memory on the other hand refers to the ability to remember larger amount of information for longer periods of time (Atkinson & Shiffrin, 1968). The long-term memory function involves both semantic memory of general facts and knowledge and episodic memory. Episodic memory is related to one's own experiences and also involves spatial and temporal characteristics of these experiences (Carlesimo & Oscar-Berman, 1992).

1.1.1. Risk factors for dementia

Aging, genetics and life style factors are the three main risk factors for dementia, where increased age is the most important (Khanahmadi et al., 2015). The incidence of dementia increases exponentially with increasing age with a doubling for every 6.3 year increase in age. At age 60-64 the incidence is 3.9/1000 person per years, and at age 90+, the incidence is 104.8/1000. The incidence of dementia appears to be higher in countries with high incomes, where the incidence doubles every 5.8 years, than in low or middle income countries where the incidence doubles every 8.6 years (Prince et al., 2015).

Several genes that affect the risk of developing dementia have been identified and studied (Khanahmadi et al., 2015). Genetic risk factors could be divided into early-onset and late-onset

according to the time of onset, where most studies so far are related to early-onset (Khanahmadi et al., 2015). Among several potential risk genes, the ApoE e4 allele is the best known genetic risk factor for Alzheimer's disease (Sachdev, 2014). ApoE is suggested to interact with vascular risk factors of dementia, such as hypertension, diabetes mellitus, smoking, and heart disease (van der Flier & Scheltens, 2005). Other modifiable risk factors for dementia are insulin resistance or the metabolic syndrome, high cholesterol, excessive alcohol use, obesity, physical inactivity, high homocysteine levels, depression, traumatic brain injury (Sachdev, 2014). Factors that might protect development of dementia are education, occupation, complex mental activity and physical exercise (Sachdev, 2014), as these are linked to maintenance of cognition (Williams & Kemper, 2010).

1.1.2. Diagnosis

The diagnosis is based on medical record, clinical examination, cognitive examinations and laboratory tests. The ICD-10 criteria for research are shown in Table 1 (WHO, 1993). All criteria have to be filled in order to establish the diagnosis.

Table 1. Criteria for dementia according to the International Classification of Diseases (ICD-10) (WHO, 1993).

I A decline in memory, mainly evident in the learning of new information.

A decline in other cognitive abilities (e.g. abstraction, judgement, thinking, planning).

II Preservation of sufficient awareness of the environment to be able to assess criterion I.

III A decline in emotional control or motivation, or a change in social behaviour, with one or more of the following: 1) emotional lability; 2) irritability; 3) apathy; 4) coarsening of social behaviour.

IV Duration of six months or more

Severity of dementia is categorized according to degrees of dementia, which are determined by the cognitive domain (memory or other cognitive functions) with the most severe impairment. This means that a person with moderate decline in memory, but only mild impairments of other cognitive abilities, has a moderate degree of dementia (WHO, 1993).

When a person is assessed with mild degree of dementia, the degree of memory loss or decline in other cognitive abilities is sufficient to interfere with everyday activities, but not so severe that it makes the person dependent on others. However, tasks that are more complicated cannot be undertaken. For moderate degree of dementia, the degree of memory loss or decline in other cognitive abilities makes the person incapable of living without support from others, and needs help in all tasks beside the most basic chores. When a person is assessed with severe dementia, the person has no longer the ability to retain new information, and often fail to recognize close relatives. The decline is characterized by an absence, or virtual absence, of intelligible ideation (WHO, 1993).

In Norway, dementia assessments are mostly done in the municipalities, often as a collaboration between the general practitioner and health and care services in the municipality. The general practitioner is responsible to diagnose and prescribe necessary treatment, while health and care services is responsible for assessing functional level and need for institutionalization. In order to enable persons with dementia and their families to benefit from the positive educational, social, psychological and pharmacological interventions that are available and to plan for their future with the illness, diagnosis should be made as early as possible (Knapp et al., 2007). Unfortunately, the large majority of people with dementia either do not receive a specialist diagnosis at any time in their illness, or do so only late in the disorder (Knapp et al., 2007). This means that it can be very difficult to rely on information regarding length of time since onset of dementia. Nevertheless, in the REDIC report, estimated time from onset of symptoms until diagnosis, in average is 3.0 years (Vossius et al., 2015).

1.1.3. Different dementia disorders

The ICD-10 classification of different dementia disorders is divided in Alzheimer's disease, Vascular dementia, other types of dementia and unspecified dementia (WHO, 2016). Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years (WHO, 2016).

Vascular dementia is the result of infarction of the brain due to vascular disease, including hypertensive cerebrovascular disease. The infarcts are usually small but cumulative in their effect. Onset is usually in later life (WHO, 2016).

Cases of dementia due, or presumed to be due, to causes other than Alzheimer's disease or cerebrovascular disease, are classified as 'Other types of dementia'. Onset may be at any time in life, though rarely in old age. Examples: Dementia in Lewy body disease, Creutzfeldt-Jakob disease, Huntington disease and Parkinson disease (WHO, 2016).

The category 'Unspecified dementia' should be used when the general criteria for dementia are met, but when it is not possible to identify one of the specific types of disorders. Examples are presentle, primary degenerative dementia and sentle dementia (WHO, 2016).

Alzheimer's disease is the most common cause of dementia, and accounts for 60–80% of cases. Common outcomes are difficulty remembering recent conversations, names or events, apathy and depression, impaired communication, disorientation, confusion, poor judgment, behaviour changes and, ultimately, difficulty speaking, swallowing and walking (Alzheimer's Association, 2015). Vascular dementia accounts for about 10% of the cases. Common outcomes are impaired judgment or impaired ability to make decisions, plan or organize, as opposed to the memory loss often associated with the initial symptoms of Alzheimer's (Alzheimer's Association, 2015).

1.2. Home-dwelling persons with dementia

More than 40% of home-dwellings over the age of 70 years who receive domiciliary care have a dementia diagnosis (Wergeland et al., 2014), and about half of the total population of persons with dementia in Norway lives in their own home (Lystrup et al., 2006). There has been a shift in policy with regard to persons with dementia, from institutional and residential care towards an emphasize on more home-based services (Tretteteig et al., 2015). Being able to live at home as long as possible is a political goal and is also seen as a right (Ministry of Health and Care Services, 2003; WHO, 2010). To be able to live at home, increase and/or at least, maintenance of functional ability is a key point. On average, persons with dementia will live at home with their diagnose for

6 years (Vossius et al., 2015). During this time, the progress of dementia gradually leads to a loss of cognitive and physical functions (McKhann et al., 1984; van Iersel et al., 2004), which will often lead to dependency of others, including a heavy burden for their relatives (Knapp et al., 2007).

It is a political goal to be able to offer most home-dwelling persons with dementia activities at a day-care centre. Day-care centres are described as respite care, providing meaningful activities for home-dwelling persons with dementia (Norwegian Ministry of Health and Care Services, 2015a). A central need of persons with dementia, especially in the early stage, is to be treated as adult and accountable persons despite their disease (von Kutzleben et al., 2012). Experiences of attending a day-care centre is found to be that it provides a social fellowship, meaningful engagement, it gives a feeling of meaningful lives and a well-being (Brataas et al., 2010). Physical activities at day-care centres are expressed by informants to increase physical fitness (Söderhamn et al., 2014). Day-care centres have been found to be of importance both for the person with dementia and at the same time a relief to the carers' burden (Norwegian Ministry of Health and Care Services, 2015a; Söderhamn et al., 2014; Söderhamn et al., 2013). The possibility to choose from a variety of suitable activities is found to be appreciated by persons with dementia (Söderhamn et al., 2013), and so the need for an increased focus on the qualitative content of day-care centers have been emphasized (Tretteteig et al., 2015).

Most participants attend the day-care centre ones or twice a week. The average cost of day-care centre is 868 NOK per participants per day (Vossius et al., 2012). Persons with dementia attending a day-care centre is found to be admitted to nursing home slightly later than non-users, however the difference is not significant (p = 0.16) (Vossius et al., 2012). Consequently, there is no evidence that attending a day-care centre will be cost-effective from an economical view (Vossius et al., 2012). Nevertheless, in order to reach the political goal, there is a vast need for more day-care centres with individual tailored offers for home-dwelling persons with dementia, as a survey in 2014 indicates only about 17% of home-dwelling persons with dementia is offered a day-care activity (Norwegian Ministry of Health and Care Services, 2015a).

1.3. Nursing home residents with dementia

A nursing home is an institution for people who are too fragile to be cared for at home, but do not need to be in a hospital. The nursing homes have nursing aides and skilled nurses on hand 24 hours a day. The staff provide medical care as well as physical, speech, and occupational therapy. Some nursing homes try to be more like home, with smaller units and specialized care for residents with distinct needs, such as dementia patients. These special care units are units for permanent stay, also sometimes called long-term units. Living in a nursing home will influence persons with dementia's way of living. Institutionalization will insure necessary care and safety when the patient is dependent of help, although dependency in itself might be negatively related to quality of life (Beerens et al., 2013).

For persons with dementia already admitted to nursing home, the need for meaningful activities that enhance engagement is of special importance, as inactivity, apathy and sedentary behaviour is very common (Bates-Jensen et al., 2004; MacRae et al., 1996). Nursing home residents are often found to participate in few activities and to be unoccupied much of the day (Smit et al., 2015), and several studies of institutionalized patients with dementia have shown that the resident's needs for meaningful activities are often unmet (Cohen-Mansfield et al., 2015; Hancock et al., 2006; van der Ploeg et al., 2013).

The annual cost of living in a nursing home for persons with dementia is estimated to be 814.166 NOK (Vossius et al., 2015). The average 2.1 years spent in nursing home from admission to mortality will annually demand a workload of 1.06 full-time equivalent (Vossius et al., 2015). So, for each person with dementia, there will be a need for more than one full-time equivalent to take care of the person with dementia.

1.4. Challanges associated with dementia

Dementia is a progressive disease, and living with dementia will affect the whole life of the person with dementia as well as his or hers relatives. Both the person with dementia and the relatives will experience major challenges (Norwegian Ministry of Health and Care Services, 2015a). In our

study, we investigated challenges such as agitation, depression, night-time behaviour disturbances, apathy/activity level, use of medications, balance and quality of life of the persons with dementia.

1.4.1. Neuropsychiatric symptoms

Neuropsychiatric symptoms are displayed as multidimensional behavioural disturbances (Nowrangi et al., 2015). The most common neuropsychiatric symptoms observed in persons with dementia are delusions, hallucinations, agitation, depression, anxiety, apathy, irritability, euphoria, disinhibition, aberrant motor behaviour, night-time behaviour disturbances, and appetite and eating abnormalities (Aalten et al., 2005). The prevalence of neuropsychiatric symptoms in persons with dementia has been reported as very high. For instance, following a two-year longitudinal study, Aalten et al. (2005) found that 95% of the patients developed one or more neuropsychiatric symptom. Symptoms can range from mild (depression, anxiety, irritability, and apathy) to severe (agitation, aggression, aberrant vocalizations, hallucinations, and disinhibition, among others) (Nowrangi et al., 2015). Lyketsos et al. (2002) found that 75% of the patients with dementia in their study population had experienced neuropsychiatric symptoms in the preceding month, and 55% reported having two or more symptoms (Lyketsos et al., 2002). The prevalence of neuropsychiatric symptoms among home-dwelling persons with dementia is in the same magnitude, and 72.1% reported having at least one symptom, with depression, apathy, and agitation as the most frequent (Wergeland et al., 2014).

Factors contributing to the development and presence of neuropsychiatric symptoms are biological, psychosocial/psychological and environmental, often in a complex interaction (Gauthier et al., 2010). The biological progression in brain pathology caused by the disease is associated with the emergence of neuropsychiatric symptoms (Gauthier et al., 2010). Many persons with dementia have a range of unmet physiological and psychological needs, such as hunger, thirst, distress, pain, feelings of abandonment, or fear of endangerment, which may be expressed by neuropsychiatric symptoms (Gauthier et al., 2010). Persons with dementia living in a nursing home are reported to have an average of 2.9 unmet needs (Cohen-Mansfield et al., 2015). Need for social contact and boredom/sensory deprivation are the most common needs,

reported for up to 2/3 of nursing home residents with dementia (Cohen-Mansfield et al., 2015), while the need for meaningful activity was reported for 50% of nursing home residents with dementia (Cohen-Mansfield et al., 2015).

Excessive noise/stimulation, inadequate lighting, confusing surroundings, lack of daily structure/routine, the distressing behaviour of others, excessive demands, and loneliness/boredom are environmental factors implicated in triggering neuropsychiatric symptoms (Gauthier et al., 2010).

Both pharmacological and non-pharmacological therapies have been used to manage neuropsychiatric symptoms among persons with dementia, usually symptomatically based (Nowrangi et al., 2015). Due to major side effects of medication (Tripathi & Vibha, 2010), non-pharmacological therapies should be the first choice (Douglas et al., 2004; Gauthier et al., 2010; Iden et al., 2014).

1.4.1.1. Agitation

Agitation has been defined as an 'inappropriate verbal, vocal, or motor activity that is not explained by needs or confusion *per se'* (Cohen-Mansfield & Billig, 1986). Agitated behaviour may be expressed through physically aggressive behaviours, physically non-aggressive behaviours (e.g. manipulation of objects), verbally aggressive behaviours, and verbally non-aggressive behaviours (e.g. negativism, complaining, disruptive interruptions, verbal bossiness, and whining), with verbally non-aggressive behaviour as the most frequent (Cohen-Mansfield, 2008). Disruptive behaviour such as irrelevant vocalizations, cursing, screaming, handling things inappropriately, wandering, strange movements, and restlessness may indicate discomfort, and have been found to be more frequently expressed by women (Cohen-Mansfield, 2008).

The prevalence of agitation among persons with dementia is found to be 20–30% (Lyketsos et al., 2002; Wergeland et al., 2014). The causes of agitated behaviour are psychological, neurological, physical (pain), functional, interpersonal, environmental, and restraint factors (Kong, 2005; van Dalen-Kok et al., 2015). Physically non-aggressive behaviours are related to cognitive impairment (Cohen-Mansfield, 2008), and is often expressed by persons with dementia

who have unmet needs related to boredom and sensory deprivation, and verbal agitation is often expressed by persons with dementia who have unmet needs related to loneliness (Cohen-Mansfield et al., 2015). Aggression may be linked to the person's personality and behaviour before they developed dementia, severity of dementia, dementia disorder, comorbidity, environmental factors, lack of ability to articulate their needs and anxiety, among others (Engedal & Haugen, 2009; Gauthier et al., 2010). Individuals may also be predisposed to become agitated by deficits in cognitive functioning and cerebral impairment (Cohen-Mansfield et al., 1990).

Agitation is often treated with medications such as Citalopram, atypical anti-psychotics, anti-epileptic mood stabilizers, and/or non-pharmacological treatments (Nowrangi et al., 2015). Agitation is a strong predictor of poor quality of life (Wetzels et al., 2010), and is one of the leading predictors for institutionalization (Gauthier et al., 2010).

1.4.1.2. Depression

Depression is highly correlated with dementia diagnosis, and especially severe depression has many of the same characteristics as dementia (Engedal & Haugen, 2009). Depression can be a first sign of dementia, and could be co-existing. A good diagnosis is therefore very important (Mahendra, 1985). Common symptoms of depression are: apathy, low self-esteem, suicidal thoughts or attempts, crying, weight loss, loss of interest in activities and hobbies, social withdrawal, isolation, trouble concentrating, and impaired thinking (Engedal & Haugen, 2009). Depression is one of the most common neuropsychiatric symptoms among persons with dementia. Depression is found to be more common among persons with severe dementia, behavioural symptoms, and those with pain (Gruber-Baldini et al., 2005). The prevalence of depression is found to be between 20% and 50% (Gauthier et al., 2010). A recent Norwegian study found a 31% prevalence of depression among recently admitted long-term care patients (Iden et al., 2014), while Wergeland et al. found a prevalence of 37.2% in home-dwelling persons with dementia (Wergeland et al., 2014).

Depression may be caused by both psychological and biological factors (Engedal & Haugen, 2009). Lack of mastering and trouble adapting to the dementia diagnosis may be causative

(Engedal & Haugen, 2009), but alterations in monoaminergic neurotransmitter functioning and brain metabolism is found to be an underlying cause (Nowrangi et al., 2015).

Depression is often overlooked and untreated in persons with dementia. This goes for both persons with dementia admitted to nursing homes, as well as for home-dwelling persons with dementia (Livingston et al., 2008). However, depression might be treated with medications such as Serotonin (serotonin selective reuptake inhibitor, or SSRI) and norepinephrine (serotonin-norepinephrine reuptake inhibitor, or SNRI) (Nowrangi et al., 2015), which may decrease symptoms such as irritability and aberrant motor behaviour (Engedal & Haugen, 2009) and/or non-pharmacological treatments (Nowrangi et al., 2015). Depression is a strong predictor of poor quality of life (Wetzels et al., 2010), and is, along with agitation, one of the leading predictors for institutionalization (Gauthier et al., 2010).

1.4.1.3. Night-time behaviour disturbances

Sleep disruption in persons with dementia include frequent night-time awakenings, an increased daytime sleep and both slow-wave sleep and REM sleep are decreased (Tractenberg et al., 2005).

Sleep disruption is common among dementia patients (Tractenberg et al., 2005). It has been estimated that between 25% and 54% of Alzheimer's disease patients suffer from sleep disturbances (Gauthier et al., 2010) and two-thirds of nursing home residents is reported to have sleep disturbance problems (National Sleep Foundation, 2015). Persons with dementia usually sleep for long durations (Engedal & Haugen, 2009). However, apathy, trouble concentrating and paying attention may lead to excessive napping during the daytime, which may lead to trouble falling asleep at night (Engedal & Haugen, 2009). Sleep disorders could be a result of circadian rhythm disruptions, which have been found to be frequent in aging populations, and even more so for institutionalized patients and persons with dementia (van Someren et al., 1996; Wu & Swaab, 2007). Such sleep- and circadian-disruptions have a significant impact on the patient's cognitive and physical function and may be associated with relevant psychological distress and depression. Poor sleep results in an increased risk of morbidities and mortality in persons with dementia, and is a source of stress for caregivers (Guarnieri et al., 2014). Treatment depends on

type of sleep disruption, but medications (i.e. melatonin, antidepressants, benzodiazepines, non-benzodiazepines, and antihistamines) are widely used, and also light therapy and alternative treatments such as massage (Bliwise, 2004; Deschenes & McCurry, 2009). Sleep disturbances such as difficulty falling asleep (insomnia) or waking up several times during the night may lead to reduced cognitive functioning and physical health issues, are associated with poorer quality of life (Kripke et al., 2002; Simon & VonKorff, 1997), and is also a precipitant of institutionalization (Gauthier et al., 2010).

1.4.1.4. Apathy and activity

Persons with dementia may show decreased goal-directed behaviour and decreased goal-directed cognitive activity resulting in apathy (Nowrangi et al., 2015). Biological factors associated with apathy is dysfunction of the prefrontal and anterior cingulate regions, including both cortical and subcortical regions (Nowrangi et al., 2015).

Level of physical activity is shown to decline with increasing age (Päivi et al., 2010). Sedentary behaviour such as sitting or lying down for long periods of time is not unusual among nursing home residents, and it is reported that nursing home residents spend up to 94% of their time sitting or lying down during day-time (MacRae et al., 1996). A study of 15 nursing homes reported that most of the residents spent at least 17 hours per day in bed (Bates-Jensen et al., 2004). Institutionalized older adults seem to have lower levels of physical activity than elderly living in community-dwellings (Król-Zielińska et al., 2010; Salguero et al., 2011). This might be because of several barriers, such as environmental constraints and health problems (Chen, 2010; Król-Zielińska et al., 2010). The high prevalence of inactivity, apathy and sedentary behaviour among persons with dementia living in nursing homes (Bates-Jensen et al., 2004; MacRae et al., 1996), reflects that nursing home residents are frequently reported to participate in few activities and to be unoccupied much of the day (Smit et al., 2015). Engagement in daytime activities may increase alertness and decrease boredom (Cohen-Mansfield et al., 2010e) and enhance quality of life (Smit et al., 2015). Apathy is often treated with medications such as methylphenidate, amantadine, d-amphetamine, modafanil, and/or non-pharmacological treatments (Nowrangi et al., 2015).

1.4.2. Medication

Medication among patients with dementia is commonly used (Iden et al., 2014; Selbæk et al., 2007; Tripathi & Vibha, 2010), and is found to have increased during the last decade (Ruths et al., 2013). Use of psychotropic medication is found to be prescribed to almost 50% of homedwelling persons with dementia (Wergeland et al., 2014), and 75% of persons with dementia in nursing homes (Selbæk et al., 2007), demonstrating an extensive use. 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 & Vibha, 2010), and some pharmacological treatment is related to worse quality of life (Gonzalez-Salvador et al., 2000; Wetzels et al., 2010).

1.4.3. Balance

Balance can be defined as the ability to maintain the body's centre of mass in relationship to the base of support (Shumway-Cook & Woollacott, 2012). The complex interaction to achieve balance includes both musculoskeletal and neural systems (Shumway-Cook & Woollacott, 2012). Good balance is important to be able to perform everyday activities (Scherder et al., 2007). In a study of Downs, et al., they found that by age, it was a significant decline in balance measured with Berg Balance Scale per year at a rate of 0.7 points (Downs et al., 2014).

A consequence of failing to maintain balance is increased risk of falling. Physiological systems critical for postural control are cognitive processing (attention and learning), biomechanical restraints (strength and limits of stability), sensory strategies, movement strategies, orientation in space, and control of dynamics (Horak, 2006). The dementia disorder probably affects some or all of these resources, and causes reduced postural balance (Horak, 2006). Persons with dementia have a two-fold increased risk of falls compared with non-demented elderly (Tinetti et al., 1995).

Effective rehabilitation of balance requires an understanding of the many systems underlying postural control (Horak, 2006). Complex interventions targeting several risk factors related to

falls have been considered most effective for reducing the risk of falls and are therefore recommended (Cameron et al., 2010; Gillespie et al., 2009). Health care workers should carry out an initial assessment and give recommendations for further action. When two or more categories of intervention are given, and these are linked to each individual's risk profile, it is called a multifactorial intervention (Cameron et al., 2010).

Fall accidents are a major cause of disability, immobility and mortality among elderly, and have a huge impact on each individual's quality of life (Todd & Skelton, 2004). Mobility impairments have been found to increase risk of institutionalization (Hajek et al., 2015).

1.4.4. Quality of life

A general definition of quality of life is that 'Quality of life is the multidimensional evaluation, by both intrapersonal and social-normative criteria, of the person — environment system of an individual in time past, current, and anticipated' (Lawton, 1991). There are no standard definition of quality of life among persons with dementia, and the conceptualizations of quality of life vary (Dichter et al., 2013; Ettema et al., 2005). However, the definition by Lawton (1991) who states that 'quality of life is a multidimensional concept, which in older adults includes behavioural competence, the objective environment, psychological well-being, and perceived quality of life', is frequently used (Ettema et al., 2005; Logsdon et al., 2002). Lawton defines behavioural competence as the 'social-normative evaluation of the person's functioning in the health, cognitive, time-use and social dimensions', which should be objectively measured (Lawton, 1991). Within environment lies home, neighbourhood and social networks (Lawton, 1991). Psychological well-being is the ultimate outcome, and typical indicators include mental health, cognitive judgments of overall life satisfaction, and positive and negative emotion experienced as either states or traits (Lawton, 1991). Perceived quality of life is the person's subjective evaluation of function in health, cognitive, time-use and social dimensions (Lawton, 1991).

Quality of life among persons with dementia is often diminished (Barrios et al., 2013). Poor quality of life has been found associated with several of the same risk factors as found for institutionalization, such as low cognitive function, impaired mobility, lack of social activities,

major depression, prevalence of neuropsychiatric symptoms and low performance in activities of daily life (Barca et al., 2011; Mjørud et al., 2014a; Nagatomo et al., 1997; Telenius et al., 2013; Wetzels et al., 2010).

1.4.5. How the factors interact

Cognitive function (degree of dementia), physical function, neuropsychiatric symptoms (depression, agitation and apathy), engagement and quality of life are interconnected, and affect each other. Cognitive function, neuropsychiatric symptoms and physical function affect engagement (Kolanowski et al., 2006), as well as quality of life (Logsdon et al., 2007; Mjørud et al., 2014a). On the other hand, engagement affect neuropsychiatric symptoms (Cohen-Mansfield et al., 2007), and quality of life (Logsdon et al., 2007). Improved physical function decrease depression (Teri et al., 2003) and enhance quality of life (Telenius et al., 2013). Cognitive function also affect physical function (Härlein et al., 2009), neuropsychiatric symptoms (Beerens et al., 2013; Mjørud et al., 2014a), and quality of life (Barca et al., 2011; Bárrios et al., 2012; Logsdon et al., 2007; Mjørud et al., 2014a). Neuropsychiatric symptoms affect engagement (Kolanowski et al., 2006) and quality of life negatively (Beerens et al., 2013; Logsdon et al., 2007; Mjørud et al., 2014c). This interaction means that deterioration may occur, but also that improvement in one of these factors might lead to improvement in some other factor(s). Change in quality of life amongst persons with dementia is mainly associated with change in neuropsychiatric symptoms (Samus et al., 2005; Wetzels et al., 2010), which means a decrease in neuropsychiatric symptoms may increase quality of life.

1.4.6. Management of dementia

As a consequence of the major side-effects of medications (Tripathi & Vibha, 2010) and the need for meaningful activities (Cohen-Mansfield et al., 2015), several non-pharmacological interventions have been developed and should be the first choice in treating behavioural problems in persons with dementia (Cohen-Mansfield, 2001; Gauthier et al., 2010; Salzman et al., 2008).

In a review of Douglas et al. (2004), they examined some of the non-pharmacological approaches that were current in the beginning of this century. Behavioural analysis is often the starting point of most forms of therapeutic intervention (Douglas et al., 2004). Modern behavioural approaches can be consistent with person-centred care, which focus on maintaining personhood, individualizing care by collecting and using personal experiences of life, involving relatives in care and prioritizing relationship and not only care tasks (Terada et al., 2013). Behavioural therapy requires a period of detailed assessment in which the antecedents, unwanted behaviours and consequences are identified and their relationships is made clear to the patient (Douglas et al., 2004). Interventions are then based on an analysis of these findings. Three key features should be in focus when designing an intervention: taking account of the individual's preferences; changing the context in which the behaviour takes place; and using reinforcement strategies and schedules that reduce the unwanted behaviour (Douglas et al., 2004). Because behaviours will have diverse causes and maintaining factors, behavioural interventions should be individually tailored.

Reality orientation used to be one of the most widely used management strategies for dealing with people with dementia (Douglas et al., 2004). It was supposed to help people with memory loss and disorientation by reminding them of facts about themselves and their environment. It has, however, been claimed that reality orientation can remind the participants of their deterioration, and thereby lowering the mood in those attending the sessions (Douglas et al., 2004). Also, carers have experienced further frustration at using the method and at having repeatedly to try to orient individuals, with little noticeable long-term effect (Douglas et al., 2004).

Validation therapy attempt to communicate with individuals by emphasizing with the feelings and meanings hidden behind their confused speech and behaviour (Douglas et al., 2004). The emotional content of what is being said is more important than the person's orientation to the present. Reminiscence therapy aims at helping persons with dementia to relive past experiences, especially those that might be positive and personally significant (Douglas et al., 2004). The therapist may use activities such as art, music and artefacts to provide stimulation. The aim of reminiscence therapy is to increase levels of well-being and provide pleasure and cognitive

stimulation. Activities such as drawing and painting are meant to give the individuals an opportunity for self-expression, and will also give them the chance to exercise some choice in terms of how the art should be (Douglas et al., 2004). Music therapy involves engagement in listen to songs or music, singing or playing an instrument (Douglas et al., 2004). Activity therapy involves different forms of activities, such as dance, sport and drama (Douglas et al., 2004). In addition, other complementary therapy involves, for example, massage, reflexology, reiki, therapeutic healing, herbal medicine and aromatherapy (Douglas et al., 2004). Multisensory approaches is usually performed in a room special designed to provide several types of sensory stimulation such as touch, smell, sound, light and texture. The light is often specialized, using fibre optics, which can move and be flexible. Different textures might be used, such as cushions and vibrating pads. The use of these different stimulation is tailored to the individual and all of them may not be used in one session (Douglas et al., 2004). Social stimuli of different attributes such as realistic, animated, human, or alive is frequently used to create engagement (Cohen-Mansfield et al., 2010f). The purpose is to engage the individuals, as well as being a resource for touch, conversation and social interactions.

Many of the mentioned approaches serves as a sensory stimulation, a common form of intervention for persons with dementia in order to increase alertness, reduce agitation and enhance quality of life (Strøm et al., 2016). A resent review concludes that even though most of interventions included in the review (music, acupressure/reflexology, massage/aromatherapy, light therapy, doll-/pet-/toy therapy, Sonas, and Snoezelen) report some effect on neuropsychiatric symptoms, more research of high quality is needed (Strøm et al., 2016).

A systematic Cochrane -review 'Effect of psychological interventions for people with dementia' analysed available evidence about the efficacy of psychological interventions for persons with dementia in regards to: cognition, agitation, depression, anxiety, quality of life, activity of daily living and 24-hours care (Dahm et al., 2014). Interventions of cognitive training and rehabilitation, cognitive stimulation, reminiscence therapy, validation therapy, music therapy and multi-sensory stimulation were evaluated. Only cognitive stimulation was found to increase cognitive function and quality of life. According to their evaluation of the evidence, cognitive training and rehabilitation, reminiscence therapy and validation therapy probably have little or

no effect for people with dementia. They were not able to draw any conclusions about the effect of music therapy and multi-sensory stimulation due to low level of reliability of studies examined. Psychological interventions such as cognitive behavioural therapy, probably reduce depression and might reduce anxiety, but seem to have little or no effect on cognitive function, quality of life and daily activity level (Dahm et al., 2014).

1.5. Animal-assisted interventions

The introduction (Section 1.0) emphasizes the need for more research in the field of non-pharmacological interventions with a health promoting effect. Amongst non-pharmacological interventions and complementary treatment, animal-assisted interventions have become a popular alternative, especially in nursing homes and among persons with dementia (Bernabei et al., 2013; Cohen-Mansfield, 2001).

1.5.1. Definition

Animal-assisted intervention is '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 activity is a sub discipline of animal-assisted interventions, whereby companion animals are taken by their human handlers to visit for 'meet and greet' activities (IAHAIO, 2014). Animal-assisted activities are usually conducted on a volunteer basis by individuals who do not have a health, education or human service degree, but may also work formally and directly on specific documentable goals (IAHAIO, 2014). Only domesticated animals such as dogs, cats, horses, farm animals, guinea pigs, rats, fish, birds should be involved in animal-assisted interventions (IAHAIO, 2014).

1.5.2. Previous findings

Looking at studies relevant for this thesis, previous research of animal-assisted interventions for persons with dementia have shown that animal-assisted interventions might be beneficial for social, behavioural, and psychological outcomes, such as increased social behaviour (Banks &

Banks, 2002, 2005; Barak et al., 2001; Bernstein et al., 2000), decreased depression (Friedmann et al., 2015a; Majic et al., 2013), increased mood (Marcus et al., 2012), decreased agitation (Richeson, 2003; Sellers, 2006), increased cognition (Moretti et al., 2011), and enhanced physical function (Friedmann et al., 2015a; Herbert & Greene, 2001). Studies of physiological outcomes such as changes in cortisol (Odendaal & Meintjes, 2003; Polheber & Matchock, 2014) lower epinephrine and norepinephrine (Cole et al., 2007), increase of plasma oxytocin, prolactin, phenylethylamine, and dopamine (Odendaal, 2000; Odendaal & Lehmann, 2000; Odendaal & Meintjes, 2003) have been performed in other populations, and such outcomes probably also have an effect on persons with dementia.

To identify relevant research papers in the field of animal-assisted interventions with dogs for persons with dementia, a search in major databases (PubMed, and ISI Web of science) for papers from peer-reviewed journals was conducted. The following key words were used: animal-assisted and elderly, animal-assisted and dementia, animal assisted elderly, animal assisted dementia, pet-assisted, pet therapy). To some extent, the 'Snowball effect' method was used, by searching reference list to find relevant literature. As several authors have provided the field with comprehensive reviews (Bernabei et al., 2013; Filan & Llewellyn-Jones, 2006; Perkins et al., 2008; Souter & Miller, 2007; Virués-Ortega et al., 2012), only single studies of animal-assisted interventions with dogs for persons with dementia published after 2013 is included in the table in addition to the relevant reviews. In addition, the following limitations were set: Only reviews and meta-analysis on animal-assisted interventions with dogs and elderly/persons with dementia were included. Papers on animal-assisted interventions with dogs and elderly/persons with dementia concluded before the last review was thereby excluded.

An overview of research in animal-assisted interventions with dogs for persons with dementia is shown in Table 2.

Table 1. Overview of research in animal-assisted interventions with dogs for persons with dementia divided into reviews, RCTs and single group studies.

Reviews	Title	Sample	N	Main findings
Bernabei et al. (2013)	Animal-assisted interventions for elderly patients affected by dementia or psychiatric disorders: A review	Persons with dementia	18 papers	Calming of agitated behaviour, enhanced quality of social interactions and positive effect on mood disturbances.
Virués-Ortega et al. (2012)	Effect of animal-assisted therapy on the psychological and functional status of elderly populations and patients with psychiatric disorders: a meta-analysis	Elderly. The mean age of individuals participating in these studies ranged from 57 to 94	21 papers	Improvement in social function. Moderate effects were found for depression, anxiety and behavioural disturbances.
Perkins et al. (2008)	Dog-assisted therapy for older people with dementia: a review	Persons with dementia	9 Papers	Significant increases in a range of social behaviours in addition to benefits in agitation, apathy and other problematic behaviours.
Souter and Miller (2007)	Do animal-assisted activities effectively treat depression? A meta-analysis	The studies took place in various institutional settings. The mean age of individuals participating in these studies ranged from 47 to 85.	5 papers	Indication of significant improvement in depression.
Filan and Llewellyn-Jones (2006)	Animal-assisted therapy for dementia: a review of the literature	Persons with dementia	11 papers	Small studies suggest a decrease in aggression and agitation, as well as increased social behavior.

RCTs	Title	Sample	N	Intervention	Assessments and time point of measures	Follow-up	Main findings
Bono et al. (2015)	Effects of animal assisted therapy (AAT) carried out with dogs on the evolution of mild cognitive impairment	Home-dwelling persons with dementia diagnosed with early stage or mild AD	24	60-minutes sessions twice a week for 8 months.	Barthel, ADAS, and CSDD were assessed at baseline and after end of intervention		Significant positive effect of intervention on Barthel, ADAS, and CSDD.
(Friedmann et al., 2015a)	Evaluation of a Pet- assisted Living Intervention for Improving Functional Status in Assisted Living Residents With Mild to Moderate Cognitive Impairment: A Pilot Study	Persons with dementia living in nursing homes.	40	60- to 90- minute sessions with a therapy dog twice per week for 12 weeks	24 hours Actigraphy. Barthel Index, Zimmerman's short version of the AES, CSDD and CMAI were assessed before intervention, and at the end of every month of the intervention period.		No effect was found.
Thodberg et al. (2015)	Therapeutic effects of dog visits in nursing homes for the elderly	Elderly living in nursing homes (mainly diagnosed with dementia).	100	10 minutes visit with a dog, Paro or a soft toy cat 2 times per week for 6 weeks	One night of Actigraphy before, during and after intervention, GBS, GDS and CAM was measured before and after intervention.		No effect on behavioural, cognitive function or BMI. A passing effect on sleep duration was found as the dog group slept longer one night after 6 visits.

Nordgren and Engstrom (2014b)	Effects of dog-assisted intervention on behavioural and psychological symptoms of dementia	Persons with dementia living in nursing homes.	33	10 sessions, 45-60 minutes once or twice per week.	CMAI and MDDAS, before, three and six months after inclusion.	Three and six months after inclusion.	No effect was found.
Majic et al. (2013)	Animal-assisted therapy and agitation and depression in nursing home residents with dementia: a matched case-control trial	Persons with severe dementia living in nursing homes.	65	45 minutes AAT, one time per week for 10 weeks.	MMSE, CMAI, DMAS, psychotropic medication were assessed at baseline and after end of intervention.	Observations and assessments lasted for 4 weeks after post intervention.	Remained level of depression in the intervention group, while the control group worsened.
Travers et al. (2013)	An Evaluation of Dog- Assisted Therapy for Residents of Aged Care Facilities with Dementia	Persons with dementia living in nursing homes	55	40-50 minutes animal- assisted group therapy with a dog three/two times per week for 11 weeks.	QOL-AD, MMSE, SF-36, GDS-SF, MOSES were assessed one week before the intervention started, and after end of intervention.		Significantly higher quality of life in one facility, but not in the other two.

Single group studies							
Swall et al. (2015)	Can therapy dogs evoke awareness of one's past and present life in persons with Alzheimer's disease?	Older persons with Alzheimer's disease living in nursing homes.	5	Scheduled AAT with a therapy dog team one visit a week over a period of 10 weeks.	Video observation of the encounters between the participants and the therapy dog for every session.		Through phenomenological hermeneutical research method, they found that the participants seemed to get in touch with existential thoughts and memories and were able to talk about them.
Nordgren and Engstrom (2014a)	Animal-assisted intervention in dementia: effects on quality of life	Persons with dementia living in nursing homes.	9	10 sessions, 45-60 minutes once or twice per week.	QUALID was assessed at baseline and after end of intervention.		Significant improvement in quality of life.
Swall et al. (2014)	A therapy dog's impact on daytime activity and night-time sleep for older persons with Alzheimer's disease - A case study	Older persons with Alzheimer's disease living in nursing homes.	5	Scheduled AAT with a therapy dog team one visit a week over a period of 10 weeks.	24 hours per day actigraphy for 16 weeks. One-week baseline (before the visits of the therapy dog teams), during 10 weeks of scheduled visits and for a five-week follow-up after the visits ended.	After 5 weeks	Need for individual tailoring. No clear pattern of effect of AAT.

The reviews included in this thesis, conclude that animal-assisted interventions seems to have a positive influence on social behaviour, a beneficial effect on agitation and other behavioural disturbances, and indications of significant improvement in depression (Bernabei et al., 2013; Filan & Llewellyn-Jones, 2006; Perkins et al., 2008; Souter & Miller, 2007; Virués-Ortega et al., 2012).

Bono et al. examined effect of animal-assisted intervention in 24 outpatients with mild cognitive impairment. The intervention group received animal-assisted intervention for 60 minutes twice per week for eight months. The control group was followed at home at the same intervals. Assessments on daily activities, cognitive function and depression were carried out. The authors found a significant positive effect of the intervention on all measurements (Bono et al., 2015).

A recent study by Friedmann et al. (2015) found that depression among persons with dementia living in nursing home decreased during the intervention period with animal-assisted group intervention. The reminiscing group, used for comparison, did not experience a decrease in depression, however, no significant effect was found between groups. The intervention was conducted twice a week for 12 weeks (Friedmann et al., 2015a).

Thodberg et al. (2015) conducted a large sample sized study (100 nursing home residents with dementia) with a rather short intervention (10 minutes visit two times a week for six weeks). They found no effect on behavioural, cognitive function or body mass index (BMI), however a passing effect on sleep duration was found at one night midway in the study period (Thodberg et al., 2015).

Effects of animal-assisted intervention on behavioural and psychological symptoms of dementia were assessed by Nordgren and Engström (2014b). Twenty nursing home residents with dementia received ten sessions of dog-assisted intervention once or twice per week. The sessions lasted between 45 and 60 minutes. Thirteen nursing home residents with dementia continued treatment as usual. No effects were found, however some positive tendencies were observed with a decrease in physical non-aggressive behaviours and verbal agitation in the intervention group.

Effect of animal-assisted intervention on agitation and depression was studied by Majic et al. (2013). A total of 65 nursing home residents with dementia were randomized to treatment as usual, or with animal-assisted intervention in addition to treatment as usual. The intervention group received animal-assisted intervention with a dog 45 minutes once a week for 10 weeks. The control group showed significantly increased prevalence of agitation/aggression and depression symptoms throughout the study period of 10 weeks, while the intervention group remained on the baseline level, indicating the animal-assisted intervention had a stabilising effect (Majic et al., 2013).

Travers et al. (2013) conducted a randomized controlled trial in three different nursing homes (N = 55). Participants were allocated to either animal-assisted intervention, or human-therapist-only intervention. Both interventions consisted of 40-50 minutes group sessions two/three times per week for 11 weeks. A significant effect of animal-assisted intervention was found on quality of life in one of the participating facility, however no effect was found in the other two participating facilities (Travers et al., 2013). The authors still conclude that the dog-assisted therapy is beneficial for some residents with mild to moderate dementia (Travers et al., 2013).

A qualitative study with a phenomenological hermeneutical approach was conducted to illuminate the meaning of the interaction between participant and dog in an animal-assisted intervention (Swall et al., 2015). Five nursing home residents were included, and received 30 minutes sessions of animal-assisted intervention once a week for ten weeks. All sessions were videotaped. The authors found that the sessions made the person recount memories and feelings, and that they were able to communicate this during the session. The dog seemed to promote laughter and positive feelings (Swall et al., 2015).

In a pilot project without control group in 4 nursing homes, effects of animal-assisted intervention on quality of life among 9 nursing home residents were examined (Nordgren & Engstrom, 2014a). The intervention consisted of ten 45-60 minutes sessions of animal-assisted interventions once or twice per week. Measurements were assessed one week before start of intervention and one week after last session of the animal-assisted intervention. Statistical

significant improvement was found between baseline and post-test (Nordgren & Engstrom, 2014a).

In a case study including five nursing home residents, the participants received 30 minutes sessions of animal-assisted intervention once a week for ten weeks (Swall et al., 2014). Acigraphy registration of activity and sleep curves was conducted over a period of 16 weeks. The registration started one week before the first session with the dog, and continued for 5 weeks after the last session. No clear pattern of effect was found (Swall et al., 2014).

As the literature illustrates, research in the field of animal-assisted interventions is increasing, however, many of the studies show no or mixed effect, and sample size is small. Earlier research, included in the reviews, also lack important information regarding setting, patient population, type of animal, duration of visits, and frequency of animal interactions (Souter & Miller, 2007). Currently conducted research is found to be of a higher quality than earlier research (Fine et al., 2015), still the limited empirical support is stressed, and the need for more research to promote the efficacy of animal-assisted interventions is constantly emphasized (Fine, 2015). There is also a lack of theoretical foundation in the research of animal-assisted interventions, which makes it difficult to compare effect (Strøm et al., 2016).

1.6.Theoretical framework

From back in 1984, the biophilia hypothesis (Wilson, 1984) has been used as an umbrella theory for responses seen in contact with animals (Fine et al., 2015). Effects of animal-assisted interventions are also suggested to be explained by social catalyst and social support (Beetz et al., 2012a), and change in physiological state (Odendaal, 2000). In 2009, Cohen-Mansfield et al. introduced the Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009a). This theory was developed in order to assess engagement, which is essential when non-pharmacological interventions are implemented in dementia care (Cohen-Mansfield et al., 2009a). The Comprehensive Process Model of Engagement might be used to comprehend some of the aspects of the animal-assisted intervention, and provide a link between the activity with the animal and the outcomes seen in studies of persons with dementia.

1.6.1. The biophilia hypothesis and the human-animal bond

Humans and animals have a shared evolutionary history, and the biophilia hypothesis by Wilson (1984), suggests that humans of all ages need and want contact with nature (Wilson, 1984). The theory suggests that this is due to an innately interest in animals, as attention to animals was beneficial for survival. Neuroscientists have found that neurons in the human amygdala responded preferentially to animal pictures rather than to pictures of persons or landmarks, demonstrating that humans have a category-specific response to animals (Mormann et al., 2011). Humans presumable have a self-interest to engage in therapies or activities with animals (Wilson, 1984), and the first pioneer in this field, Boris Levinson, went so far as arguing that animals through evolution have become an integral part of our psychological well-being (Serpell, 2015). This innate human desire for contact with the natural world lays the basis for animal-assisted interventions, and it is said that these kind of interventions where one build relationship with nature might help people learn how to build relationships with each other (Fine et al., 2015). Contact with other species may also have significant impact on human cognition, health, and well-being (Wilkes, 2009).

1.6.1.1. Possible mechanisms explaining effect of animal-assisted interventions

Evolution of dogs has led to dogs interacting with humans in a unique way, making dogs functional similar to humans in some cognitive, behavioural and social aspects (MacLean & Hare, 2015; Topál et al., 2005). Regarding social aspects, some social competence of dogs can be considered as functioning in the same way as those in humans (Miklosi & Topal, 2013). For example, dogs can recognize human emotions (Albuquerque et al., 2016), and humans represent dogs' emotions in a somewhat similar way to their own (Konok et al., 2015). As humans recognize dogs as companions, attachment and social support are suggested to be one of the potential mechanisms in animal-assisted interventions (Serpell, 2006). Beneficial effects of social support makes a person feel cared for, loved or esteemed and may fulfill basic needs (Serpell, 2015). The dog in animal-assisted activity is previously reported to have a social catalyst effect (Beetz et al., 2012b), and as stated above, reviews on animal-assisted interventions on persons with dementia have concluded that this kind of intervention may increase social behaviour and interaction

(Bernabei et al., 2013; Filan & Llewellyn-Jones, 2006; Perkins et al., 2008; Virués-Ortega et al., 2012).

Oxytocin is found to be released via tactile stimulation between humans and dogs (Odendaal & Meintjes, 2003), and activation of the oxytocin system is suggested to be a key factor in explaining the effects of human-animal interactions (Beetz et al., 2012b). Oxytocin is a peptide hormone produced in the hypothalamus. Oxytocin receptors are distributed in various brain regions associated with behaviour and the ability to form normal social attachments (Kosfeld et al., 2005). Oxytocin is released in response to positive social interactions, and is associated with the regulation of the behavioural and endocrine stress response. Oxytocin has mainly been found to increase positive behaviour such as social cognition and the interpretation of social signals (Heinrichs et al., 2009; Onaka et al., 2015), thus there is not sufficient evidence to show that oxytocin has a positive effect on negative behaviours such as agitation (Alcorn et al., 2014; Campbell, 2008). The effect of oxytocin on depression has been discussed, but the authors of a review from 2009 concludes that the divergent research do not let us draw stringent conclusions (Heinrichs et al., 2009).

It is also worth noting that researchers lately question previous research on oxytocin and the effect on human behaviour (Leng & Ludwig; McCullough et al., 2013). The reason for this is that earlier studies have measured the hormone level in blood, saliva or urine, while oxytocin acts in the central nervous system. The fact that oxytocin does not cross the brain-blood barrier and the uncertainty on accurate measures of oxytocin in the blood or saliva, makes contemporary researchers in neuroscience doubt previous reports (Leng & Ludwig; McCullough et al., 2013). New methods for demonstrating effect on hormones and other physiological outcomes are continuously developed, and there should be a focus on new technologies to prove the potential benefits of animal-assisted interventions (Herzog, 2015). Nevertheless, research already conducted in the field of animal-assisted interventions have found a stress-reduction effect of interacting with animals through a decrease in cortisol measured in saliva and attenuated heart rate (Polheber & Matchock, 2014) in addition to the before mentioned increase of oxytocin, prolactin, phenylethylamine, and dopamine (Odendaal, 2000; Odendaal & Lehmann, 2000; Odendaal & Meintjes, 2003). Moreover, even though most of the research conducted on

physiological outcomes during interactions with a dog is based on pet owner ship, the same effect as interacting with one owns dog is found when interacting with a therapy dog (Friedmann et al., 2015b).

In 2008, Nancy Parish-Plass published an article on animal-assisted interventions in psychotherapy for children (Parish-Plass, 2008). Parish-Plass uses the concepts 'Normalcy, safety and friendliness of the therapy setting', 'Development of more adaptive representations and strategies', 'Acceptance', 'Enabling connection', 'Reality at a safe psychological distance', 'Empathy', 'Self-esteem', 'Need for control', 'Touch' (Parish-Plass, 2008). Many of the mechanisms she presents in this article are related to the biophilia hypothesis, and are applicable in animal-assisted interventions in general. Regarding animal-assisted group activity with a dog for persons with dementia, 'Normalcy, safety and friendliness of the therapy setting' would be that the presence of the dog gives the participants a sense of normalcy and might encourage natural and spontaneous behaviour. The way the dog handler treats the dog will create trust among the participants, and make them feel comfortable. It is important to behave appropriate when interacting with the dog, and this may lead to development of more adaptive representations and strategies. For example, the participant cannot behave agitated or aggressive, and he/she may have to adjust the tone of his/her voice. This provides opportunities for learning and expressing more appropriate behaviour also in settings without the dog present. Dogs do not prejudge. Consequently, participants will feel that they are accepted, despite their disease. Both by the dog, but also by the dog handler in the way the dog handler accepts the dog. The way the dog handler treats the dog may also lead the participants to perceive the dog handler in positivistic way, and enable connection. Even though dogs share many social functions with humans, they also suddenly behave in an unpredictable way. This may awaken memories, associations, and emotions that may be projected through the dog and expressed as, for example, 'Oh, you are tired, yes I understand. It is so noisy here'. This allows the participants to have reality at a safe psychological distance. The feeling of being important to the dog when petting it or feeding it treats gives the opportunity to show empathetic behaviour and may enhance self-esteem. It also lets the participant be in control, a feeling that might not be very common among persons with dementia, especially when admitted to nursing home. Elderly people may have limited opportunities for *touch*. Petting the dog allows for touching another living being, a sensory stimulation that might lead to a psychological sense of wellbeing.

1.6.2. Engagement theory

Nursing home residents participate in few activities and are unoccupied much of the day (Smit et al., 2015). This leads to high prevalence of inactivity, apathy and sedentary behaviour (Bates-Jensen et al., 2004; MacRae et al., 1996). By reducing boredom and loneliness and increasing interest and positive emotions, change in level of engagement is found to generate valuable effects (Cohen-Mansfield et al., 2009a). Engagement may be defined as 'the act of being occupied or involved with an external stimulus' (Cohen-Mansfield et al., 2009a), and the conceptual framework of Cohen-Mansfield et al.'s Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009a) proclaims that engagement with a stimulus is influenced by attributes of the environment, the participant and the stimulus itself (Figure 1). Knowledge about attributes of the environment, the participant and the stimulus itself are essential in order to design proper non-pharmacological interventions (Cohen-Mansfield et al., 2009a).

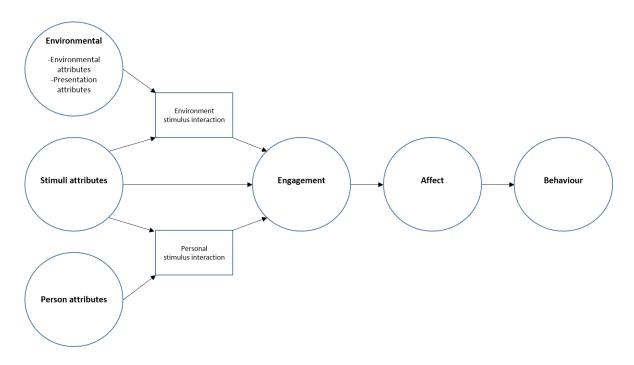


Figure 1. The Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009).

Environmental attributes are described as surroundings, such as time, place, number of people around and temperature, as well as the manner of stimulus presentation. In an animal-assisted intervention, that would refer to the design of the intervention, including group versus individual intervention, as well as how the sessions are carried out. Stimulus attribution might be human aspect, social versus non-social, and live versus not alive. In an animal-assisted intervention, the dog serves as an adjunct for the handler, bringing both the live, social human attribute available alongside with the live, social, non-human attributes of the dog. Person attributes constitutes cognitive function, demographic characteristics, general level of activity and interest. These are all aspects that will influence interaction with the dog as well as it's handler in an animal-assisted intervention. Interaction between stimulus and environment is highly relevant in animal-assisted interventions, as many dogs might be sensitive to the setting characteristics, which they should be, since responsiveness to modelling is one of the advantages of dogs in animal-assisted interventions. Person-stimulus interactions in animal-assisted interventions would be participant's preference for dogs.

In order to measure engagement, the Comprehensive Process Model of Engagement postulates five dimensions, which are: rate of refusal of the stimulus; duration of time that the participant was occupied or involved with a stimulus; level of attention to the stimulus (e.g. facial feedback, eye tracking); attitude toward the stimulus (e.g. smiles, laughs, negative facial expressions); the action towards the stimulus (e.g. holding it or talking to the stimulus itself or another resident) (Cohen-Mansfield et al., 2009a). Refusal, attention and attitude has been found to be the most important ones in evaluating engagement (Cohen-Mansfield et al., 2009a). The model further illustrates how change in engagement have emotional impact, and that this change in affect may influence problematic behaviour (Cohen-Mansfield et al., 2009a).

1.6.3. Aims of the thesis

To handle the rising number of older people with dementia who is dependent on help from the professional health care system, and to ensure good quality of care, we need more evidence-based knowledge about modifiable factors related to physical functioning and mental health in

this population. Thus, the main aim of the thesis was to investigate animal-assisted group activity with a dog as a health promoting activity for persons with dementia.

An important goal in dementia care is to provide for and ensure a good quality of life (Beard et al., 2015; Beerens et al., 2013; WHO, 1986). There is a great intention to able people to live at home as long as possible (Ministry of Health and Care Services, 2003; WHO, 2010), both because of cost-efficacy, but also because institutionalization is associated with negative factors such as apathy, higher use of medication, major depression, lack of social activities, and low performance of daily activities (Barca et al., 2011; Selbæk et al., 2007; Smit et al., 2015). It is therefore important to gain more knowledge of quality of life and known associated risk factors in persons with dementia living at home and persons with dementia living in nursing homes. Consequently, the first aim in this study was to investigate quality of life and related factors in home-dwelling persons with dementia and persons with dementia admitted to nursing home.

The high amount of neuropsychiatric symptoms in persons with dementia (Aalten et al., 2005; Lyketsos et al., 2002) urges attention, and since most of the medicines have major physical and mental side effects (Tripathi & Vibha, 2010), there is a vast need for health promoting activities. Animal-assisted interventions have become a popular non-pharmacological alternative. However, the review of literature on animal-assisted interventions shows inconsistency in demonstrating effect, and there is a huge variety in how the interventions are carried out. In addition, there is a lack of adequate study design and limited use of control groups and follow-up measures (Table 2). The second aim in this study was therefore to investigate if animal-assisted group activity would reduce symptoms of agitation and depression and enhance quality of life among persons with dementia admitted to nursing home. As literature have shown that cognitive level influence affect (Cohen-Mansfield et al., 2011), we also wanted to examine if degree of dementia would impact possible effect.

Home-dwelling persons with dementia were found to have better cognitive and functional function. However, health-promoting activities are still needed for this group (Norwegian Ministry of Health and Care Services, 2015a). Falls and fractures are common among homedwelling older persons (Jensen et al., 2003; Thomas et al., 2002; Tinetti et al., 1995; van Doorn

et al., 2003), and one-third of people over the age of 65 years fall every year (Gillespie et al., 2012). Persons with dementia have a two-fold increased risk of falls compared with non-demented elderly (Tinetti et al., 1995). The society's health care costs due to fall injuries is substantial (Kjølstad et al., 2009). More important, fall accidents are a major cause of disability, immobility and mortality among elderly, and have a huge impact on each individual's quality of life (Todd & Skelton, 2004). On the other side, persons with dementia with better physical capabilities such as strength and balance, also score higher on quality of life (Telenius et al., 2013). The third aim was therefore to investigate if animal-assisted group activity would improve balance function and enhance quality of life among home-dwelling persons with dementia.

As persons with dementia have a high prevalence of inactivity, apathy and sedentary behaviour (Bates-Jensen et al., 2004; MacRae et al., 1996), and having an opportunity to participate in activities and activities that amount to something is important for increasing a sense of independence and positive self-image (Allen, 2011), the last aim was to systematically map different behaviours occurring during animal-assisted activity with a dog, and investigate if this kind of intervention would create engagement among the participants. We also wanted to see if home-dwelling persons with dementia and persons with dementia admitted to nursing home would display different behaviours during the intervention.

The objectives of the different papers were as follows:

- Paper 1. To compare quality of life and factors related to quality of life in persons with dementia in nursing homes and home-dwelling persons with dementia, and examine whether residency was associated with quality of life. To investigate the association between residency and change in quality of life over time.
- Paper 2. To examine the possible effects of an intervention with animal-assisted activity on depression, agitation and quality of life in nursing home residents with dementia or cognitive impairment.
- Paper 3. To examine the possible effects of an intervention with animal-assisted activity on balance and quality of life in home-dwelling persons with dementia attending day-care centres.
- Paper 4. To systematically register behaviours related to engagement in an animal-assisted group activity for persons with dementia in nursing homes and among home-dwelling persons with dementia attending a day-care centre, and to investigate possible differences between the two populations.

2. Material and methods

2.1.Research approach

The project was planned and conducted as a prospective and cluster randomized multicentre trial. This thesis consist of four papers using different designs: Paper 1, is a cross-sectional study using baseline data. Paper 2 and 3, are prospective and cluster randomized multicentre studies with 3 month follow-up measures. Paper 4 is a descriptive study that uses video recordings and ethograms for systematically observation of behaviour in the intervention groups. The project is registered in ClinicalTrials.gov (identifiers: NCT01998490 and NCT02008630), a service of the U.S. National Institutes of Health.

2.2. Recruitment and participants

2.2.1. Recruitment

The county development centres for dementia care in three counties (Østfold, Akershus, and Vestfold) in the south-eastern part of Norway were responsible in recruiting nursing homes and day-care centres in their municipalities. Inclusion criteria for both nursing homes and day-care centres were that they had to be registered as adapted units for dementia, that they could provide staff to handle the assessments, and that they could make a room available to carry out the intervention with the dog. 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, including the time to follow-up.

All nursing homes and day-care centres in the three counties who fulfilled the inclusion criteria were invited to participate in the study. Out of 90 nursing homes with adapted units for persons with dementia, 15 nursing homes were willing to participate and were included in the study. Out of 73 adapted day-care centres for home-dwelling persons with dementia, 21 were willing to participate. In addition, we recruited 2 (out of 35) adapted day-care centres for home-dwelling

persons with dementia from a fourth county (Oslo) in order to be able to include enough participants. Total sample of institutions recruited was thereby 15 nursing homes with adapted units for persons with dementia and 23 adapted day-care centres for home-dwelling persons with dementia. After recruitment, each institution was randomized by computerized random numbers at Uni Helse in Bergen. The nursing homes were randomized to either animal-assisted activity with a dog, control group with treatment as usual, or to a different kind of intervention not part of the interventions studied in this thesis. The day-care centres were also randomized to either animal-assisted activity with a dog, control group with treatment as usual, or to a different kind of intervention not part of the interventions studied in this thesis.

The included institutions were asked to recruit 5-8 participants each. The inclusion criteria for both nursing home residents and home-dwelling persons with dementia attending a day-care centre 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 & Engedal, 2009). The exclusion criteria were: fear of dogs or dog allergy.

2.2.2. Participants

In Paper 1, baseline data for participants at all institutions (nursing homes and day-care centres) were used (N = 193). In this cross-sectional study, baseline data for the participants randomized to the other previous mentioned interventions were included too. Demographic data are presented in Table 3.

Table 3. Demographic data, quality of life (QUALID), and ActiGraph data relating to persons with dementia in nursing homes (PWD NH) and persons with dementia living at home (home-dwelling persons with dementia).

	Persons with dementia	Home-dwelling persons with	
	living in nursing home	dementia	p-value
Women (%)	52 (66.7) (n = 78)	74 (64.3) (n = 115, 1 missing)	0.877
Age Mean (SD) in years	84.6 (6.50) (n = 78)	82.6 (6.84) (n = 103, 12 missing)	0.803
Education (%)			0.226
Below upper secondary school	40 (51.3)	43 (37.4)	
Upper secondary school	10 (12.8)	21 (18.3)	
Above upper secondary school	12 (15.4)	28 (24.3)	
Missing	11 (14.1)	21 (18.3)	
Quality of life	(n = 77)	(n = 109)	
QUALID (SD)	24.06 (7.13)	15.99 (4.33)	< 0.001
Clinical Dementia Rating (CDR) scale (%)			< 0.001
Mild	7 (9.0)	50 (43.5)	
Moderate	34 (43.6)	54 (47.0)	
Severe	37 (47.4)	6 (5.2)	
Missing	0 (0)	5 (4.3)	
Walking aids (%)	n = 78	n = 115	< 0.001
None	24 (30.8)	69 (60)	
Walking sticks/Cane/Crutches	7 (9)	19 (16.5)	
Rollator/High walker	37 (47.4)	21 (18.3)	
Wheelchair	9 (11.5)	0 (0)	
Needs support walking	1 (1.3)	0 (0)	
Missing	0 (0)	6 (5.2)	
Social contact with family/friends (%)			< 0.001
Every day	5 (6.4)	39 (33.9)	
Several times per week	20 (25.6)	48 (41.7)	
Once per week	31 (39.7)	14 (12.2)	
Once every other week	8 (10.3)	2 (1.7)	
Rare	11 (14.1)	5 (4.3)	
Never	0 (0)	0 (0)	
Missing	3 (3.8)	7 (6.1)	
Psychotropic medication			
llaa af /0/\	69.1	35.2	< 0.001
Use of (%)	05.1	33.2	.0.002

Notes: Differences in means between groups were examined using chi-square statistics for categorical variables and one-way ANOVA for continuous variables. p < 0.05 (level of significance). * Differences in N are due to missing

For Paper 2, 3 and 4, the sample consists of participants from the 10 nursing homes and 16 day-care centres who were randomized to either animal-assisted activity or control. Figure 2 is a flow diagram of the progress through the phases of the enrolment, intervention allocation, follow-up, and data analysis for nursing home residents.

CONSORT Statement Flow Diagram

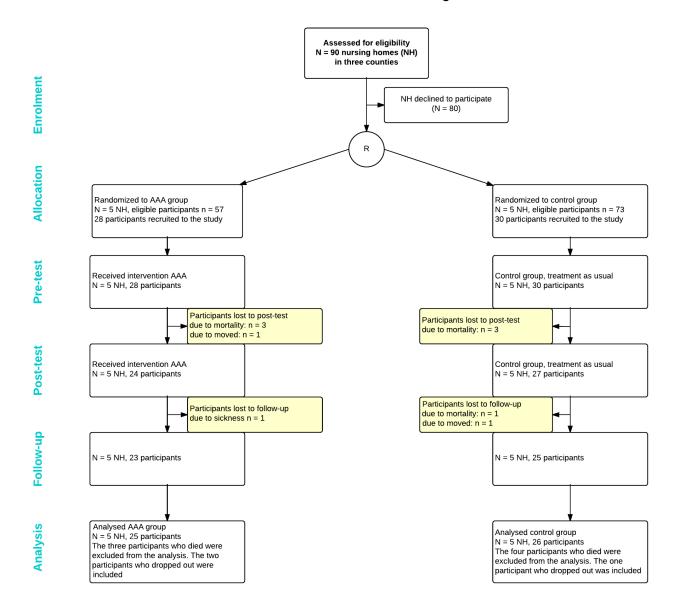


Figure 2. Flow diagram of nursing home participants.

Of 130 eligible patients in the 10 nursing home units (Figure 2) that were randomized to either animal-assisted activity or control, 58 patients (45%) agreed to participate, and 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. The demographic data

relating to participants at nursing homes used in the study reported in Paper 2 are presented in Table 4.

Table 4. Demographic data for participants in control group and intervention group at nursing homes.

	Control (n = 26)	animal-assisted activity (n = 25)	p-value
Gender Women (%)	17 (65.4)	15 (60.0)	0.69
Missing	O	0	
Age Mean (SD) in years	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)	
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	O ,	8 (32.0)	
Clinical Dementia Rating (CDR) 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	
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)	

Notes: Differences in means between groups were examined using chi-square statistics for categorical variables and one-way ANOVA for continuous variables. p < 0.05 (level of significance)

Of 344 participants registered at the recruited day-care centres (Figure 3), a total of 80 participants were included in the study: 42 in the intervention group and 38 in the control group. One of the participants in the intervention group withdrew and was therefore excluded from the analysis.

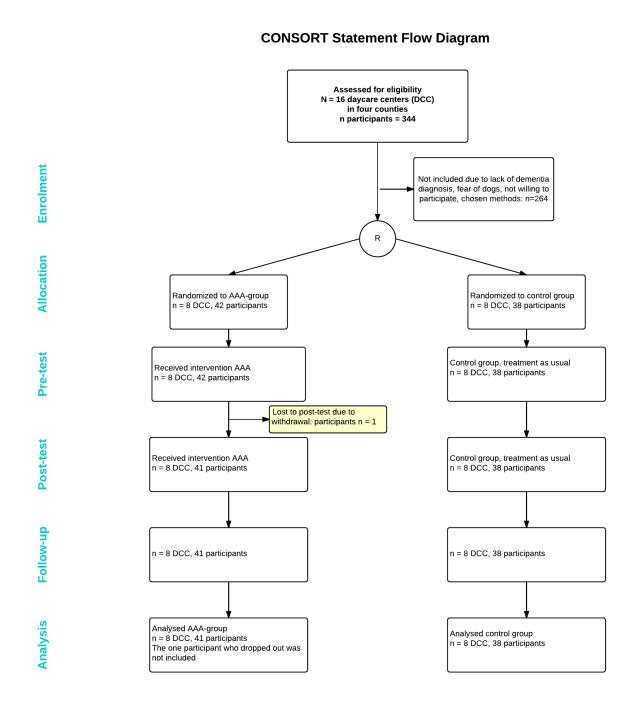


Figure 3. Flow diagram of home-dwelling participants.

Demographic data for participants at day-care centres included in Paper 3 are presented in Table 5.

Table 5. Demographic data for participants in control and intervention group at day-care centres.

	Control (n = 38)	Animal-assisted activity (n = 41)	p-value
Women (%)	23 (60.5)	21 (51.2)	
Missing	1 (2.6)	2 (4.9)	0.47
Age Mean (SD) in years	81.71 (7.24)	83.97 (6.59)	0.18
Missing	7	3	
Enjoy animal-contact (%)	25 (75.8)	30/4 (88.2)	0.19
Missing	5	7	
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	
Clinical Dementia Rating (CDR) scale (%)			0.89
0	1 (3)	2 (4.9)	0.03
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)	
5 Missing	1 (3) 5	0	
Walking aids (%)	J	<u> </u>	0.01
None	25 (69.4)	18 (47.4)	0.01
Walking sticks	4 (11.1)	2 (5.3)	
Cane	2 (5.6)		
Crutches	, ,	3 (7.9)	
	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 (%)	25 (24.5)	25 (27 5)	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	

Notes: Differences in means between groups were examined using chi-square statistics for categorical variables and one-way ANOVA for continuous variables. p < 0.05 (level of significance)

An overview of participants in the different papers is shown in Figure 4, with the total sample consisting of 193 participants from nursing homes and day-care centres described in Paper 1. Extracted from this total sample, 51 participants from 10 nursing homes were analysed in Paper 2. In Paper 3, 16 day-care centres with 80 participants were analysed, and for Paper 4, 49 participants from the intervention groups at both nursing homes and day-care centres were analysed.

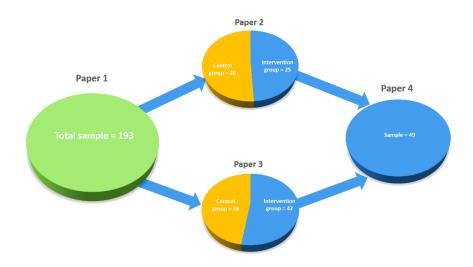


Figure 4. Number of participants extracted to each paper.

In Paper 4, we included participants from the intervention groups at both nursing homes and day-care centres, see Figure 4. The population consisted of 28 nursing home participants from 5 different nursing homes, and 42 home-dwelling participants from 8 different day-care centres. Due to death, 3 nursing home participants were excluded from the analyses. One of the participants at day-care centre withdrew from the intervention, and was excluded. Participants who were only present at one of the video recordings were also excluded from the analyses (n = 4 nursing home participants and n = 13 participants at day-care centre). Thus, the study population consisted of 21 nursing home participants, and 28 participants at day-care centres. Demographic data for participants in Paper 4 are presented in Table 6.

Table 6. Demographic data for participants at nursing homes and day-care centres present at both video recorded sessions.

	NH (n = 21)	day-care centre (n = 28)	p-value
Women (%)	13 (61.9)	13 (46.4)	.425
Missing	O ,	2	
Age Mean (SD)	84.8 (5.9)	84.08 (6.2)	.691
Missing	1	2	
Enjoy animal contact (%)	15 (71.4)	21 (75.0)	.709
Missing	4 (19.0)	3 (10.7)	
Education level (%)	,	, ,	.880
Below upper secondary school	8 (38.1)	12 (42.9)	
Upper secondary school	3 (14.3)	1 (3.6)	
Above upper secondary school	2 (9.6)	7 (25.0)	
Missing	8 (38.1)	8 (28.5)	
Clinical Dementia Rating (CDR) Scale (%)	, ,	3 /	<.001
0	0	1 (3.6)	
0.5	0	2 (7.1)	
1	2 (9.5)	10 (35.7)	
2	8 (38.1)	15 (53.6)	
3	11 (52.04)	0	
Missing	0	0	
Walking aids (%)			.405
None	9 (42.9)	11 (39.3)	
Walking sticks	0	2 (7.1)	
Cane	1 (4.8)	2 (7.1)	
Crutches	`o ´	1 (3.6)	
Rollator	10 (47.6)	9 (32.1)	
High walker	`o '	0	
Wheelchair	1 (4.8)	0	
Needs support walking	O	0	
Missing	0	3 (10.7)	
Social contact (%)		, ,	.014
Daily	2 (9.5)	11 (39.3)	
Several times a week	6 (28.6)	11 (39.3)	
Once a week	11 (52.4)	5 (17.9)	
Every other week	O	0	
Rare	1 (4.8)	1 (3.6)	
Missing	1 (4.8)	O	
Hobbies (%)	, ,		.061
Cognitive activities	3 (14.3)	6 (21.4)	
Physical activities	7 (33.3)	15 (53.6)	
Combination	8 (38.1)	4 (14.3)	
Missing	3 (14.3)	3 (10.7)	
Mean use of psychotropic medications	.93	.41	.046
Missing	7	6	_

Notes: Differences in means between groups were examined using chi-square statistics for categorical variables and one-way ANOVA for continuous variables. p < 0.05 (level of significance)

2.3. Design and research methods

2.3.1. Research setting and intervention

The nursing homes were all special care units, which means small units with a maximum of 8 residents, which is representative in Norwegian terms (Gjøra et al., 2015). The same was true for the recruited day-care centres, whom mainly were located at a nursing home, also in line with most day-care centres in Norway (Gjøra et al., 2015). Both day-care centres and nursing homes in Norway are administrated by the public health services. Norway has a high level of care, in fact, Norway is one of the countries that use highest percentage of Gross domestic product on institutional care (Knapp et al., 2007). So even though there might be differences in quality of care, these differences are small.

The intervention consisted of 30 minutes sessions with animal-assisted activity twice a week for 12 weeks in groups of 3-7 participants. The time span of 30-minutes was chosen due to the nature of dementia with a typically short attention span. Frequency of the intervention (twice a week for 12 weeks) was based on clinical experience, practical issues and previous findings (Berget et al., 2008; Friedmann et al., 2015a; Pedersen et al., 2011). Group activities have been found to represent a secure environment that contributes to strength, inspiration and joy (Sundsteigen et al., 2009). As some of the main aims of the study were to create engagement, decrease depression and increase quality of life, social interactions plays an important role. It was also essential that the results from this study should have clinical implications, and it was therefore necessary that the intervention was realistic and transferable to clinical practice. Animal-assisted activity is usually conducted as a meet-and-greet activity in the public area of institutions. This is both in order to create engagement and social interactions between present people, but also because it is time saving. Number of participants (3-7) relied on previous findings where groups of four to nine people in the room is found to significantly increase engagement to the stimulus (Cohen-Mansfield et al., 2010d).

2.3.2. Intervention design

A protocol (Appendix 1) for conducting animal-assisted activity secured equally intervention sessions between units. The protocol was deliberately designed in order to affect the main outcomes: agitation, depression, balance and quality of life, but also to be able to standardize the intervention as much as possible, both across sessions and across the different institutions. Additionally, the protocol makes the study replicable for other researchers. The programme theory underpinning the protocol was based upon several principles, such as knowledge in dementia, target outcomes, competence in animal-assisted interventions, and the care workers knowledge of the patient. For each session, the participants were followed to the room dedicated to the carrying out of the intervention and were randomly seated in a half-circle (Figure 5).



Figure 5. Illustration of intervention setting.

The dog handler arrived with the dog in a leash, standing in front of the group of participants. The dog handler presented herself and the dog. The dog handler approached the first participant, and asked if he/she would greet the dog. If the participant chose to do so, the dog handler asked the dog to make contact with the participant. Every session started with a greeting round, where each participant got to pet the dog and feed it treats. The dog handler had to assure that the dog approached the participant gently. This first contact is important in order to build a good relationship, even if the participant had met the dog before. The physical contact may help to

initiate physiological responses as lowered heart rate and increased excretion of positive hormones so that the patient would feel calm and content (Odendaal & Meintjes, 2003). This first contact would also allow the participant to care for another living being, and experience that the dog enjoyed the care it received (Parish-Plass, 2008).

Then the handler started the different activities, which could be petting the dog, brushing the dog, feed the dog a treat or throw a toy for the dog to fetch (Figure 6).

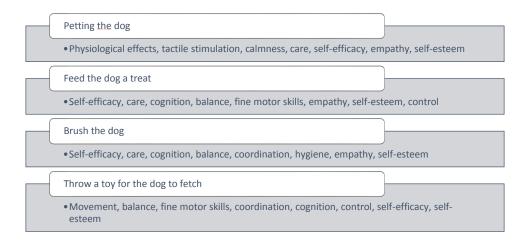


Figure 6. Intervention content and possible outcomes of interaction with the dog.

Earlier studies have found similar interventions with dogs to have a positive influence on cognition (Moretti et al., 2011), depression (Friedmann et al., 2015a; Majic et al., 2013), agitation (Richeson, 2003; Sellers, 2006), quality of life (Nordgren & Engstrom, 2014a) and performance-based physical outcomes (Friedmann et al., 2015a; Herbert & Greene, 2001). Some of the activities could be described as isotonic exercise, such as turning to see the dog, bending to pick up a toy, lifting the toy and throwing it. In many ways, the animal-assisted activity sessions could be compared with a seated, group-based programme limited to range of motion exercises that is kind of standard exercise for elderly people (Lazowski et al., 1999). 'Range of motion exercises' programmes usually consist of 30–45 minutes sessions with components as introduction/discussions, vocal exercises, word/memory games, range of motion (fingers, hands, arms, knees, and ankles), and finally relaxation exercises. Seated group-based exercise programmes have been found to improve functional capability (McMurdo & Rennie, 1993).

The dog handler was responsible for distributing the time allotted so that all participants got an equal chance to interact with the dog. The conversation with each participant could contain repetition of the dog's name, questions about the participant's previous experience/ownership of dog/animal, talk about resent events, and news. The participant's interest of the dog should be acknowledged, and signs of unwillingness to be respected. Participation in the programme was voluntary, and any signs that the participant wanted to cancel the current activity or session of the whole should be complied.

Closure of the session was part of the activity. An important part of the closer was to evaluate the session together with the participants, for the dog handler to get a good impression of their experience. This was done while the participants and the dog interacted. Dog hair was removed from participant's clothes and the participant washed and disinfected their hands. This could contribute to increased awareness of their own hygiene, as well as being part of the activity.

Even though the sessions should follow the protocol, they should also be individually tailored. No activities were mandatory, and the sessions included activities that naturally occurred between the participants, and between each participant and the dog. Each session was documented through a log, where the dog handler had to describe how individually participants and the dog had behaved each session (see Appendix 2). This log served as information for the health care workers and the handler regarding how to individually tailor the progression in the intervention. It was also used to evaluate the dogs' welfare.

The overall attendance was high, as 80% of nursing home residents attended more than 75% of the sessions, and 60% attended more than 90% of the sessions. The same was true for participants at day-care centres, as 89% attended more than 75% of the sessions, and 50% attended more than 90% of the sessions.

2.3.3. Dogs and their handlers

The animal-assisted activity sessions were led by a qualified dog handler, who was well educated and found suitable for this type of work. Among the 16 dog teams involved in the studies included

in the thesis, there were only female handlers. All dog handlers had to attend a 36 hour course for animal-assisted activities with dogs. The course consisted of theoretical lectures regarding ethology, training techniques, dog health, dog welfare and practical lessons in how to prepare the dogs for animal-assisted activities. The course also included lectures regarding interaction with the participants, such as counselling strategies, communication and listening skills. In addition, most handlers had either a bachelor degree or prior experiential learning within biology or social care.

The dogs had to conduct and pass a screening test containing different elements aiming to assess personality traits, such as boldness, aggressiveness, sociability and exploration, in addition to assess the dogs behaviour when being handled and petted. Dog-trainers and ethologists at the Norwegian Centre of Anthrozoology executed these tests. A health certificate conscribed by a veterinarian was also required. The handler and her dog had to pass a practical exam where their skills as visiting teams were evaluated. The same dog team visited the same group of participants throughout the period. Handlers and their dogs had a gathering at the Norwegian Centre of Anthrozoology both in front of the intervention period and in the middle of the intervention period in addition to voluntary lessons every week. This was to ensure quality and uniformity of the intervention.

According the dogs, there were several different breeds, most of them large breeds. Standard Poodle (N = 2), Collie (N = 2), Flat Coated Retriever (N = 1), Golden Retriever (N = 1), Alaskan Malamute (N = 1), Border Collie (N = 1), Springer Spaniel (N = 1), Portuguese Water Dog (N = 1), Pomeranian (N = 1), Shetland Sheepdog (N = 1), and mixed breed (N = 4). There were 7 male (1 neutered) and 9 female dogs. The age varied between 2.5 and 13 years old, with an average age of 5.6 years.

The dogs were kept both in and off leash, depending on the situation. No dogs were forced to do anything they were not comfortable doing, and as for the participants, no activity was mandatory.

2.3.4. Control group

The control group was not offered any new activities and their care and treatment continued as usual. During the study, participating institutions (both nursing homes and day-care centres) were asked to provide information regarding which activities they normally offered at their unit. A total of 80% of the control units at nursing homes answered, but only 25% of day-care centres who were randomized to control filled out the questionnaire. However, the range of doings were equal, consisting of diverse group activities such as reading out loud, reminiscence, quiz, singing, music therapy, cocking, activities of daily living, walking, exercise, and excursions. This implies that participants in the control groups on a regular basis were offered a range of different activities.

2.4. Ethical considerations

The project was conducted in accordance with the Declaration of Helsinki, which emphasizes that it is a duty to protect the life, health, privacy, and dignity of the human subject when doing research (World Medical Association, 2013). The Regional Committee for Medical Research Ethics approved the project.

Since the randomization was done on an institutional level, the participants were aware of the conditions under which they would participate when they were recruited. This made participation in the project predictable, and eliminated the risk of disappointment due to being randomized to a condition they were not motivated for. Participants' ability to consent was evaluated by health care workers close to the participant in close relationship with the participant's relative. A procedure was developed for evaluating the participants' capacity to give informed written consent. This was done according to the Norwegian law of patients right § 4 (Norwegian Ministry of Health and Care Services, 2015c). Written and verbal information about the study was given to potential participants and their relatives by their primary caregivers. The information contained necessary information according the Helsinki declaration, and was customized for persons with dementia. This means that the information was precise, presented clearly, and illustrated with photos. Even if the participant expressed willingness to participate,

the information was repeated the next day to make sure that the participant truly had understood what participation would implicate. If the participant remembered the information that was given the previous day and seemed to understand it, they were asked to give their written consent to participate in the study. In cases where the participant did not seem to fully understand what it would mean to participate, either their health care workers and/or their next-of-kin took the decision as to whether to give written consent on their behalf. Participants were informed that they could withdraw from the study at any time. Associated health staff allocated eligible participants, provided information about the study, and gathered the written consent.

One of the inclusion criteria was a wash-out period without any organized dog activity for both the intervention group, as well as the control group. As some of the institutions already had more or less organized dog visits from time to time, this could actually deprive some of the participants from this kind of activity. Another ethical dilemma is to introduce an intervention that has a positive influence on the participants and then end the intervention after 12 weeks. Proper and adapted information was given before inclusion to ease possible disappointment among the participants. In addition, the dog handler prepared the participants in the intervention group the last sessions about the fact that the intervention was about to be finished, and the participants were told that they could resume regular, organized contact with a dog after the 3 month follow-up period. All institutions in the control group were offered animal-assisted activity with a dog after end of the assessment period.

Doing research involving vulnerable participants is an ethical issue. Often, persons with dementia are aware of the disease and one's own situation, but the complexity of the disease also leads to lack of insight. This makes self-evaluation difficult, and will also raise issues regarding informed consent and the potential risk of psychological strains through research participation (von Kutzleben et al., 2012). To ease the burden on the participants, proxy measures were deliberately used where appropriate, although research has shown that especially persons with dementia with mild or moderate dementia are capable of completing self-reports (Logsdon et al., 2002).

Some of the assessments, such as Mini-Mental State Examination and Berg Balance Scale (BBS) could be a stress for the participants. It takes approximately 10-15 minutes to perform each test.

Participants at day-care centres had to perform the BBS several times, which could cause an extra burden. On the other hand, participants expressed positive feedback during assessment of the BBS, as they were able to challenge them self at some point, and it gave them the opportunity to be in focus of the health care worker for some 'alone-time'.

Video recordings constitute another ethical issue. The videos were recorded by members of the project group, and were not to be watched by others. The participants were informed about the video recordings in the informed consent letter, and were told the day in advance as well as the same day of the recording, that a member of the project group would do the video recording during that day's session with animal-assisted activity. They were told that they were free to withdraw from that session, but could continue to be part of the project if they were uncomfortable with the video recording. The videotapes were kept in a locked file cabinet.

The use of actigraphy could be seen as an ethical consideration. An actigraph does not gather sensitive information, and is considered not to be invasive. However, for persons with dementia, carrying the device for a whole week several times might be a burden, since they might forget why they had to wear it, and also that it did not collect sensitive information. The shape of the device is like a watch, and easy to remove. The participants were free to remove the device at any time. Both relatives and health care workers were given information about the device, and could answer questions if the participant seemed insecure or frustrated regarding what this was and why he/her had to wear it.

Even though there are several ethical issues when including persons with dementia in research, such as protecting vulnerable individuals and maintaining an individual's right to take part in research, it is important to include persons with dementia in research to gain more knowledge about this particular group. By considering the ethical issues well, the burden on recruited participants hopefully was not too heavy. A lot of effort was put into giving proper information both before inclusion, as well as during the study period in order to prevent participants of being disappointed for any reason. To prevent possible injuries or adverse events, the participants were followed closely during the assessments. They were asked if they needed breaks, and they were

also instructed that they had the ability to withdraw from further testing and from the entire study at any time. No adverse events were recorded.

2.4.1. Animal welfare

Another ethical consideration is the use of dogs in animal-assisted interventions. All dogs had to pass a screening test in addition to an exam to see that they were suited for this kind of work (see Section 2.3.3). We also made sure that they would not be exposed to negative experiences by doing the intervention, by modelling the sessions, and by having a health care worker present to observe unwanted behaviour from the participants. The dogs' welfare was considered continually, both from their handlers' view, but also by the Norwegian Centre of Anthrozoology. The dogs' behaviour was registered in a log after each session (see Appendix 2). A master thesis to examine the animal welfare was conducted alongside this study. The master thesis was supervised by two ethologists. This thesis concluded that animal welfare of the dogs working in the project was not compromised (Barstad, 2014). This is an important aspect of studies of animal-assisted interventions, and demonstrates that the project have stressed to consider all aspects of the intervention.

2.4.2. Potential risk factors of animal-assisted interventions with dogs

Zoonosis are diseases and infections that are naturally transmitted between vertebrate animals and humans (Pan American Health Organization, 2003). Zoonosis are a relatively small problem in the interaction between humans and dogs, and especially in Norway and Scandinavian countries. Transmission of most zoonosis can easily be avoided by thorough hand wash and normal hygiene. By keeping the dog clean, treat it against parasites, take hygienically precautions and avoid contact with urine and faces the contamination risk will be kept at a bare minimum. A health certificate conscribed by a veterinarian should be required.

Allergic reactions can occur in people through spit, hair, urine and other secretes from animals. Symptoms may be asthma, cough and itch in nose and eyes. To prevent allergies, the dog's access to the institution should be restricted to certain rooms, preferably close to an exit to minimize

the spreading of dirt and allergens. This will help the people living there, staff, relatives and other people not participating in the intervention from being affected by the dog visiting the institution. To avoid dog hair and drool on clothes and furniture, a blanket or a towel can be used when in contact with the dog. A clothing roll can be used to remove hair from clothes and furniture. When in physical contact with the dog, the client's hands should be washed afterwards. After a visit from the dog, floors should be cleaned to reduce dirt and dust. The dog should be bathed regularly, and groomed so that excess hair is removed before visits. Washing the dog twice a week is found to reduce dog allergen levels (Hodson et al., 1999).

Some people are scared or dislike animals. There may be different reasons and experiences that may cause this, and it is important to take this into consideration when implementing animal-assisted interventions. People who are scared or dislike animals will most likely not have anything to gain through contact with animals, and it may be extra burdensome for him or her. Fear of dogs was an exclusion criterion.

Harm caused by the dog, such as bites, or claw marks from dogs may cause rifts, wounds and bruising. Bites, and in some rare cases claw marks, can cause infections in humans. Special consideration should be given to this when dealing with people who have lowered immune resistance. By screening dogs that are to work in animal-assisted interventions and only select dogs proper to do this kind of intervention, accidents are not likely to occur. However, a procedure in case of accidents was developed. Manager of the institution should be notified, and a protocol should be filled out.

2.5. Assessments and measurement points

As dementia is a progressive disease, patients will at some point become unable to express their health status in a meaningful and valid way. Therefore, alternatives such as proxies or behavioural observations will be a justifiable and necessary way to assess depression, agitation and quality of life among persons with dementia.

The raters were health care personnel working at the respective residency (in the nursing homes and at the day-care centres). Prior to the start of the study, they received mandatory lectures on how to use the instruments. The testers later scored all assessments at all three time points (pretest (T_0) , post-test (T_1) and follow-up (T_2)).

At nursing homes, agitation and restlessness were measured using Norwegian version of The Brief Agitation Rating Scale (BARS; Finkel et al. 1993), quality of life was measured using the Norwegian version of Quality of Life in late-stage Dementia (QUALID; Weiner et al.,2000), depression was measured using Norwegian version of Cornell scale for depression (Alexopoulos et al. 1988), and physical activity during day time and hours of sleep and sleep quality were measured using ActiSleep+. Sociodemographic characteristics for each participant were collected, as well as their medical journal registrations of psychotropic medicines.

At day-care centres, we in addition to QUALID and ActiSleep+, used the Norwegian version of Berg Balance Scale (BBS) (Berg et al. 1989; Halsaa et al. 2007) to measure balance. Regarding BBS, the testers received lecture in the theory relating to the instrument, and 2.5 hour 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 centres prior to the start of the study. In order to avoid bias, BBS was always performed in the same room at each centre. Also here, sociodemographic characteristics for each participant were collected, as well as their medical journal registrations of psychotropic medicines. Agitation and depression were not measured at day-care centres. 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 and are described below. The different assessments point of time when measured is described in section 2.5.9.

2.5.1. Cognitive function

Mini-Mental State Examination (MMSE) was used to assess global cognition for patients not yet being diagnosed with dementia. MMSE consists of 20 items concerning orientation, word registration and recall, attention, naming, reading, writing, following commands and figure copying. It can be scored between zero and 30, where a higher score indicates better

performance (Folstein et al., 1975). A cut-off score of 24-25 is related with cognitive impairment and is said to provide a reliable diagnosis of dementia. Although this cut off is not valid among younger individuals and individuals with very high education, were a higher cut-off should be applied (O'Connor et al., 1989), it should be considered valid in our population among older adults with moderate education level, and was therefore applied.

2.5.2. Level of dementia

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 NH residents to rate dementia and determine the severity of dementia (Nygaard and Ruths, 2003, Engedal and Haugen, 1993). A CDR of 0 implies no cognitive impairment, 0.5 = very mild dementia, 1 = mild, 2 = moderate and 3 = severe dementia. Previous nursing home studies in Norway showed that CDR is valid substitute for the syndrome diagnosis of dementia (Engedal & Haugen, 1993; Nygaard & Ruths, 2003). Consequently, we did not use an etiologic dementia diagnosis in this project.

2.5.3. Symptoms of agitation

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 & 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.

2.5.4. Symptoms of depression

Depression was measured using a validated Norwegian version (Korner et al., 2006) of the Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos et al., 1988; Barca et al., 2010). 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).

2.5.5. Quality of life

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 quality of life.

2.5.6. Sleep pattern, level of activity, and exposure to light

Sleep patterns, physical activity levels, and light exposure were measured by actigraphy (ActiSleep+, ActiGraph, Pensacola, US). ActiSleep+ is a validated 3-axis accelerometer, which has approximately the shape and size of a wrist watch and delivers advanced data relating to movements over time and exposure to light. The use of actigraphy for monitoring sleep is validated (Natale et al., 2009), also for dementia patients (Ancoli-Israel et al., 1997). The ActiSleep+ was worn on the left wrist continuously for 7 days (epoch-length Finn1 minute) during each measurement period. The actigraphy data were processed using the Scoring and Sleep functions of ActiLife, software Version 6.11.2 (ActiGraph, Pensacola, USA), after applying the Wear Time Validation tool. Days with more than 8 hours recorded were included in the further

analyses in order to ensure that the activity pattern for those days reflected the participant's typical behaviour pattern. All subjects included in the analysis had at least three valid days and nights.

Total sleep time (TST) is the amount of actual sleep during the night-time, measured in hours. The term 'wake after sleep onset' (WASO) defines the amount of time spent awake after sleep has been initiated and before final awakening; it sums all wake epochs in minutes. The default algorithm of ActiLife may have problems with analysing the sleep—wake schedule. For that reason, we manually inspected all awakenings and created a new variable called 'Number of awakenings > 5 minutes'. By using a minimum awake time of 5 minutes, we ensured that the number of awakenings were accurate. 'Sleep efficiency' was defined as the number of sleep minutes divided by the total number of minutes when the participant was in bed, and was expressed as a percentage. Because of the challenge of identifying a precise bedtime and getup-up time among the home-dwelling population, a default time-in-bed period was arbitrarily set as 23:00 to 06:00 hours. Therefore, in our study, sleep efficiency referred to the minutes of sleep within the default time period, and not the patients' actual time spent in bed, and was therefore referred to as the 'Sleep during night period'.

Physical activity levels were calculated using the Freedson Adult Cut Points (Freedson et al., 1998) in ActiLife software, and applying a time filter between 08:00 and 20:00 hours for each monitored day. ActiLife calculates three activity levels based on the frequency and intensity of the movement. These constitute the measure 'counts', which are specified as 'counts per minute' (cpm). 'Sedentary activity level' is time in percentage with no physical activity (standardized cut point value: 0–99 cpm). 'Light activity level' is defined as light intensity activity (standardized cut point value: 100–1951 cpm). Activities in this category could, for example, be standing or household activities. 'Moderate activity' (standardized cut point value: 1952–5724 cpm) equates to physical activity, such as walking at 4 km/h. The Freedson Adult Cut Points can also include measures of 'Vigorous' activity and 'Very vigorous' activity, but these were not used in the study because none of the participants scored any activity at this level. The absolute time (minutes)

spent on the different activity levels was subsequently expressed as a percentage of the overall monitoring time.

Light exposure was recorded every second and measured in counts, giving 'lux average counts', which indicated the participants' level of exposure to light.

2.5.7. Balance

To measure balance, we used the Norwegian version of the Berg Balance Scale (BBS) (Berg et al., 1989; Halsaa et al., 2007). 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. Berg Balance Scale was developed to assess balance and fall risk in adult populations, and have been tested for many different populations that experience reduction in balance function. The test-retest reliability is excellent in the general nursing home population (Conradsson et al., 2007; Holbein-Jenny et al., 2005). However, it has not yet been tested on a population with dementia at nursing homes.

2.5.8. Behavioural measurement

For the descriptive study of behaviours, videos were recorded using a camera Sony HXR-NX30E, a camcorder recording full HD with Balanced Optical SteadyShotTM and a tripod VCT-PG11RMB. The camera was placed in the room before the participants arrived, aiming not to interfere with the intervention. The recordings were done by members of the project group, all of them trained in where to place the camera in the room, and how to behave and introduce the camera to the participants. All of the participants were told that the camera was on, and they had signed a written consent in forehand. The camera was placed in the room so the camera eye could catch the participants, the dog, and the handler at all times.

2.5.8.1. Ethogram

An ethogram, which is a catalogue of behaviour descriptions (Martin & Bateson, 1986), was used to categorize the different behaviours from the video recordings. The videos were analyzed using the behaviour coding software Solomon Coder, version beta 14.10.04 by five pre-trained observers. The videos were randomized between the observers, and then registered in a randomly order, so there was no dependence whether the recordings where done early or late in the intervention.

The ethogram gives the opportunity to objectively describe the different behaviours that occurs in an intervention, and is previously used in other studies of human-animal interactions (Berget et al., 2007; Hauge et al., 2013; Pedersen et al., 2011).

Frequency (number per unit time) and/or duration (length of time for which a single occurrence of the behaviour pattern lasted) of conversation, head orientation, touching, activities, smiles and laughter, and singing, whistling or dancing, as well as stereotyped behaviour, wandering around, agitated behaviour, yawn or sigh, if they fell asleep, or if they left the session was registered (Table 7). These behaviours were registered because they are common behaviours that occur in an animal-assisted activity, and because they represent behaviours that one would categorize as positive (conversation, look at other people or the dog-activity, touching the dog or other people, do activities, smiles and laughter, and singing, whistling or dancing), negative (look at other things, stereotyped behaviour, wandering around, agitated behaviour, yawn or sigh, sleep, or if they left the session) and social (conversation, look at other people or the dog-activity, touching the dog or other people, do activities, smiles and laughter, and singing, whistling or dancing). By registering frequency and duration of these behaviours, the participants' attitude and action to the stimulus could be measured, as well as potential affect.

Table 7. Ethogram – an overview of defined behaviours.

Behaviour	Description	F/D
Conversation	Conversations with therapist, dog handler, other participants or the dog	F&D
Look at other people	Face towards therapist, dog handler, other participants that is not handling the dog	F&D
Look at the dog-activity	Face towards the dog or activities going on with the dog	F&D
Look at other things	Face towards other things than the dog, therapist, dog handler or other participants	F&D
Touch people	Physical contact with therapist, dog handler, other participants (more than 2 seconds)	F&D
Touch dog	Physical contact with the dog (more than 2 seconds)	F&D
Do activities	Throw the ball, give treats, brush the dog	F&D
Smile or laugh at people	Smiles or laughs with face oriented towards therapist, dog handler, other participants	F&D
Smile or laugh at dog	Smiles or laughs with face oriented towards dog or activities with dog	F&D
Smile or laugh at other things Sing, dance, clapping	Smiles or laughs with face oriented towards other things than the dog, therapist, dog handler, or other participants Sing, whistle, hum, dance, clapping hands	F&D F&D
hands, etc. Stereotyped behaviour	Repetitive behaviour that occurs for minimum 5 seconds	F&D
Wandering around	Wandering around in the room without leaving the room	F&D
Agitated behaviour	Cries, yell, swear, aggressive sounds	F
Yawn and sigh	Yawns or sighs	F
No response	Doesn't respond when contacted by therapist, participants, dog handler or dog	F&D
Asleep	Sleeps, sits still with eyes closed for minimum one minute	F&D
Leaving the room	Leaves the room and doesn't come back	F
Off camera	Off camera	F&D

F = scored in frequency

D = measured duration

Figure 7 illustrates a variety of different behaviours that occurred at one time. For one recording of a group of 6 participants, the video was analysed six times, registering behaviours for only one participant at a time.

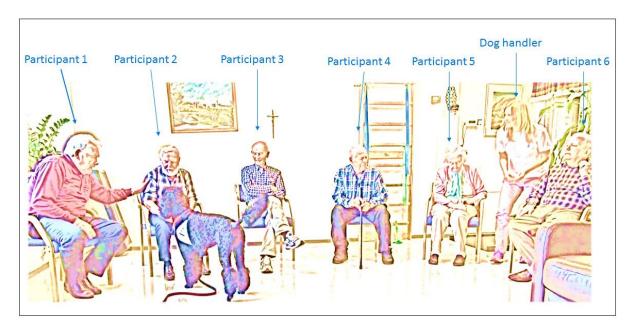


Figure 7. Illustration of the registration of behaviour.

Participant 1 was registered with the behaviours: Conversation, Touch people, Look at dogactivity. Participant 2 was registered with the behaviours: Look at dog-activity, Do activities, Smile to dog. Participant 3 was registered with the behaviours: Look at dog-activity, Smile to dog. Participant 4 was registered with the behaviour: Look at other people. Participant 5 was registered with the behaviour: Look at other things, Stereotype behaviour. Participant 6 was registered with the behaviour: Look at other dog-activity.

2.5.9. Measurement time points

MMSE, demographic data, CDR, CSDD, BARS, QUALID and BBS were collected at baseline (T_0) , one week before intervention started. During the last week before the intervention period started, the participants were the device ActiSleep+ 24 hours per day, continuously for 7 days (Table 8).

Video recordings were carried out in week 2 and week 10 of the intervention period of 12 weeks. CSDD, BARS, QUALID, BBS, and actigraphy using ActiSleep+ were assessed again at post-test (T_1) , immediately after end of intervention period. CSDD, BARS, QUALID, and BBS were additionally assessed at follow-up (T_2) , 12 weeks after end of intervention (Table 8).

Table 8. Time points of measure for all assessments used, divided into nursing homes and day-care centres.

Institution	Baseline T ₀	2 weeks	10 weeks	Post-test T ₁	Follow-up T ₂
Nursing	MMSE	Video recordings	Video recordings	One week of	CSDD
homes	One week of	of intervention	of intervention	ActiSleep+	BARS
	ActiSleep+	group	group	CSDD	QUALID
	Demographic			BARS	
	data			QUALID	
	CDR				
	CSDD				
	BARS				
	QUALID				
Day-care	MMSE	Video recordings	Video recordings	One week of	BBS
centres	One week of	of intervention	of intervention	ActiSleep+	QUALID
	ActiSleep+	group	group	BBS	
	Demographic			QUALID	
	data				
	CDR				
	BBS				
	QUALID				

In the project protocols (ClinicalTrials.gov: identifier: NCT01998490 and NCT02008630) one can see that some of the assessments were assessed at even more time points and that additional outcomes also were assessed, however they are not included in this thesis.

2.6. Statistical analyses

2.6.1. Power calculation

In order to estimate minimum number of participants needed for the randomized control trial, a power calculation was made using statistical software JMP Version 12. BARS was chosen as primary outcome measure at nursing homes, while BBS was the primary outcome at day-care centres. A power calculation for change of means in BARS with 80% probability of detecting

differences between groups, (α = 0.05, LSD = 7.0, SD = 8.4), indicated a necessary total number of 25 participants in each group at nursing homes. A power calculation (80%) on BBS (α = 0.05, LSD = 5.0, SD =14.1), estimated number of participants to 40 in the control group as well as intervention groups at day-care centres. Due to the fragile population, we estimated a 20% dropout. Consequently we intended to recruit 60 participants at nursing homes, and 100 participants at day-care centres. This was not completely achieved with respectively 58 and 80 recruited participants. Drop-out reduced the final sample size to 25 complete cases in the intervention group and 26 in the control group for nursing homes and 41 in the intervention group and 38 in the control group at day-care centres.

All further analyses were computed using statistical software IBM SPSS Statistics for Windows, Version 22.0 and 23.0. Armonk, NY: IBM Corp. We used a 5% level of significance for all analyses.

2.6.2. Intraclass Correlation Coefficient

To demonstrate consistency among observational ratings, interrater reliability of video analysis, BARS and BBS was calculated with a Two-Way Mixed model and Absolute Agreement.

To test the level of agreement between the different raters on psychometric outcomes (Paper 2), health personnel from five units with the same training in BARS scored the same participants (n = 28). This resulted in an Intraclass Correlation Coefficient (ICC) for BARS, ICC = 0.84 (single measures).

To test the level of agreement between the different raters on physical outcomes (Paper 3), two persons from the same day-care centre (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 = 0.88 (single measures).

To test the level of agreement between the different raters of the video recordings (Paper 4), they all (5 raters) blindly analysed two of the same videos. Intraclass correlation coefficient

showed a mean average measure of 0.9, range 0.76-1.0. Mean single measure was 0.71, range 0.45-0.98.

Values between 0.75 and 1.0 is considered excellent interrater reliability (Hallgren, 2012). The relative high ICC values found between the different raters of video analysis, BARS and BBS, indicates that the data collected in these assessments were correct representations of the variables measured.

2.6.3. Missing values

Missing single items of an instrument (BARS, CSDD and QUALID) were handled by using the person mean substitution method if three or fewer items were missing. In those cases, the mean of all of the participant's completed items in one instrument was calculated and imputed into the missing item. In cases were more than three items were missing, the whole scale was set as missing. For BBS, 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. This was done because a mean score can not be imputed due to the unequal degrees of difficulty in the test.

When a whole scale was missing at any time point, the multiple imputation procedure in SPSS Version 22.0/23.0 was used to estimate sum scores for BARS, CSDD, QUALID and BBS. The procedure produce 5 imputed datasets for each subject, and is then used as basis for a pooled dataset used in the statistical analysis. In paper 3 and 4 results are given for both original data and pooled data with imputed values.

2.6.4. Baseline analyses

One-way ANOVA for continuous data and chi-square tests for categorical data were used to test the differences in means between groups at baseline in all the papers. To assess internal consistency in the measurements used, Cronbach's alpha was calculated using item scores of BARS, CSDD, QUALID and BBS at baseline.

2.6.5. Paper 1

One-way ANOVA was used to test the differences between home-dwelling persons with dementia and persons with dementia living in nursing home on the following variables: quality of life, CDR, walking aids, social contact, sleep patterns, physical activity, light exposure, and psychotropic medication (Table 3). One-way ANOVA analyses was then conducted on stratified data for the three categories of cognitive level (CDR = 1, 2, or 3) derived from the CDR-score at baseline. This was done only for variables showing significant differences between the two residencies in the first One-way ANOVA-test. Since the group of participants were close to equal in size for the CDR score = 2, this CDR level was used in a multiple regression analysis to test the association between residency and quality of life controlling for age, gender, social contact, use of walking aids, activity, light exposure and medication. Standardized beta, adjusted R² and R² change was used. Finally a linear regression analysis was used to investigate the association between residency and change in quality of life from baseline to follow-up controlling for quality of life level at baseline for participants with CDR = 2. Also here, standardized beta, adjusted R² and R² change was used.

2.6.6. Papers 2 and 3

One-way ANOVA for continuous data and chi-square tests for categorical data were used to test the differences in means between the control and intervention group on the following variables: age, gender, education level, CDR, living conditions, walking aids, social contact, hobbies and if the participant enjoyed contact with animals (Table 4 and Table 5). Mixed model analyses was used to investigate changes over time (T₀, T₁ and T₂) and differences between the groups (intervention and control group) (West, 2009) in the outcome measures BARS, CSDD, BBS and QUALID. Time was modelled 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 institution 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 for these outcomes, an interaction term between groups and points of time was included in the

model. For all outcomes the analysis was repeated on data stratified by CDR level divided into CDR = 0.5+1+2 (mild to moderate dementia) and CDR = 3 (severe dementia).

A clinically significant change in depression (Paper 2) was estimated by categorizing the participants' sum scores for T_0 , T_1 and T_2 into four levels according the administration and scoring guidelines for the CSDD by George S. Alexopoulos (Alexopoulos et al., 1988). 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 change of 6.5 points on the BBS is found to be required to reveal a genuine change in balance function (Romero et al., 2011), consequently this level was used to test the clinical effect on balance in Paper 3.

2.6.7. Paper 4

One-way ANOVA for continuous data and chi-square tests for categorical data were used to test the differences in means between home-dwelling persons with dementia and persons with dementia living in nursing home on the following variables: age, gender, education level, CDR, psychotropic medication, walking aids, social contact, hobbies and if the participant enjoyed contact with animals (Table 6).

Duration of time for all defined behaviours (Table 7) was registered in seconds. Total time for each session was registered and time out of camera was withdrawn from total time for each participant. Due to differences in the total time for each session, the percentage of total time for each behaviour was then calculated, and a mean value for both recordings (week 2 and 10) were used in the statistical analysis. Analysis of variance (ANOVA) was used to test the differences in means between groups (nursing home participants and participants at day-care centre). Analysis was repeated on data for both groups stratified by CDR level divided into CDR = mild (CDR 0, 0.5 and 1), moderate (CDR 2) and severe (CDR 3), and means were compared.

3. Presentation of papers

Each of the four papers are presented in the following sections.

3.1.Paper 1

'Differences in quality of life, cognitive and physical function, social contact, sleep patterns, physical activity, light exposure, and medication in home-dwelling persons with dementia and nursing home residents – a cross-sectional study'

Background and aim: An important goal in dementia care is to provide for and ensure a good quality of life, and there is a great intention to able people to live at home as long as possible. However, dementia often eventually leads to dependency on others and finally to residential care. There is scarce and inconclusive knowledge of how living in a nursing home differs from living at home for persons with dementia with regard to their quality of life. The first aim of this paper was to compare quality of life, cognitive and physical functions, social contacts, sleep patterns, physical activity levels, exposure to light, and medication of persons with dementia in nursing homes and home-dwelling persons with dementia, and to investigate whether living in nursing homes was associated with a poorer quality of life than living at home for persons with dementia. A second aim was to examine if possible differences between residencies in quality of life were consistent over time.

Methods: In this cross-sectional study, baseline data for all of the participants recruited to the main project was used. The total sample (N = 193) consisted of 78 nursing home residents (52 women) from 15 different nursing homes with adapted units for persons with dementia and 115 home-dwelling persons with dementia (74 women) from 23 adapted day-care centres for home-dwelling persons with dementia.

Trained nurses scored sociodemographic data, degree of dementia (CDR), amount of medication, and quality of life (QUALID). Sleep patterns, physical activity levels, and light exposure were measured by actigraphy. Associations were tested with One-way ANOVA and linear regression models. See section 2.6.5 for detailed description of statistical analysis.

Results: Mean age among persons with dementia in nursing homes were 84.6 (SD = 6.5), and mean age among home-dwelling persons with dementia were 82.6 (SD = 6.8). There were no significant age, gender, or educational differences between persons with dementia in nursing homes and home-dwelling persons with dementia. Approximately half of the home-dwelling persons with dementia lived alone (52.2%), but they had significantly more social contact with their family members and friends than nursing home persons with dementia. Walking aids were used by a significantly higher number of persons with dementia living in nursing homes than home-dwelling persons with dementia. Significant differences were observed in the severity of dementia: 9% of persons with dementia living in nursing homes had mild dementia, 43.6% had moderate dementia, and 47.4% had severe dementia. By contrast, the respective percentages for home-dwelling persons with dementia were 43.5%, 47.0%, and 4.3%. The actigraphy results showed that nursing home residents scored significantly lower on almost all sleep parameters. Persons with dementia living in nursing homes experienced almost four times less light exposure compared with home-dwelling persons with dementia. They also showed significantly more sedentary and less active behaviour than home-dwelling persons with dementia. It was a significant difference in use of psychotropic medication between persons with dementia living in nursing homes and home-dwelling persons with dementia, both in the prevalence and number of medications used. Persons with dementia living in nursing homes showed a significantly lower quality of life. The differences were maintained even after stratifying on the degree of dementia. Home-dwelling persons with moderate dementia showed significantly less use of walking aids, more social contact, higher levels of activity and exposure to light, and less use of psychotropic medications. The regression model explained 28% of the variance in quality of life in persons with moderate dementia, only residency contributed significantly in the model. Residency also significantly predicted negative change over time in quality of life.

Conclusion: The study indicated that living at home as long as possible is not only desirable for economic or health political reasons but also is associated with higher quality of life for persons with moderate dementia. More studies are needed to investigate how quality of life could be increased for persons with dementia in nursing homes.

3.2.Paper 2

'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'

Background and aim: The prevalence of neuropsychiatric symptoms in persons with dementia living in nursing home is known to be very high, with depression and agitation being the most common symptoms. It is reported that 75% of persons with dementia have experienced neuropsychiatric symptoms in the preceding month, and 55% reported having two or more symptoms. Neuropsychiatric symptoms affect patients' quality of life. The aim of this study was to investigate if animal-assisted group activity had effect on symptoms of agitation, depression and quality of life among persons with dementia admitted to nursing home, and if degree of dementia would impact possible effect.

Methods: A prospective, cluster randomized multicentre trial with a follow-up measurement three months after end of intervention. Ten nursing homes were randomized to either animal-assisted group activity 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-minute session with animal-assisted activity with a dog twice weekly for 12 weeks in groups of 5-7 participants, led by a qualified dog handler. Trained nurses collected sociodemographic data relating to age, gender, education, use of walking aids, social contact, hobbies, and animal contact sociodemographic data, and scored degree of dementia (CDR), depression (CSDD), agitation (BARS) and quality of life (QUALID) at baseline. CSDD, BARS and QUALID were also assessed at post-test (after 12 week of intervention), and at follow-up (12 weeks after end of intervention).

Mixed model analyses were used to investigate changes over time and differences between the groups (intervention and control group) in the outcome measures. See section 2.6.6 for detailed description of statistical analysis.

Results: Mean age in the intervention group were 82.9 (SD = 8.5) and mean age in the control group were 84.1 (SD = 6.7). No significant differences were found between the intervention

group and the control group at baseline. No significant effects of the intervention were found from pre-test to post-test for depression in the total sample. 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 pre-test to follow-up (p = 0.037). There was a close to significant effect on depression from pre-test to post-test (p = 0.054) and a significant effect from pre-test to follow-up (p = 0.001) among participants with severe dementia. To test the clinically significant change in depression, subjects with a score that showed improvement on at least two levels from pre-test to follow-up were considered as having a clinically significant improvement in their depression symptoms. More participants in the animal-assisted activity group improved than in the control group (p = 0.03). For quality of life, a significant effect of animal-assisted activity was found both at post-test (p = 0.035) as well as at follow-up (p = 0.003) for participants with severe dementia. No effect on agitation was found.

Conclusion: The improvements in depression and quality of life show that complementary treatment such as animal-assisted activity may be useful in dementia care. The effects were found for persons with severe dementia, which supports the importance of individually-tailored interventions where person attributes such as participants' cognitive and functional levels are taken into account.

3.3. Paper 3

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

Background and aim: Functional ability, which is the intrinsic capacity of the individual and the ability to social, psychological, and physical interaction with the environment, is the key for living good independent lives throughout a life-course and obtain a high quality of life. Balance is a central function in most activities of daily living, and as there is a goal that persons with dementia live at home as long as possible, there is a need for activities that might preserve balance and quality of life. The main aim of Paper 4 was therefore to examine if there would be an effect of animal-assisted activity in home-dwelling persons with dementia attending day-care centres on

factors related to risk of fall accidents, with balance and quality of life as main outcomes. Methods: The study was conducted as a prospective and cluster-randomized multicentre trial with a follow—up. A total of 16 adapted day-care centres for home-dwelling persons with dementia were randomized to either animal-assisted group activity with a dog or a control group with treatment as usual. There were a total of 80 participants included, 42 in the intervention group and 38 in the control group. The intervention consisted of a 30-minute session with animal-assisted activity with a dog twice weekly for 12 weeks in groups of 3-7 participants, led by a qualified dog handler. The idea behind the intervention 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. Trained health care workers collected sociodemographic data for age, gender, education, use of walking aids, social contact, hobbies, and animal contact sociodemographic data, and scored degree of dementia (CDR), balance (BBS) and quality of life (QUALID) at baseline. BBS and QUALID were also assessed at post-test (after 12 week of intervention), and at follow-up (12 weeks after end of intervention).

Mixed model analyses were used to investigate changes over time and differences between the groups (intervention and control group) in the outcome measures. See section 2.6.6 for detailed description of statistical analysis.

Results: Mean age in the intervention group were 84.00 (SD = 6.6) and mean age in the control group were 81.7 (SD = 7.2). It was a significant positive effect of the animal-assisted activity intervention on balance from baseline to post-test (p = 0.03). The results were also clinical significant, as 39.4% in the animal-assisted activity group improved at least 6.5 points in the BBS. In addition, the average increase in BBS in the animal-assisted activity group of 3.16 points, suggests approximately 20% reduction in fall risk. The improvement in BBS was maintained at follow-up. No effect of the intervention was found on quality of life, however, we found a strong association between clinical improvement on the BBS and improvement in QUALID from pre-test to post-test.

Conclusion: The results indicate that animal-assisted activity might have useful clinical implications by leading to improvements in balance and thereby preventing risk of falls.

3.4. Paper 4

'Engagement in elderly persons with dementia attending animal-assisted group activity'

Background and aim: The high amount of neuropsychiatric symptoms in persons with dementia and the need for meaningful activities that enhance engagement is very important, both for persons with dementia still living at home, as well as for persons with dementia admitted to a nursing home. The aim of the study was therefore to systematically map different behaviours occurring in an animal-assisted group activity with a dog, and investigate if this kind of intervention would create engagement among persons with dementia still living at home and among persons with dementia admitted to a nursing home. We also wanted to see if the intervention would have different impact on engagement among participants in the two residencies.

Methods: Only data from the intervention groups were used in the study. In total, 21 (13 women) persons with dementia in nursing homes and 28 (13 women) home-dwelling persons with dementia attending a day-care centre received animal-assisted group activity with a dog. The participants interacted with a dog and its handler for 30 minutes, twice a week for 12 weeks. A protocol was deliberately designed to be able to standardize the intervention as much as possible, both across sessions and across the different institutions. Video recordings were carried out, and behaviours were categorized by the use of an ethogram.

Analysis of variance (ANOVA) was used to test the differences in means between groups (nursing home participants and participants at day-care centre). See Section 2.6.7 for detailed description of statistical analysis.

Results: Behaviours targeted to either the dog or other people were the ones with highest mean percentage time. These behaviours were: Look at dog-activity; Smile or laugh at dog; Conversation; Look at other people; Touch dog; Do activities with the dog; Touch people; Smile or laugh to people. Furthermore, mean values showed that actions towards the dog, such as observing it, smile, talking to it or petting it, were the behaviours with the longest duration in animal-assisted activity sessions in both populations. There was a high amount of attention to

the dog (looking at it), a positive attitude (smiles/laughs), a lot of action (touching the dog, do activities), and a positive affect (high amount of positive behaviour and low frequency and duration of negative behaviour) was found.

There were no significant differences between nursing home participants and day-care centre participants regarding age, gender, education level, use of walking aids, or whether the participants enjoyed having contact with animals. Mean age among persons with dementia in nursing homes were 84.8 (SD = 5.9), and mean age among home-dwelling persons with dementia were 84.1 (SD = 6.2). There were only minor differences in behaviour between nursing home participants and day-care centre participants.

When comparing the participants stratified by the degree of dementia (CDR), we only found a few differences in behaviours. Participants with severe dementia slept significantly more (F = 6.60, p = .003) than those with mild or moderate dementia, and they spent significantly less time (F = 6.74, p = .003) looking at the dog-activity than those with mild or moderate dementia.

Conclusion: Animal-assisted activity seems to create engagement and a positive affect in persons with dementia, and might be a suitable and health promoting intervention for both nursing home residents and participants of a day-care centre. For persons with severe dementia it should be considered which is more suitable, individual or group-based animal-assisted activity.

4. Discussion

The overall research aim of the research for this thesis was to investigate animal-assisted activity as a health promoting activity for home-dwelling persons with dementia attending a day-care centre and persons with dementia living in a nursing home.

Health promotion is accentuated in a number of White Papers (Beard et al., 2015; Norwegian Ministry of Health and Care Services, 2015a; WHO, 1986), with a focus on functional ability in order to obtain a high quality of life (Beard et al., 2015). To provide for and ensure a good quality of life is an important goal in dementia care (Beerens et al., 2013). It is therefore important to gain more knowledge of the quality of life and known associated risk factors in persons with dementia living at home and persons with dementia living in nursing homes. For this reason, data for home-dwelling persons with dementia and persons with dementia in nursing homes were collected, and the two populations' quality of life, cognitive and physical function, social contact, sleep patterns, physical activity, exposure to light, and medication were compared. Whether residency was associated with quality of life was examined, and the association between residency and change in quality of life over time was investigated (Paper 1). The results showed that home-dwelling persons with moderate dementia made significantly less use of walking aids, had more social contact, higher levels of activity, and more exposure to daylight, and less frequently used psychotropic medications. They also had a significantly higher quality of life than persons with dementia in nursing homes, both at baseline and over time.

When the effect of animal-assisted group activity on depression, agitation, and quality of life among persons with dementia living in a nursing home was investigated, it was found that the intervention significantly decreased depression among patients with severe dementia, both statistically and clinically from pre-test to follow-up. A significant effect of the intervention was found on quality of life for persons with severe dementia, both at post-test and at follow-up. No effect was found on agitation (Paper 2).

The intervention's effect on balance and quality of life among home-dwelling persons with dementia attending a day-care centre was investigated in Paper 3. A significant positive effect of the animal-assisted activity on balance from baseline to post-test was found, both statistically and clinically. The average increase in the BBS score in the animal-assisted activity group suggested a c.20% reduction in fall risk, and the improvement in balance was found sustained at follow-up, three months after the end of the intervention. No effect was found on quality of life.

For the study reported in Paper 4, behaviours during interactions with the dog were systematically mapped, and we investigated whether the intervention had a different impact on engagement among persons with dementia living in nursing home and home-dwelling persons with dementia attending a day-care centre. Behaviours targeted at either the dog or other people were associated with the highest mean percentage time, and during the intervention only minor differences in the behaviours smiling or laughing, conversing, and sleeping were found between nursing home participants and day-care centre participants. When stratified by the degree of dementia, participants with severe dementia slept significantly more and spent less time looking at the dog compared with those with mild or moderate dementia. Nonetheless, the intervention seemed to create engagement and positive affect among both populations.

In the following subsections, the results of the project are discussed on the basis of the theoretical framework of the Comprehensive Process Model of Engagement developed by Cohen-Mansfield et al. (Cohen-Mansfield et al., 2009a). The main components in the model – person attributes, stimuli attributes, environmental attributes, and engagement – are discussed in relation to intervention. Thereafter, the main outcomes of agitation, depression, and balance, as well as quality of life are discussed on the basis of the engagement model, the biophilia hypothesis, and knowledge of the human-animal bond. To a certain extent, the subsections overlap because all of the outcomes are related to each other. Finally, methodological issues are considered.

4.1. Person, stimuli, and environmental attributes that influence engagement

In the engagement model by Cohen-Mansfield et al. (2009a), important personal attributes are cognitive function, demographic characteristics, general level of activity, and interest. Stimulus attributes represents human aspects, social versus non-social, and live versus not alive, and

environmental attributes are described as surroundings, such as time, place, number of people around, and the manner of stimulus presentation. In an animal-assisted intervention with a dog, all of these aspects will influence the participants' interaction with the dog and its handler. Interaction between stimulus and environment is highly relevant in animal-assisted interventions, since responsiveness to modelling is an important factor. Another important factor is person-stimulus interactions, such as participants' preference for dogs, see Figure 8 (Cohen-Mansfield et al., 2009a).

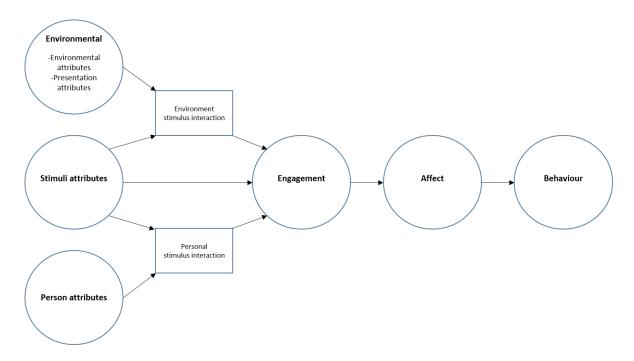


Figure 8. The Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009).

In Paper 4, we report that participants with severe dementia were found to spend less time looking at the dog activity and to sleep more during the sessions than those with mild or moderate dementia. Home-dwelling persons with dementia showed more behaviours such as smiling or laughing towards the dog, were engaged in more conversation, and slept less during the sessions than persons with dementia living in a nursing home. This finding might be related to the lower degree of cognitive loss and less use of medications in the home-dwelling population. This would be in line with the study by Cohen-Mansfield et al. (2009b), who analysed

the impact of participants' attributes and found that higher cognitive function positively affected engagement in terms of duration, attention, attitude, and refusal towards the stimulus (Cohen-Mansfield et al., 2009b). However, Cohen-Mansfield et al. did not find any correlation between the number of psychotropic medications and engagement (Cohen-Mansfield et al., 2009b).

Demographic characteristics are assessed in all four papers in this thesis, especially in Paper 1. Significantly more persons with dementia in nursing homes had severe dementia, but even when stratified by the degree of dementia, persons with moderate dementia living in nursing homes had significantly more use of walking aids, less social contact, lower levels of moderate activity, and a higher use of psychotropic medication. These results provide important information, which is essential when an intervention is to be implemented. In order to provide the best intervention, health care workers need to gain as much knowledge as possible about the persons in their care (Cohen-Mansfield et al., 2009a). This knowledge includes demographic data, past and present interests, and psychological and physiological challenges, as well as the reason for implementing an intervention, which could be either to decrease boredom, loneliness, and problematic behaviour or to increase positive affect and improve physical impairments, to mention a few examples.

Participants with a past interest in pets have been found to have a longer duration of engagement in their interactions with a dog and participants who reported that they currently enjoyed dogs paid a significantly higher attention towards the dog in interactions with a dog (Cohen-Mansfield et al., 2010c). The high amount of attention paid towards the dog activity and the overall long duration of engagement seen in both places of residence reported in Paper 4 was probably affected by the fact that in the study reported in Paper 1 we found that the majority of nursing home residents and home-dwelling participants enjoyed contact with animals.

With regard to stimulus attributes, the social qualities of the dog might influence the level of participants' engagement (Cohen-Mansfield et al., 2010f; Marx et al., 2010), since social stimuli have been found to create significantly more engagement among persons with dementia than non-social stimuli, and participants have been found significantly more attentive and with significantly more positive attitude towards a social stimulus than to a non-social stimulus

(Cohen-Mansfield et al., 2011; Cohen-Mansfield et al., 2010f). The high degree of participants' involvement, as well as indications of them having a positive attitude (frequent smiles and laughter) reported in Paper 4 implies that the intervention both created engagement among the participants and had a positive affect on them. Also, the dog's size and/or breed influences the amount of engagement towards it (Marx et al., 2010). In our study, we deliberately used different dogs of different sizes and breeds. We examined possible differences between the different nursing home units, and found no significant differences. It therefore seems that in terms of breed or personality individual dogs did not influence the amount of engagement. Although the dogs were of different breeds, they were rather homogenous in the sense that they shared preferred traits and had received the same training. This was also the case for the handlers, who were all female, had similar background, and had received the same training and education. In an animal-assisted activity, the dog serves as an adjunct to the therapist/dog handler. The dog's handler should therefore be considered as part of the stimulus attributes, but also part of environmental attributes, as a central component in modelling the intervention.

A very important environmental factor in the study was the group design and modelling of the intervention. In group activities, the group represents a secure environment that contributes to experiences of strength, inspiration, and joy (Sundsteigen et al., 2009). The number of participants in each group in our study varied between three and seven. Including dog handler and a health care worker, the number of people present in the room varied between five and nine. Attention to the engagement stimulus has been previous found significantly higher when there are between four and nine people in the room, as opposed to fewer than four or greater than nine (Cohen-Mansfield et al., 2010d). The intervention modelling was done by the dog handlers. The dog handlers were required to follow the standardized intervention protocol (Appendix 1), but were free to facilitate the session for the maximum benefit for the individual participant. The intervention modelling, such as in which way the dog is presented and the guidance provided to the participant on how to interact with the dog, is very important in animal-assisted activities. Modelling appropriate behaviour has been found to increase the duration of engagement significantly, and to create a significantly more positive attitude among persons with dementia when interacting with a stimulus (Cohen-Mansfield et al., 2010d). Other important

environmental attributes in the study were time and place. The sessions were conducted in the same room every time and therefore the location became familiar to the participants. Predictability was also ensured by always holding sessions on the same weekdays and within a certain time span, between 12:00 and 13:30. Time of the day affects participants' level of engagement, since both the duration of engagement and the span of attention to the stimulus are shorter during the morning (10:00–12:00) than in the afternoon (Cohen-Mansfield et al., 2010d).

4.2.Engagement

Engagement may be measured as the rate of refusal of the stimulus, duration of time involved with a stimulus, level of attention to the stimulus, attitude toward the stimulus, and the action towards the stimulus (Cohen-Mansfield et al., 2009a).

In the study reported in Paper 4, video recordings in conjunction with the use of an ethogram were used to register behaviour. An ethogram is a catalogue of defined behaviours, which is used to measure the duration and frequency of behaviours of interest. In Paper 4, we report that a behavioural pattern during animal-assisted activity indicated a high level of engagement, both by home-dwelling persons with dementia and persons with dementia in nursing homes. The participants spent much their time on behaviours targeted at either the dog or other people, such as 'Look at dog activity', 'Smile or laugh at dog', 'Conversation', 'Look at other people', and 'Touch dog'. The dog clearly attracted the participants' attention, as they spent six times longer looking at the dog than at other people or other things. This finding is in line with previous research on the impact of stimuli on engagement. For instance, Marx et al. found an increase in engagement with dog-related stimuli when measured through direct observations (Marx et al., 2010). Likewise, among the participants categorized as unresponsive to stimuli there were higher levels of engagement towards a real dog than to other types of stimuli in a study that looked at what type of stimulus created the most engagement, which stimulus was most often refused, and which stimulus was most appropriate for persons that were not likely to respond to any stimuli (Cohen-Mansfield et al., 2010a). Such attention paid to the dog can probably be related to the biophilia hypothesis, which postulates that humans have an innate attraction to nature and animals (Wilson, 1984). Looking at animals actually triggers specific neurons in the human brain (Mormann et al., 2011), and presumably it is in humans' self-interest in engaging in therapies or activities with animals (Wilson, 1984). Co-evolution with animals, especially dogs, is said to have made animals an integral part of our psychological well-being (Serpell, 2015). In our study, affect was measured by registering smiles, laughs, or other manifestation of happiness, by tracking eye movements, by negative expressions such as crying or agitated behaviour, and by stereotyped behaviour (Table 7). The long duration of positive behaviours (e.g. the look-at-dog-activity smile or laugh and conversation) and the low occurrence of negative behaviour (stereotyped behaviour, yawn and sigh, agitated behaviour, and wandering) implies that the intervention had a positive emotional impact.

Positive emotions produce flourishing, not simply within the present, pleasant moment but in the long term too (Fredrickson, 2001). Experiences of a positive affect will stimulate individuals to engage with their environments and partake in activities (Fredrickson, 2001). Hence, in the case of animal-assisted activity, there might be a reciprocal effect: the dog is a stimulus that encourages engagement, and interaction with the dog offers pleasant moments that facilitate positive emotions, which in turn increases the amount of engagement. Positive emotions are a means to achieve psychological growth and improved well-being over time (Fredrickson, 2001), and this argument is supported by the findings of decreased depression and increased quality of life at follow-up reported in Paper 2.

In Paper 1, we report on our finding that personal attributes that could interfere with participants' level of engagement were quite different between persons with dementia living in nursing homes and home-dwelling persons with dementia. However, the intervention was the same for both residencies. To summarize, in the dog activity, stimulus attributes, environmental attributes, and the interaction between person and stimulus as well as the environment and stimulus interaction were the same for home-dwelling persons with dementia attending a day-care centre and persons with dementia living in a nursing home. The results in Paper 4 indicate that the participants had a long duration of involvement with the stimulus (e.g. touching the dog, brushing the dog, and feeding the dog a treat), and with regard to the level of attention (looking at dog activity), the participants' attitudes (with a lot of smiles) and their actions towards the

stimulus (i.e. petting the dog) indicate that animal-assisted activity is a suitable intervention for persons with dementia for both types of residencies, as long as the intervention is individually tailored and personal attributes such as participants' cognitive function and degree of interest in dogs are taken into account. In order to obtain maximum benefits from the intervention, groups of participants might need to be more homogenous in terms of gender, age, and physical and cognitive functioning. Alternatively, it might be the case that persons with severe dementia would benefit more from individually based animal-assisted activity, as one-one-on socializing has been found to give the highest ranking for duration, attention, and/or attitude towards a stimulus (Cohen-Mansfield et al., 2010a).

4.3. Agitation

Agitation is one of the most difficult behavioural symptoms to manage in dementia patients. However, the provision of stimuli and engagement has been found to appease, prevent, and reduce agitation in these patients (Cohen-Mansfield et al., 2007; Cohen-Mansfield et al., 2010b; Cohen-Mansfield & Werner, 1997). Some early research in animal-assisted interventions reported positive effects on agitation (McCabe et al., 2002; Richeson, 2003; Sellers, 2006), but more recent studies have failed to support those findings (Friedmann et al., 2015a; Nordgren & Engstrom, 2014a; Thodberg et al., 2015).

In our study, agitation was only measured among persons with dementia living in nursing homes. The assessment used to measure agitation (BARS) was based on the display of agitated behaviour during the preceding two weeks. In Paper 2, we report that no significant differences in symptoms of agitated behaviour between the intervention group and control group were found at any time point measured on BARS. When stratified by the degree of dementia, persons with severe dementia were found to have slightly more agitated behaviour than those with mild or moderate dementia. We did not set any degree of symptoms as inclusion criteria; rather, a low mean score on BARS was seen at baseline in both groups. This could well have been the reason for the lack of changes between T_0 to T_1 and T_0 to T_2 . The level of agitation observed at baseline is in line with a reliability study of the Norwegian version of BARS (Sommer et al., 2009). This indicates a frequency of observed agitated behaviours of one or two times per week. It can only

be speculated as to whether health personnel could have captured further reductions in the assessment. It might have been more accurate to measure the frequency and duration of agitated behaviour after each or some of the sessions, to see whether the participants showed less agitated behaviour as a result of the session. However, even in studies that did have degree of agitation as inclusion criteria, observational studies have been difficult because participants are not agitated much of the time (Cohen-Mansfield et al., 2010b).

It might have been the case that the engagement found in the study was more of a stimulating effect, rather than a calming effect. In Paper 4 we report the long duration of positive affects and that the participants spent quite some time doing activities with the dog. Although engagement and positive affect have been found to decrease agitated behaviour (Cohen-Mansfield et al., 2010b), it might be that this intervention is more effective for other outcomes.

Agitated behaviour may be manifested through physically aggressive behaviours, physically non-aggressive behaviours (e.g. manipulation of objects), verbally aggressive behaviours, and verbally non-aggressive behaviours (Cohen-Mansfield, 2008). Stimuli interventions have been found more effective for physical types of agitation (e.g. pacing and repetitive behaviours) than for verbal or vocal agitation (e.g. screaming, complaining, groaning, and attention-seeking) (Cohen-Mansfield et al., 2010b). We did not analyse effect on subscales of agitation, and it is therefore open to speculation whether an effect would have been found if such analyses had been conducted.

In their interactions with the dog, participants are not allowed to behave inappropriately and this may lead to the development of more adaptive representations and strategies (Parish-Plass, 2008). For example, the participants cannot behave in an agitated or aggressive manner, and may have to adjust the tone of their voice in the presence of the dog. Verbally non-aggressive behaviour such as verbal bossiness is very common among persons with dementia (Cohen-Mansfield, 2008). Interaction with the dog provides opportunities for learning and expressing more appropriate behaviour. The dog handler will model the intervention by telling the participant to behave calmly and respectfully in the presence of the dog, and the dog might not even listen if commands are expressed in a verbally 'bossy' way rather than in a more appropriate

way, with praising. This development of more adaptive representations and strategies might also be used in settings without the dog present. Furthermore, interaction with the dog might give participants the feeling of acceptance, despite their disease and behaviour, since dogs do not prejudge (Parish-Plass, 2008).

4.4. Depression

Social withdrawal, apathy, and loss of interest in activities and hobbies are common symptoms of depression (Engedal & Haugen, 2009), and it has been suggested that in order to prevent depression among the elderly, group activities in which the participants themselves can influence the development of the activity are the most effective (Cattan et al., 2005). A meta-analysis of five randomized controlled trials found empirical support for animal-assisted interventions as an effective treatment for depression in patients in various institutional settings such as nursing homes (Souter & Miller, 2007). However, the results from a number of more recent studies are mixed (Bono et al., 2015; Friedmann et al., 2015a; Majic et al., 2013; Moretti et al., 2011; Mossello et al., 2011).

A study conducted by Moretti et al. found that, from scores on the Geriatric Depression Scale, both the animal-assisted activity group and the control group improved, but the improvement was significant in the animal-assisted activity group (Moretti et al., 2011). Friedmann et al. (2015a) found that depression decreased during the intervention period with animal-assisted intervention, while the reminiscing group, used for comparison, did not experience a decrease in depression. However, no significant effect was found between the two groups (Friedmann et al., 2015a). Majic et al. (2013) studied the effect of an individual-based animal-assisted intervention 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 a constant frequency and severity of symptoms of depression (Majic et al., 2013). Mossello et al. did not find any effect on depression, although the animal-assisted activity was associated with an increase in positive emotions and a decrease in sadness (Mossello et al., 2011). In a study conducted by Bono et al. (2015), no symptoms of depression were found

at baseline or at post-test. However, the control group showed a decrease on the CSDD scale, while the intervention group showed an increase (Bono et al., 2015).

In Paper 2, we describe how we found that the intervention had a significant effect on depression among persons with dementia living in nursing homes. The effect was found at follow-up, and when stratified by the degree of dementia, the effect was found within patients with severe dementia. Furthermore, within the latter group, a strong tendency for a beneficial effect immediately after end of intervention was found too. This might seem to contradict the findings in Paper 4, namely that participants with severe dementia were somewhat less engaged than persons with mild or moderate dementia. However, it has been found that the lower cognitive status, the greater the relationship between high activity involvement and positive affect seems to be (Smit et al., 2015), and in Paper 4 we describe a positive affect also among participants with severe dementia.

The animal-assisted activity applied in our study includes many components that may have affected depression among the participants. Humans have an innate need for touch (Parish-Plass, 2013), yet elderly people may have limited opportunities for touching another living being. Petting the dog allows such behaviour and this sensory stimulation might lead to a change in the person's physiological state (Odendaal, 2000; Odendaal & Lehmann, 2000; Odendaal & Meintjes, 2003) as well as a psychological sense of well-being (Parish-Plass, 2008). Tactile stimulation has become an increasingly common approach in care as part of multisensory stimulation (Baker et al., 2003; Strøm et al., 2016). Stroking a dog will activate tactile receptors in the participant's hand. A dog's body temperature is slightly higher than a human's (respectively 38–39 degrees Celsius and 37 degrees Celsius), and the warmth of the dog's body might relax and calm the participant. Although we did not find that this potential calming effect had any impact on agitation, it might be that touching the dog had a positive influence on the participants' wellbeing. Touch may reduce anxiety, prevent feelings of isolation, create trust, and form conditions for emotional availability (Parish-Plass, 2013). In Paper 4, we describe how we found a long duration of the behaviour 'Touch the dog', which indicates that most participants enjoyed their physical contact with the dog, and spent a lot of time stroking and petting it.

Even though there were no data concerning former ownership of pets in the study, pet ownership is very common in Norway, and many elderly have kept pets earlier in their lives (Kristiansen, 1994). The presence of the dog therefore might have given the participants a sense of normalcy (Parish-Plass, 2008), and thereby led to reminiscences. The situation is perceived as friendly and safe, and the sense of normalcy opens up for natural and spontaneous behaviour and communication (Parish-Plass, 2013). Further, the presence of the dog allows the participants to have reality at a safe psychological distance (Parish-Plass, 2008), and their own feelings may be projected through the dog and be expressed as, for example, 'Oh, you look so sad! Are you unhappy? Do you miss your mum?' In this way, the behaviour of the dog (looking sad) gives the participant an opportunity to comment on something bothering him or her (loneliness). This message may then be intercepted by the dog handler or health care worker, who can talk to the participant about it by asking such questions as 'Do you feel lonely, Mr Nilsen?' Through interpersonal conversation, the health care worker may gain knowledge about the participant and a personal relationship may be formed. Interpersonal communication has been reported as effective regarding depression (van Hees et al., 2013).

4.5.Balance

As falls and fractures are common among home-dwelling older persons (Jensen et al., 2003; Thomas et al., 2002; Tinetti et al., 1995; van Doorn et al., 2003), the intervention was designed in order to enhance balance. The intervention consisted of different activities, such as turning around to pet the dog, having a conversation with the dog and other people, remembering the dog's name, giving commands, bending down to pick up a ball, throwing the ball, brushing the dog's hair, and picking out a treat from a small container to feed the dog. Only a few studies of the effect of animal-assisted interventions on performance-based physical outcomes have been conducted to date (Friedmann et al., 2015a; Herbert & Greene, 2001). Friedman et al. found that physical activity increased slightly over time for the dog intervention group but not for the reminiscence group that was used as a control (Friedmann et al., 2015a). However, no significant effect was found. Herbert & Greene found that elderly adults walked significantly farther when a dog was present than when they walked alone (Herbert & Greene, 2001).

The RCT study described in Paper 3, showed a statistically and clinically significant effect of the animal-assisted activity with a dog on the participants' balance. The average increase in scores on the BBS in the intervention group suggested a c.20% reduction in the risk of falls. The clinical effect on balance is of major significance. The risk of institutionalization significantly increases when a person's physical function is impaired (Hajek et al., 2015) and, as we found in Paper 1, institutionalization worsens the residents' quality of life. Rehabilitation or, at least, the maintenance of physical function should be emphasized among home-dwelling persons with dementia. The results presented in Paper 4 indicate that animal-assisted group activity designed to improve balance can rehabilitate balance throughout the intervention period, and that the achieved level of balance is sustained for at least three months after the end of intervention. It is open to speculation as to whether the animal-assisted activity made the participants more confident and motivated them to become more physically active in everyday life and thereby improve their performance in the BBS test, but the engagement and behaviours reported in Paper 4 suggest that this could be a plausible outcome.

Some of the activities could be described as isotonic exercise, such as turning, bending, and lifting. In many ways, the animal-assisted activity sessions could be compared with a seated, group-based programme limited to range of motion exercises that are 'standard' for elderly people (Lazowski et al., 1999). Range-of-motion-exercises programmes usually consist of 30–45 minute sessions with elements such as introduction and/or discussions, vocal exercises, word or memory games, range of motion (fingers, hands, arms, knees, and ankles), and finally relaxation exercises. Seated group-based exercise programmes have been found to improve functional capability (McMurdo & Rennie, 1993).

Horak (2006) 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. These multiple mechanisms are important in order to retain good balance and to prevent falls, and it might be that the animal-assisted activity offers several such mechanisms, due to the complexity of the intervention. The

participants were encouraged to remember the dog's name, different commands, and how to perform different tasks, among other tasks, and this kind of intervention has previously been found to increase cognition (Moretti et al., 2011). During the 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 leant forward to pet the dog, all of which are movements that require good postural control. Unfortunately, we did not use the ethogram to register physical movements, and hence the duration and frequency of physical activity was not measured during the sessions.

Balance and mobility impairments are associated with decreased balance confidence. Balance self-efficacy refers to a person's degree of confidence to perform tasks without losing their balance or becoming unsteady (Powell & Myers, 1995). Most of the tasks in the animal-assisted activity sessions with the dog could enhance self-efficacy, such as feeding the dog a treat, brushing the dog's hair, or throwing a ball for the dog to catch. This theory is supported by previous findings from animal-assisted interventions with farm animals, in which participants' self-efficacy was shown to improve through mastering work tasks related to the animals (Pedersen et al., 2011). The theory of self-efficacy has also been used to explain increased physical activity in animal-assisted activities with dogs (Friedmann et al., 2015a).

4.6. Quality of life

Improving the quality of life has been identified as one of the primary goals of dementia treatment (Logsdon et al., 2007). Quality of life is a multidimensional concept, which in older adults includes the objective environment, behavioural competence, psychological well-being, and perceived quality of life (Lawton, 1991).

4.6.1. Environmental factors

Environmental characteristics are relevant for the ability to engage, for behavioural competences, and for the perceived quality of life (Cohen-Mansfield et al., 2010d; Lawton, 1991). In Paper 1, we describe how we found a significantly lower quality of life among persons with

dementia in nursing homes compared with home-dwelling persons with dementia, which is in line with previous findings (Barca et al., 2011). The findings support the emphasis that Lawton puts on the environment in his conceptualization of quality of life, in which the environment includes home and social networks (Lawton, 1991). Institutionalization will decrease autonomy due to environmental parameters, adjustments to daily life in the nursing home, and the nursing staffs' competence and attitudes. Heggestad et al. (2013a), suggest that nursing homes should be more home-like and less institutional. In their qualitative research, they did participant observations in two nursing home units, and held qualitative interviews with five residents living in those nursing homes. Their main findings revealed that residents did not feel at home in the unit, but instead they felt as though they were prisoners and they missed their former homes (Heggestad et al., 2013a).

Increased focus on the effects of living environments (scale and design) have led to more homelike environments, with relatively small groups of residents. These small-scale care settings are meant to be more home-like, and the residents are encourages to continue their habitual activities of daily life. The small groups makes it easier for residents to interact with each other, and fewer professional caregivers leads to closer social relations with the residents (de Rooij et al., 2012; Verbeek et al., 2012). In the Netherlands, it has been shown that such small-scale settings facilitate better social relationships than traditional settings, and a significantly higher score on the quality-of-life subscale 'positive affect' from the QUALIDEM (Quality of life in dementia) have been found (de Rooij et al., 2012). However, there are huge differences between nursing homes, both within countries, and between countries. For instance, de Rooij et al. (2012), found different results between Belgium and the Netherlands. The positive effect of small-scale settings in the Netherlands were not found in the Belgian sample, and residents in traditional settings in Belgium felt 'more at home' over time (de Rooij et al., 2012). In Sweden, a qualitative study found that the majority of residents, as well as their relatives, were satisfied with life in their care home (Andersson et al., 2007). In our study, all nursing homes sampled were categorized as small-scale settings. We found that nursing home residents scored significantly lower on many of known risk factors associated with quality of life (Barca et al., 2011; Mjørud et al., 2014a; Nagatomo et al., 1997; Telenius et al., 2013). Persons with dementia living in nursing homes experienced almost four times less exposure to light compared with home-dwelling persons with dementia, and they scored significantly lower on almost all sleep parameters. They were less active than home-dwelling persons with dementia and showed significantly more sedentary behaviour and less 'moderate active' behaviour than them too. Persons with dementia living in nursing homes had higher use of psychotropic medications than home-dwelling persons with dementia, both in the prevalence and number of medications used. These factors are directly relevant for the dimensions of quality of life (Lawton, 1991), and could be a part of the reason why persons with dementia living in nursing homes were found to have a significantly lower quality of life (Paper 1).

The longitudinal quality-of-life data from the subgroup with moderate dementia, reported in Paper 1, enabled us to take unobserved heterogeneity into account and thereby detect developments or changes in the characteristics of the population. The fact that nursing home residents had a decrease in the mean change in their quality of life, whereas home-dwelling persons with dementia were stable over a 6-month period, indicates that living in a nursing home affected their quality of life negatively. However, it is reasonable to assume that the persons with dementia living in nursing homes had poorer health in general, and more comorbid somatic diseases, as might be indicated by the significant differences between the groups in medications and use of walking aids. Nonetheless, general somatic health was not found associated with quality of life in another Norwegian study of patients with dementia in nursing homes (Mjørud et al., 2014c). Hence, the results indicated that living at home as long as possible is associated with higher quality of life for persons with moderate dementia.

4.6.1.1. Person-centred and relationalship-centred care

Mixed results in the effects of small-scale settings (Verbeek et al., 2012) and findings that show beneficial effects from both small-scale and traditional settings regarding quality of life (de Rooij et al., 2012) may indicate the importance of nursing staffs' competence and skills. Verbeek et al. suggests that the personal attention of care workers at small-scale living facilities may have the greatest impact (Verbeek et al., 2012).

According Lawton (1991), social networks are part of the environmental factors and refer to the structure among a set of relationships. Institutionalization and the concept of nursing homes seems to increase patients' feeling of not being heard and seen (Heggestad et al., 2013a). Nursing home residents' social needs, such as company and daytime activities, have been reported as often unmet (Hancock et al., 2006). It has also been found that units that practice personcentered care include residents in everyday activities to a greater extent, which may promote their quality of life (Edvardsson et al., 2014). However, time and resources may prevent care workers from interacting with residents to a great extent.

The discussed intervention may contribute to an increase in social interactions in general and closer relationships between the participants and staff. By observing the participants during the sessions, health care workers might be able to see other qualities in them. During the sessions, the participants might become more engaged than usual, smile more, have more conversations, and tell stories that their health care worker has not heard before. The care worker could then use that shared experience and gain more information relating to the care of the participant, and thereby improve the relationship between the participant and health care worker. Implementing animal-assisted activity might create 'Normalcy, safety and friendliness of the therapy setting' (Parish-Plass, 2008), which might open up for communication and reminiscence (Swall et al., 2015). Reminiscence might increase levels of well-being and provide pleasure and cognitive stimulation (Douglas et al., 2004). Care workers need to gain in-depth knowledge about the resident, and they should not only get to know the resident, but also try to obtain information about their former life, experiences, and interests. Care workers who know about the residents' life stories are able to use that information to calm the patients (Heggestad et al., 2013b). The relationship between the recipient of care and the care giver is of huge importance, and even in cases of severe dementia, it is possible to establish a relationship (Ericsson et al., 2013). It has been argued that in order to be person-centred, dementia care must be relationship-centred (Ericsson et al., 2013), and relational needs should be met (Heggestad et al., 2013b).

4.6.2. Behavioural competence and social interactions

A person's functioning in the dimensions of health, cognition, time-use and social interaction is expressed as 'behavioural competence' (Lawton, 1991). Previous studies of animal-assisted interventions have shown that they might improve social behaviour and function (Filan & Llewellyn-Jones, 2006; Virues-Ortega & Buela-Casal, 2006), increase social interaction and conversation (Bernstein et al., 2000; Kramer et al., 2009), and reduce loneliness (Banks & Banks, 2002).

In Paper 4, social interactions with the dog handler and with other participants are reported as having long durations, which gives excellent opportunities to enhance behavioural competence. A dog has many unique qualities, including the social catalyst effect (Beetz et al., 2012b). Being part of a group intervention where a dog is the centre of attention might reduce any pressure in social interactions, and the dog might serve as a mediator for conversation and thus promote social cohesion within the group (Beetz et al., 2012b). The video recordings showed that the participants looked at other people, smiled at them, talked with them, and had physical contact with them. The group setting and the presence of the dog might have represented a secure environment that allowed the participants to engage in the activity and interact socially with the other members of the group. The sessions were modelled by the dog handler and during some activities the participants had to wait for their turn. Such internal control is important regarding behavioural competence in social interaction.

4.6.3. Well-being

Quality of life has been identified as an important indicator of the overall impact of interventions for individuals with dementia (Logsdon et al., 2007). Life satisfaction, self-acceptance, environmental mastery, self-esteem, depression, internal control, positive relations with others, and autonomy are variables that affect well-being (Ryff, 1989), which is seen as the ultimate outcome of quality of life (Lawton, 1991). All of these variables are naturally affected by living in a nursing home, and might be reasons why many nursing home residents report that they do not feel at home in their unit and that they miss their former home (Heggestad et al., 2013a). Along

with other factors, this might partly explain the difference in quality of life among home-dwelling persons with dementia and nursing home residents with dementia, reported in Paper 1, and why nursing home residents with moderate dementia had a poorer quality of life over time than home dwelling persons with moderate dementia. Correspondingly, it is possible that the animal-assisted activity contributed to improve some of these variables (for depression we measured a significant statistical and clinical effect), and hence led to the improved quality of life (Paper 2).

Quality of life is highly correlated with depression (Barca et al., 2011; Beerens et al., 2014; Beerens et al., 2013; Mjørud et al., 2014a), and Livingston et al. (2008) found that managing depression, in addition to relieving current distress, had long-term benefits for well-being. Furthermore, the animal-assisted activity facilitates opportunities for practicing mastery through controlling the behaviour of the dog. The possibility to participate in activities, especially meaningful ones, is important for improving a sense of independence and a positive self-image (Allen, 2011). The participant's self-esteem might be enhanced by the experience of being able to control the dog and tell the dog what to do and how to behave. This also requires internal control, as the participant needs to keep control of their own feelings and behaviour. Sudden behaviour or verbal or vocal agitation might frighten the dog, and the internal control might lead to more adaptive behaviour. This in turn would lead to more positive relations with others, as also found in the high number of social interactions (Paper 4).

Our results support the findings of a pilot project without a control group conducted in four nursing homes (Nordgren & Engstrom, 2014a). The intervention consisted of 10 sessions of animal-assisted intervention, and measurements of quality of life were assessed one week before start of intervention and one week after the last session. The researchers found a statistically significant improvement in quality of life between baseline and post-test (Nordgren & Engstrom, 2014a).

Scores on QUALID are summed in the range 11–55, where a lower score indicates a higher quality of life. In Paper 1, we describe how we found that the quality of life among home-dwelling persons with dementia was high (15.99 (SD 4.33)) compared with the nursing home population in our study (24.06 (SD 7.16)) and other studies (Barca et al., 2011; Mjørud et al., 2014b). This

might explain why we did not detect a change in quality of life among home-dwelling persons with dementia attending a day-care centre (Paper 3). However, the literature suggests that physical function is related to quality of life (Logsdon et al., 2007; Telenius et al., 2013), and we found a strong association between improvement in balance and improvement in quality of life for the subgroup of participants with clinical change in scores on the BBS (Paper 3). This finding is in line with Telenius et al.'s finding of a significant correlation between BBS and QUALID scores in a group of 168 participants (Telenius et al., 2013).

4.6.4. Perceived quality of life

By definition, perceived quality of life is subjective (Lawton, 1991). In our study, a proxy measure was used to assess the study population's quality of life. Although the instrument used (QUALID) is reliable and validated (Røen et al., 2015; Weiner et al., 2000), proxy assessments will always have less validity than self-assessments. For instance, persons with dementia have generally reported that they have a better quality of life than their close relatives or care workers do (Beerens et al., 2014; Logsdon et al., 2002). This means that perceived quality of life should have been much higher than was measured with QUALID (Paper 3), thus making it even more unlikely to achieve any improvement. However, this probably did not interfere with the results reported in Paper 2, since the significant effect of the intervention was found between groups. Interestingly, the effect found within persons with severe dementia was significant at both post-test and follow-up, despite the fact that the significant effect on depression was first found at follow-up.

Preventative interventions should be a future possibility (Livingston et al., 2008), and the animal-assisted activity's ability to create normalcy, facilitate social interactions, decrease depression, and lead to improved physical function is a good reason to implement animal-assisted activity as a preventative and health-promoting intervention among persons with dementia, with the objective to enhance their quality of life.

4.7. Effect at follow-up

In Papers 2 and 3, we report our follow-up measures. To date, such measures have only been reported in a few studies of animal-assisted interventions for persons with dementia (Table 2). A study conducted by Pedersen et al. of animal-assisted activity with farm animals found a significant decrease in depression during the intervention period, which was maintained at follow-up three months later (Pedersen et al., 2011). In our study, the improvement in balance found within the intervention group remained constant from post-test to follow-up (Paper 3). This is an important result because it indicates a potential long-term establishing effect. In Paper 2, we describe how, despite a positive development of depression throughout the intervention and a close to significant effect at post-test, the significant effect was first established at followup. This is in line with the findings by Berget et al., who report the effects of intervention with farm animals from pre-test to 6 months follow-up and from post-test to follow-up, but not during the intervention period (Berget et al., 2008). The reason for delay in effect in both Berget et al.'s study and our study could be that the intervention period was too short to influence change in the assessment. Alternatively, it could also be that the intervention started a process that continued beyond the end of intervention period. The facilitation of social interactions described in the previous sections may have been sustained and led to a general increase in social interactions between the participants, as well as between the participants and staff.

It can only be speculated whether the animal-assisted activity had a more wide-ranging effect than just affecting the participants and outcomes measured. The regular visits of the dog and its handler might also have influenced the whole unit. Animal-assisted interventions are said to have an impact on the unit milieu by softening the harsh environments often seen in institutions and by improving staff morale (Arkow, 2015). When a dog is brought into a unit, health care workers often seize the opportunity to interact with the dog. A reduction in serum and salivary cortisol was found within a group of health care workers who interacted with a dog for only five minutes (Barker et al., 2005). This stress-reductive effect is likely to affect the behaviour of health care workers and lead to improvements in the relationships between patients and staff following the implementation of animal-assisted interventions (Jorgenson, 1997).

4.8. Methodological issues

Doing interventional research is a challenge. During the course of a study, several threats to validity of results can occur (Shadish et al., 2002): from the planning phase, with the power estimation, to the interpretation of results and their generalizability. Randomized controlled trials are considered the most robust evaluative method (Puffer et al., 2005), but even though the study design handles many of the threats to the results' validity, important violations need to be discussed in order to prevent biased conclusions. In this section, the most important threats that might have violated the results during the course of the study are discussed and related to the following concepts: *statistical conclusion validity* (the role of effect size and use of appropriate statistics to make a valid conclusion regarding the relationship between treatment and outcome); *internal validity* (whether it could be claimed that a causal relationship exists between treatment and outcome); *construct validity* (which refers to whether the study measures what it is supposed to measure); and *external validity* (the possibility that the study's results are valid for other individuals and at other times) (Shadish et al., 2002).

4.8.1. Design and power calculation

As described in Section 2.6, the power analysis conducted to estimate the necessary number of participants indicated a total of 25 participants in each group at nursing homes, and 40 participants in each group at day-care centres. These totals were achieved during recruitment.

According normal procedure, a power analysis was performed on the primary outcome measures (BARS and BBS), and might therefore not be valid for the other assessments used as outcomes in the study. This might be the reason why differences were not found within the total sample of QUALID and CSDD scores. These issues may threaten statistical conclusion validity.

In the study, a cluster design was chosen due to practical concerns. In Norway, units for persons with dementia at both nursing homes and day-care centres are rather small (often limited to eight persons), and therefore consist of too few participants to divide samples into both an intervention group and a control group within the same unit. A possible cluster effect should be accounted for in the power analysis, but this was not done. With cluster randomization, it is

necessary to have more participants, since individuals could be more similar to each other within each facility.

4.8.2. Recruitment

During the recruitment process, all nursing homes and day-care centres for persons with dementia in the counties of Østfold, Akershus, and Vestfold received an invitation to participate in the study. Out of 90 nursing homes with adapted units for dementia, 15 were willing to participate and were included in the project. Out of 73 day-care centres for home-dwelling persons with dementia, 21 were willing to participate. In order to reach number estimated in the power calculation, a further 2 day-care centres from a fourth county (Oslo) were invited and recruited. A rather open e-mail invitation was forwarded, with no requests for a reply, thus making it easy to overlook and/or forget. Only some of the institutions agreed to participate, and since we do not have any records of the ones who did not respond to the invitation, it was impossible to draw any conclusions regarding differences between the study population and the population of institutions in general. It is likely that the participating institutions wanted to engage and wanted to keep track on what is going on in research, thus making them 'the better ones' and causing a recruitment bias that could have threatened the generalizability of the results. However, in general, nursing homes and day-care centres in Norway provide a high level of care. There are only small variations in the quality of care and the quality of the institutions (Health department of Oslo municipality, 2014), and the subjects' characteristics and prevalence of neuropsychiatric symptoms were in line with that reported in other studies (Beerens et al., 2014; Wergeland et al., 2014), thus indicating that the sample was representative and reducing a potential problem of selection bias.

Due to the nature of interventions studies, which adhered to the voluntary principles of the Declaration of Helsinki, the participants were invited to join the study and as such our sample was a convenience sample. It might be that subjects who enrolled in the intervention trial with animal-assisted activity were more likely to engage than those who refused to take part in the intervention. If so, this could have caused a recruitment bias, with the more positive participants agreeing to join the project.

The issue of recruitment bias also concerns the randomization procedure, which was done after recruitment of the nursing homes and day-care centres and before the recruitment of participants at each facility. This was done due to ethical concerns, as discussed in Section 2.4. The person recruiting participants had knowledge of the group in which the unit was allocated and used that information to recruit participants, by asking questions such as 'A dog and its handler will visit us two times a week for 12 weeks. Would you like to be part of a research project and meet with them?' In the control group, the provided information concerned being part of a research project. This might have led to a higher number of participants interested in dogs being included in the intervention group compared with the control group and could have caused a recruitment bias between groups, resulting in better results in the intervention group. However, no significant differences were found between groups at baseline regarding demographic data and interest in animals. Regarding outcome measures, a difference between the control group and intervention group was found in the BBS scores, and this was handled within the mixed model framework (see Section 2.6.6).

The convenient sample and the possible recruitment bias could have threatened external validation, and any generalization of the results should be done with caution. However, we still consider that the effect found also would hold in other nursing homes and day-care centres with persons with dementia interested in the type of activity that we used.

4.8.3. Implementation

Treatment as usual was chosen as control condition in the study. Using another activity as a control condition would have implied a wish to compare different interventions' effectiveness, which was not within the scope of this study. As the control group continued ordinary treatment, any effect found in the study would implicate the usefulness of implementing a new activity into ordinary clinical practice. However, the chance that possible effects might have been related to the handler accompanying the dog, rather than to the dog would not have been revealed. In order to discover the mere effect of the dog, a third arm would be needed, with only a human visiting and organizing a group activity. However, animal-assisted activity is defined as a human and animal team. In animal-assisted interventions, the dog serves as an adjunct to the handler,

and the dyad represents the stimuli, whereby the handler facilitates the intervention with the dog. Thus, to try to measure the mere effect of the dog and not the dyad, would not be relevant when the effect of animal-assisted interventions is studied.

Another methodological issue arising when using treatment as usual is the possibility of a novelty effect. It might be argued that many outcome will improve somewhat with almost any new intervention by creating interest and excitement and thereby causing an unusually high response among the intervention group (Shadish et al., 2002). This potential situation cannot be discounted in our study. However, not all assessments showed positive response, thus indicating that in general the novelty effect did not contribute to the effect and hence did not threaten external validity.

Although animal-assisted interventions should be individually tailored, standardization is important in order to make this complex intervention similar across intervention sites and thereby replicable. It is important to have a precise protocol and ensure proper training of the handlers. Proper training for the dogs and handlers was provided (see Section 2.3.3), and a standardized protocol was developed for conducting the intervention (see Appendix 1). In addition, individual supervision was given throughout the course of the intervention. Optional gatherings were held every week, and a mandatory meeting halfway through the intervention period was arranged. However, the need for individualization is equally important. The video recordings demonstrated that the intervention was performed according to the protocol, and the need for standardization seems to be achieved and therefore the study should be replicable.

4.8.4. Dropout

Attrition is a major problem in studies with elderly people with dementia, due to their age and disease. Attrition bias, such as participants dropping out due to lack of interest in the intervention, is a threat to internal validity since dropout that is not random may lead to bias in the results because the most positive persons will complete the intervention. The reasons for dropout were therefore reported. Mortality was the main reason for dropout in nursing homes (7 participants). In addition, two participants were lost because they moved to another unit, and

one participant was not able to fulfil the intervention period due to sickness. Only one home-dwelling participant withdrew from the intervention group due to lack of interest, and was not included in the analysis. Based on the dropout reports, attrition bias is not likely to be a threat to the internal validity of the study.

4.8.5. Proxy measurements

As described in Section 2.4 and 4.6, proxy measurements are a common way to assess outcomes in persons with dementia. In our study, only proxy outcome measures were used. Most proxy measurements require profound knowledge of the participant, and therefore makes blinding raters to an activity-based intervention in a unit almost impossible. For the balance outcome (BBS), blind assessment would have been possible by having an external rater without knowledge of the unit's group belonging. The study design, with multiple sites and measurement time points, made external rating difficult and expensive to manage.

Since the raters were not blind to whether the participants were part of the animal-assisted activity group or the control group, they may have had positive expectations that something positive was happening with the participant and thus biased the study results. This was not the case in the control group units and could have caused a more positive development in the outcome measures within the intervention groups. This expectation bias is a threat to the internal validity, and in our study it was not possible to estimate or control for it.

Another aspect of the expectation bias is that the intervention actually affects the environment. Health care workers observed the intervention and could see other sides to the participant than they usually did. The video recordings revealed a high number of smiles and positive interactions that otherwise might not have been shown during 'normal' days. This could have led to a positivistic spiral, in which the health care workers were affected by the intervention and therefore behaved in a way that affected the participants positivistically. If so, this could also explain the positive development after post-test. This bias could threat internal validity, since the intervention is not a sole provider of a possible effect on outcomes.

Assigning units to intervention and control may cause social competition if the control group wants to demonstrate that their participants can do as well as those in the intervention group. Being in a control group may increase the focus on what activities that are offered and lead to the health care workers providing enhanced care and/or activities. In our study, it was emphasized that the health care workers should not implement any new activities, but should continue treatments as usual. We kept records of regularly offered activities in the control groups (see Section 2.3.4), but it was not possible to eliminate any informal focus on care and activity. Hence, social competition might have occurred, resulting in a bias toward a change in the control group not based on treatment as usual and hence threatening internal validity.

4.8.6. Statistical issues

There is always an increased risk of a Type I error (i.e. detecting an effect that is not present) when doing multiple tests, which should be counteracted for by using, for example, Bonferroni correction. In our study, we mainly ran only a few tests for each outcome measure, and corrections for a Type I error were therefore not done. When analysing the videos, several tests were done, and Bonferroni correction hypothetically might have increased the limited statistical differences between nursing home residents and home-dwelling persons with dementia even more. This would only have strengthened our conclusion that the two populations responded similarly to the intervention. Nevertheless, the multiple tests were a threat to statistical conclusion validity.

The power calculation for change of means on BARS or BBS with 80% probability of detecting differences between groups was equivalent to a 20% possibility of not finding differences between the groups, despite differences in the study population (Type II error). In the study, the probability of making a Type II error might have been higher due to the cluster design, and could be the reason why we did not find an effect on BARS and only a very close to significant effect on CSDD at post-test.

4.8.7. Quantitative versus qualitative methods

One limitation of quantitative research is that it narrows the possible findings to what exactly is measured. The fact that it is still difficult to identify why some people benefit from interacting with dogs in certain situations should have forced us to dig deeper into qualitative research, despite the demand for quantitative research in the field of animal-assisted interventions. Qualitative research is used to gain insight into people's attitudes, behaviours, and motivations. It is therefore more often concerned with explaining the why and how of a phenomenon (rather than the what, when, and where), which is exactly what we were looking for in our research into animal-assisted interventions. However, the nature of dementia will at some point make even simple conversations difficult, and make it problematic for persons affected to express their health status in a meaningful and valid way. Nevertheless, it could be that, by using the ethogram and a quantitative approach in the observational study (Paper 4), we might have missed some important information that could have been picked up using qualitative methods. Therefore, an additional qualitative analysis of conversation in the videos could have strengthened the study.

5. Conclusions and implications

5.1.Summary of findings and conclusions

Home-dwelling persons with dementia with moderate dementia showed significantly less use of walking aids and had more social contact, higher levels of activity, and more exposure to daylight, and used fewer psychotropic medications. They also showed a significantly higher quality of life than persons with dementia in nursing home.

Both persons with dementia in nursing home and home-dwelling persons with dementia attending a day-care centre were able to engage in animal-assisted activity, and showed a high level of social behaviour during the animal-assisted activity sessions. However, participants with severe dementia slept significantly more than participants with mild or moderate dementia, and spent less time on the looking-at-the-dog-activity than the others.

A significant and clinical effect of animal-assisted activity on depression was found for persons with severe dementia living in nursing homes. Persons with severe dementia also had a significant higher quality of life after 12 weeks of intervention with the dog compared with the control group who received treatment as usual. This difference was significant at follow-up too.

A significant and clinical effect of the animal-assisted activity was found on balance in home-dwelling persons with dementia attending a day-care centre compared with the control group. The intervention resulted in clinically better balance and a reduced risk of falls among the participants in the intervention group. We also found a strong association between improvement in balance and a higher quality of life.

In conclusion, the findings suggest that animal-assisted group activity with a dog is a suitable health-promoting intervention both for persons with dementia in nursing homes and homedwelling persons with dementia attending a day-care centre. The intervention created engagement and social interactions between the participants, and the results demonstrated an increase in physical function among home-dwelling persons with dementia, and a decrease in

depression and increased quality of life among participants with severe dementia in nursing homes.

5.2. Theoretical implications

In this thesis, the Cohen-Mansfield et al.'s engagement theory and theories applied in the field of human-animal interactions has been used to explain the results. The engagement theory considers both attributes of the environment, the stimuli, and personal attributes, as well as interactions between the environment and stimuli, and interactions between stimuli and the participant. The theory then looks at how these attributes affect engagement, which in turn modifies affections and changes behaviour. In the study, in addition to the effect on behavioural and physical outcomes, we saw that the intervention and/or change in behaviour led to a higher quality of life, which is a more multidimensional concept (Figure 9). The biophilia hypothesis is likely to strongly influence the model, especially through the stimulus attributes, person attributes, and the interaction between the two.

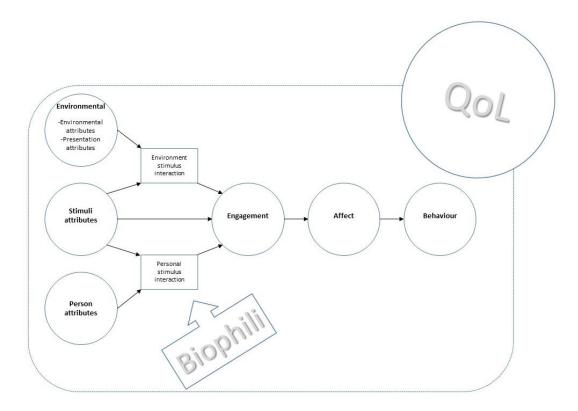


Figure 9. Illustration of quality of life as a multidimensional concept in relation to the Comprehensive Process Model of Engagement.

There is a lack of theoretical foundation in research in the field of animal-assisted interventions (Strøm et al., 2016), and therefore, by describing how the mechanisms behind the intervention work, this thesis hopefully will be of value when animal-assisted interventions are implemented. Knowledge of why interaction with animals might be beneficial for some persons (the biophilia hypothesis) and what this interaction might lead to – such as social support, enhanced social competence, and increased social behaviour and interaction (Beetz et al., 2012b; Bernabei et al., 2013; Perkins et al., 2008; Serpell, 2006; Virués-Ortega et al., 2012), positive change in physiological outcomes (Odendaal & Lehmann, 2000; Odendaal & Meintjes, 2003; Polheber & Matchock, 2014), and change in behavioural outcomes (Friedmann et al., 2015a; Majic et al., 2013; Richeson, 2003; Sellers, 2006) – is important when considering animal-assisted interventions. This thesis provides support to the existing literature, and by discussing the results in the light of the engagement theory, advantages of designing and implementing an intervention based on this theory have been highlighted and given a means whereby data in animal-assisted interventions can be interpreted.

The results indicate that the intervention created engagement among the participants. The theoretical framework of the biophilia hypothesis might be relevant in order to explain the interaction between stimulus and participant attributes and why animal-assisted interventions seem to promote engagement. Further, positive affect was found, both by measuring attention and attitude and by psychometric measurement to assess depression, demonstrating that engagement do impact affect. Further, the intervention was found to enhance the quality of life among persons with severe dementia, which supports Cohen-Mansfield et al.'s claim that affect is a major indicator of quality of life (Cohen-Mansfield et al., 2011). The results support the biophilia hypothesis as well as the assertion that humans presumably have a self-interest in engaging in activities with animals (Wilson, 1984) and that this leads to psychological well-being (Serpell, 2015). The engagement theory is a valuable tool that can be recommended to facilitate and evaluate the interventions in a more effective way (Cohen-Mansfield et al., 2009a), and thereby improve future research. In this thesis the potential of making a theoretical connection between animal-assisted activity as a health-promoting intervention and outcome measures that

are valued in dementia care, such as need for meaningful activities, stimulation, and engagement have been demonstrated.

5.3.Implications for further research

The study on which this thesis is based demonstrated that it is feasible to conduct research on an animal-assisted intervention in clinical practice.

Since we included a rather high number of participants, the collaboration with the county development centres for dementia care was of great value. They were responsible for recruiting nursing homes and day-care centres in their municipalities. A successful recruitment process is essential to achieve enough power to detect possible differences between groups.

The relatively low presentation of agitated behaviour among nursing home residents and very high quality of life among home-dwelling participants in the study suggests the need for more rigid inclusion criteria. To find a possible effect, a cut-off score on chosen outcomes must be determined. This argument is supported by the fact that many recent studies have failed to demonstrate effect of animal-assisted interventions between groups (Bono et al., 2015; Friedmann et al., 2015a; Nordgren & Engstrom, 2014b; Thodberg et al., 2015).

It is likely that a well-designed protocol for the dog-activity is important for the intervention to be effective. It is probable that the length of the session will influence the outcomes, and the results of this study proved that a time-span of 30 minutes is sufficient for detecting any possible effects of the intervention regarding depression and quality of life among persons with dementia. Due to their cognitive decline, persons with dementia might find it difficult to concentrate for long periods of time, and this aspect has also been considered in earlier research (Le Roux & Kemp, 2009). However, more research is needed to optimize the duration and frequency of the intervention, not only with regard to maximize effect but also with regard to financial recourses.

Our experience with the use of actigraphy in the dementia patient group was positive. Actigraphy is a non-invasive way to obtain objective, standardized information, and we recommend the use

of this device in future research when appropriate. A more unified use of assessments would be of value in order to build on the research in this field, as studies would become more comparable.

Our study did not specifically investigate the importance of the stimulus attributes. Persons with dementia have been found to be sedentary most of their time, but with the dog present, a high amount of engagement was observed. We used a number of dogs of different kind of size and breed. Differences between the clusters (and hence between different dogs) were examined, and no effects were found. It therefore seems that the different dogs did not influence the amount of engagement. This might be due to the consistent selection of dogs and handlers, as all of the dyads went through the same screening and training process. This method will be important in future research, both to ensure that the dyads are suitable to perform an animal-assisted intervention, and to ensure that no harm will be done to the participants.

5.4. Clinical implications

Some of the challenges associated with dementia described in this thesis are inevitable in dementia patients, whereas other factors may not. Therefore, the findings highlight the possibility of preventing and rehabilitating some of the challenges associated with dementia, both behavioural and functional factors. To our knowledge, not many studies have collected data for variables such as activity level, light exposure, sleep patterns, and quality of life from both persons with dementia in nursing homes and home-dwelling persons with dementia. Since we found significant differences in quality of life between the two study populations and demonstrated that the participants' quality of life was decreased as a result of living in a nursing home, these results provide valuable information for governments and communities when planning dementia care.

One strength of the study is that in addition to analysing the data for statistical significance, we also analysed the clinical significance. Since we found that both the decrease in depression among nursing home residents and the increase in physical function among home-dwelling participants was of clinical significance, it is recommended that animal-assisted activity with a dog should be applied clinical practice in the way described in this thesis. However, individual

tailoring must be emphasized. If applied in clinical practice, it might open up new possibilities for delaying or preventing admission to institutional care, and thereby have positive consequences for public health. The social aspects of interacting with dogs are also stated in a White Paper on public health in Norway (Meld. St. 19 (2014–2015) (Norwegian Ministry of Health and Care Services, 2015b), and the positive potential of interacting with animals at care farms is emphasized in the Care Plan 2020 (Norwegian Ministry of Health and Care Services, 2015a).

An animal-assisted intervention is very complex and contains many aspects that might be impossible to measure, but by evaluating each of the constructs in the engagement model, the risk of implementing an intervention that is not suitable for the target person can be limited.

The main finding of this thesis is that a 30-minute session with a dog is sufficient to engage persons with dementia, and that by doing this two times per week for 12 weeks the intervention is likely to have an effect on depression, balance, and quality of life. This thesis contributes increased knowledge of animal-assisted interventions for persons with dementia, and shows the value of incorporating animal-assisted intervention into traditional treatment for nursing home residents and participants of day-care centres. Animal-assisted intervention with dogs should be considered for use as a health promoting activity in the future.

6. References

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Appendix

Protocol for animal-assisted activity

The intervention should be individually tailored, taking the participant's needs and interest into account. Each participant's session should be documented through an individual, standardized log.

The participants are followed to the room dedicated to the carrying out of the intervention and is seated in a semicircle. In order to standardize the interventions to the extent possible, each session should follow this protocol.

The dog handler arrives with the dog in a leash, standing in front of the group of participants. The dog handler present him/her self and the dog. The dog handler approaches the first participant, and asks if he/her will greet the dog. If the participant choose to do so, the dog handler asks the dog to make contact with the participant.

The dog handler must assure that the dog approaches the participant gently. This first contact is important in order to build a good relationship, even if the participant has met the dog before. The physical contact can help to initiate physiological responses as lowered heart rate and increased excretion of positive hormones so that the patient feel calm and content. This first contact will also allow the participant to care for another living being, and experience that the dog enjoys the care it gets.

The dog handler is responsible for distributing the time allotted (approximately 30 minutes) so that all participants get an equal chance to interact with the dog. The conversation with each participant can include repetition of the dog's name, questions about the participant's previous experience / ownership of dog / animal etc.

The participant may additionally to pet the dog be allowed to feed it treats, brush the dog's fur or throw a toy for the dog to fetch. To dare to give the dog a treat can make the patient feel mastery, in addition to that they also care and can get the feeling of "giving." Fine motor skills may be enhanced by picking up the treat from a small box, as well as self-efficacy, care, cognition, and balance. Self-efficacy, care, cognition, balance, coordination, hygiene are potentially outcomes of brushing the dog's fur. By throwing a toy for the dog to fetch, the participants may practice fine motor skills, coordination, cognition, self-efficacy, movement, and balance.

The participant's interest of the dog should be emphasized, and signs of unwillingness to be respected. Participation in the program is voluntary, and any signs that the patient wants to cancel the current activity or session of the whole shall be complied with.

There should be plenty of time to finish the session, as this is part of the activity. An important part of the closure is to evaluate the session together with the participants, for the clinician to get a good impression of their experience. This is done while the participants and the dog interact. Dog fur is removed from participant's clothes and the participant washes and

Appendix 1

disinfects hands. This may contribute to increased awareness of their own hygiene, as well as being part of the physical activity.

The participants are followed back to the common areas, and the dog handler wash the floor where the dog stayed. It is important to also remember hand hygiene in the practitioner with thorough hand washing and disinfection. The dog handler takes the dog outside, letting it get to be "free", so the dog can run freely and reset from the work, and have the opportunity to defecate. The dog must be offered fresh water. The dog handler documents today's session.

The design is prepared by the Norwegian Centre of Anthrozoology

Log for animal-assisted activity to be filled in by dog handler

This form should be filled in by the dog handler as a log in the wake of every session with animal-assisted activity. This form is for private use and will contain what has been happening in each session with the participant.

Date:			
Session nr.:			
1. What was done (mul	tiple choice pos	sible)	
Conversation		Feed the dog a treat	
Throw a toy for the dog		Brush the dog	
Pet the dog		Other	
Comments:			
2. Participant assessme	<u>ents</u>		
2.1. Participation			
Participant was very	<i>ı</i> active		
Participant was pret	ty active		
Participant was quit	e active		
Participant was not	that active		
Participant was not	active		

Appendix 2

	Emotional status		
	Participant expressed a lot of smiles and laughter		
	Participant expressed a pretty lot of smiles and laughter		
	Participant expressed quite a lot of smiles and laughter		
	Participant did not express any feelings		
	Participant seemed sad		
	Participant seemed angry		
	Participant cried		
2.3.	Concentration		
	Participant was calm and concentrated		
	Participant was calm and somewhat concentrated		
	Participant was calm but not concentrated		
	Participant was somewhat agitated but yet somewhat c	oncentrated	
	Participant was very agitated and not very concentrated		
2.4.	Communication		
	Participant communicated a lot		
	Participant communicated pretty lot		
	Participant communicated quite a lot		
	Participant communicated not that much		
	Participant did not communicate		
25	Interaction with the dog		
2.5.	Participant interacted a lot		
2.5.	•		
2.3.	Participant interacted pretty lot		
2.3.	Participant interacted pretty lot Participant interacted quite a lot		
2.3.			

Appendix 2

3. The dog's behaviour

3.1. Expressing happiness	
The dog expresses much happiness \Box	
The dog expresses some happiness \Box	
The dog did not expresses happiness \Box	
3.2. Focused on handler	
The dog was very focused on handler	
The dog was some focused on handler	
The dog was not focused on handler $\hfill\Box$	
3.3. Displacement signals	
The dogs showed much displacement signals	
The dogs showed some displacement signals \qed	
The dogs showed no displacement signals	
2.4. Dannanai yanaa ta tha mantisinant/a sanananda	
3.4. Responsiveness to the participant's commands	
The dog executed commands from the participant in a positive way	
The dog executed commands from the participant in a satisfactory way	
The dog executed commands from the participant in a unsatisfactory way	
The dog did not execute commands from the participant	
Not relevant	
3.5. Responsiveness to the handler's commands	
The dog executed commands from the handler in a positive way	П
The dog executed commands from the handler in a satisfactory way	
The dog executed commands from the handler in an unsatisfactory way	
The dog did not execute commands from the handler	
Comments:	

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Paper I

RESEARCH ARTICLE

Open Access



Differences in quality of life in homedwelling persons and nursing home residents with dementia – a cross-sectional study

Christine Olsen^{1*}, Ingeborg Pedersen¹, Astrid Bergland², Marie-José Enders-Slegers³, Nina Jøranson¹, Giovanna Calogiuri⁴ and Camilla Ihlebæk^{1,5}

Abstract

Background: Dementia often eventually leads to dependency on others and finally to residential care. However, in Norway about half of the dementia population lives at home, due to individual and political wishes. There is scarce and inconclusive knowledge of how living in a nursing home differs from living at home for persons with dementia (PWDs) with regard to their quality of life (QoL). The first aim of the study was therefore to compare QoL, cognitive and physical functions, social contacts, sleep patterns, physical activity levels, exposure to light, and medication of PWDs in nursing homes and home-dwelling PWDs, and whether living in nursing homes was associated with a lower QoL than living at home for PWDs. A second aim was to examine if possible differences between residencies in QoL were consistent over time.

Methods: The cross-sectional study was based on baseline data from two RCT studies of PWDs. A total of 15 nursing homes with adapted units for PWDs and 23 adapted day care centres for home-dwelling PWDs recruited 78 and 115 participants respectively. Trained nurses scored sociodemographic data, level of dementia (on the Clinical Dementia Rating scale), amount of medication, and QoL (QUALID). Sleep patterns, physical activity levels, and light exposure were measured by actigraphy. A multiple regression analysis was used to test the association between residency and QoL. The association between residency and change in QoL over time was investigated by linear regression analysis of a subsample with follow-up data.

Results: Home-dwelling PWDs showed significantly higher QoL than PWDs in nursing homes. This difference was maintained even after stratifying on the severity of dementia. Home-dwelling PWDs with moderate dementia showed significantly less use of walking aids, more social contact, higher levels of activity and exposure to daylight, and less use of psychotropic medications. The regression model explained 28 % of the variance in QoL in persons with moderate dementia. However, only residency contributed significantly in the model. Residency also significantly predicted negative change over time in QoL.

Conclusion: The study indicated that living at home as long as possible is not only desirable for economic or health political reasons but also is associated with higher QoL for persons with moderate dementia. More studies are needed to investigate how QoL could be increased for PWDs in nursing homes.

Keywords: Dementia, Geriatrics, Nursing home, Home-dwelling, ActiGraph, Institutionalization, Sleep, Light exposure, Activity level, Quality of life

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Background

Dementia is among the leading causes of disability and death in the elderly [1, 2], and there are currently 47.5 million people with dementia worldwide [3]. There is no cure for dementia [4], and development of dementia eventually leads to a loss of cognitive and physical functions [5, 6]. This in turn will often lead to total dependency on others and finally to residential care [7]. In Norway, 80 % of nursing home residents suffer from dementia [8].

The incidence of institutionalization varies between European countries [9], and in Norway a higher percentage of the elderly live in nursing homes compared to in other countries [10]. However, it has been estimated that half of the dementia population in Norway still lives at home [11]. Several studies have evaluated risk factors for the institutionalization of the elderly and persons with dementia (PWDs), and older age, cognitive impairment, poor social support, loss of physical function, and use of medication are all factors associated with increased risks of long-term admission to care facilities [9, 12–14].

Residential care can ensure necessary care and safety when PWDs are dependent on help. However, living in a nursing home will affect the lives of PWDs. Many studies have investigated the effect of nursing home environments on different health and behavioural factors [15–18] and the difference between traditional nursing home and small-scale group living [19, 20]. However, few studies have investigated the differences in how living in a nursing home differs from living at home with regard to PWDs' quality of life (QoL), and they differ in their conclusions [21, 22]. Furthermore, few studies have investigated the QoL of home-dwelling PWDs.

There is no standard definition of QoL among PWDs, and the conceptualizations of QoL vary too [23, 24]. However, the definition by Lawton [25], who states that QoL is a multidimensional concept, which in older adults includes behavioural competence, the objective environment, psychological well-being, and perceived QoL, is frequently used [26].

QoL among elderly persons with dementia is often diminished [27], and poor QoL has been found associated with several of the same risk factors as found for institutionalization, such as low cognitive function, impaired mobility, lack of social activities, major depression, and low performance in activities of daily life [28–31].

Another factor known to affect QoL is sleep disorders [32]. Sleep disruption is common among dementia patients [33], and it has been reported that two-thirds of nursing home residents have sleep disturbance problems [34]. Light exposure, which is an important regulator of circadian rhythm, has been reported to affect activity levels and sleep in nursing home residents [16]. Institutionalized older adults have lower levels of physical activity than elderly persons living in community dwellings

[35, 36], and it has been reported that nursing home residents spend up to 94 % of their time sitting or lying down during the daytime [37]. A study of 15 nursing homes revealed that most of the residents spent at least 17 h per day in bed [38]. Another factor that might affect QoL is medication, and some pharmacological treatments have been found associated with lower QoL [39]. In addition to these risk factors, both institutionalization and increased dependency might be negatively related to QoL [21, 40], although for some PWDs admission to long-term facilities might increase their QoL [21].

An important goal in dementia care is to provide for and ensure a good quality of life [40], and it is a common political goal among European governments to enable PWDs to live at home as long as possible [10]. It is therefore important to gain more knowledge of QoL and known associated risk factors in PWDs living at home and living in nursing homes. Furthermore, more studies are needed to investigate the association between residential care and QoL when other risk factors are taken into consideration. The first aim of this article was therefore to compare QoL, cognitive and physical function, social contact, sleep patterns, physical activity, light exposure, and medication in PWDs in nursing homes and home-dwelling PWDs, and examine whether residency was associated with QoL. A second aim was to investigate the association between residency and change in QoL over time.

Method

Our study was based on data from two RCT studies of PWDs in nursing homes and home-dwelling PWDs in Norway (RCTs registered at ClinicalTrial.gov; NCT02008630 and NCT01998490).

Recruitment and subjects

In Norway, the municipalities are legally responsible for providing domiciliary and residential care, and the administration of nursing homes and day care centres is organized within the municipalities' public health services. Most patients receive domiciliary care for as long as possible prior to admittance to a nursing home. The municipalities' health care and other care services in cooperation with patients' general practitioners assess patients' need for residential care. Most nursing homes have both ordinary units and special care units, and often include day care facilities. Special care units are adapted units that usually only house 7–8 PWDs.

For our study, the county development centres for dementia care in three counties in the south-eastern part of Norway were responsible in recruiting nursing homes and day care centres in their municipalities. All nursing homes and day care centres in the three counties were

invited to participate in the study, and 15 nursing homes with adapted units for PWDs and 23 adapted day care centres for home-dwelling PWDs were willing to participate.

Each participating institution was asked to recruit between 5 and 8 participants. The inclusion criteria were: aged 65 years or older and either a diagnosis of dementia or a cognitive deficit measured as a score less than 25 on the Mini-Mental State Examination test [41–43].

A total of 209 participants were recruited (88 PWDs living in a nursing home (PWD NH), and 121 homedwelling PWDs). Due to death or because of withdrawal from the study, 16 participants were excluded from the analyses, which meant that data relating to 193 participants (78 PWD NH and 115 home-dwelling PWDs) were included in the analyses. Home-dwelling participants all took part in a day care centre programme at least once per week. The baseline data collection was carried out in winter-spring 2013 (N = 43 (PWD NH = 17, home-dwelling PWDs = 26)), autumn-winter 2013 $(N = 78 \text{ (PWD NH} = 31, home-dwelling PWDs} = 47)),$ and spring-summer 2014 (N = 72 (PWD NH = 30, home-dwelling PWDs = 42)), mainly due to practical limitations and to avoid seasonal biases. In addition, a subsample consisting of 11 PWDs in nursing homes and 8 home-dwelling PWDs that were randomized to control groups (treatment as usual) was assessed for QoL 6 months after baseline.

Assessments and procedures for data collection

The participating patients' primary nurses scored all psychometric assessments and collected information on the participants' age, gender, educational level, use of walking aids, and social encounters. Before the project, they all participated in mandatory education on the use of the instruments.

Quality of life (QoL) was measured using the Norwegian version of the Quality of Life in Late-stage Dementia (QUALID) scale [44, 45]. The proxy rating scale consists of 11 items that are rated on a five-point scale. 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 = .815 (nursing home = .764, home-dwelling = .719). A lower score indicates a higher quality of life.

The Clinical Dementia Rating (CDR) scale, is a 5-point scale used to assess six domains of cognitive and functional performance relating to dementia [46–48]. CDR staging is a valid substitute for a dementia assessment among nursing home residents when rating dementia and determine the severity of dementia [47, 48]. A CDR global score of 0 implies no cognitive impairment, 0.5 = very mild dementia, 1 = mild dementia, 2 =

moderate dementia, and 3 = severe dementia. Before the analyses, the CDR scores were recoded into three groups: mild (0, 0.5 and 1), moderate (2), and severe dementia (3).

Actigraphy (ActiSleep+, ActiGraph, Pensacola, US) was used to measure sleep patterns, physical activity levels, and light exposure. ActiSleep + is a validated 3axis accelerometer, which has approximately the shape and size of a wrist watch and delivers advanced data about the wearer's movements over time and their exposure to light. The use of actigraphy for monitoring sleep is validated [49], also for dementia patients [50]. The ActiSleep + was worn on the left wrist continuously for 7 days (epoch-length 1 min). Participants were free to remove the ActiSleep + device but were encourage not to do so. Relatives and caregivers were instructed to encourage the participants to put it back on if it had been removed. Before the measurements started, ActiSleep + was introduced orally, visually, and in written form to the participants by their primary nurse, as well as by their relatives and caregivers.

The actigraphy data were processed using the Scoring and Sleep functions of ActiLife, software Version 6.11.2 (ActiGraph, Pensacola, USA), after applying the Wear Time Validation tool. Days with more than 8 h recorded were included in the further analyses in order to ensure that the activity pattern for those days reflected the participant's typical behaviour pattern. All subjects included in the analysis had at least three valid days and nights.

Total sleep time (TST) is the amount of actual sleep during the night-time, measured in hours. The term 'wake after sleep onset' (WASO) defines the amount of time spent awake after sleep has been initiated and before final awakening; it sums all wake epochs in minutes. The default algorithm of ActiLife may have problems with analysing the sleep-wake schedule. For that reason, we manually inspected all awakenings and created a new variable called 'Number of awakenings > 5 min'. By using a minimum awake time of 5 min, we ensured that the number of awakenings were accurate. 'Sleep efficiency' was defined as the number of sleep minutes divided by the total number of minutes when the participant was in bed, and was expressed as a percentage. Because of the challenge of identifying a precise bedtime and getup-up time among the home-dwelling population, a default time-in-bed period was arbitrarily set as 23:00 to 06:00 h. Therefore, in our study, sleep efficiency referred to the minutes of sleep within the default time period, and not the patients' actual time spent in bed, and below this is referred to as the 'Sleep during night period'.

Physical activity levels were calculated using the Freedson Adult Cut Points [51] in ActiLife software, and applying a time filter between 08:00 and 20:00 for each monitored day. ActiLife calculates three activity levels

based on the frequency and intensity of the movement. These constitute the measure 'counts', which are specified as 'counts per minute' (cpm). 'Sedentary activity level' is time in percentage with no physical activity (standardized cut point value: 0-99 cpm). 'Light activity level' is defined as light intensity activity (standardized cut point value: 100-1951 cpm). Activities in this category could, for example, be standing or household activities. 'Moderate activity' (standardized cut point value: 1952-5724 cpm) equates to physical activity, such as walking at 4 km/h. The Freedson Adult Cut Points can also include measures of 'Vigorous' activity and 'Very vigorous' activity, but these were not used in the study because none of the participants scored any activity at this level. The absolute time (minutes) spent on the different activity levels was subsequently expressed as a percentage of the overall monitoring time.

Light exposure was recorded every second and measured in counts, giving 'lux average counts', which indicated the participants' level of exposure to light.

Records of patients' use of **psychotropic medication** (antipsychotics, antidepressants, anxiolytics, and hypnotics/sedatives) were collected (from no/yes responses) and a score for number of different types of psychotropic medications (0–4) was constructed.

Ethics

All participants were informed that they could withdraw from the study at any stage. The ActiGraph device worn by the participants did not register what type of activity they engaged in or their localization, and therefore the usage was not considered invasive.

Analyses

All statistical analyses were performed using IBM SPSS Statistics Version 23.0 for Windows (Armonk, NY: IBM Corp). Cronbach's alpha was calculated for all sum scores. Group differences between PWD NH and homedwelling PWDs were tested with one-way ANOVA for continuous variables' and with chi-square for categorical data. Stratified analyses of the three categories of cognitive level derived from the CDR test were conducted for variables showing significant differences between groups.

A multiple regression analysis was used to test the association between institutionalization and QoL. This model was only tested for PWDs with moderate dementia, due to the low number of persons with mild dementia in nursing homes and low number of persons with severe dementia living at home. Age, gender and variables that were significantly different between the two groups of PWDs in the bivariate analysis, namely social encounters, use of walking aids, physical activity level (moderate), light exposure, and medication, were entered into the analysis in order to control for these factors.

Before the analysis, dichotomous variables for walking aids (no/yes) and social contacts (< once per week/≥ once per week) were constructed. Collinearity statistics showed acceptable values (max VIF < 2.3). Heteroscedasticity was not observed.

The association between residency and change in QoL was investigated by linear regression analysis of the subsample with follow-up data (n = 19). Change in QUALID was used as the dependent variable, and residency was entered as predictor variable. In order to control for different baseline levels in QoL, the QUALID baseline score was included in the analysis.

Results

Group characteristics

There were no significant age, gender, or educational differences between PWDs in nursing homes and homedwelling PWDs (Table 1). Approximately half of the home-dwelling PWDs lived alone (52.2 %), but they had significantly more social contact with their family members and friends than nursing home PWDs. Walking aids were used by a significantly higher number of PWDs living in nursing homes than home-dwelling PWDs (Table 1). Significant differences were observed in the severity of dementia: 9 % PWDs living in nursing homes had mild dementia, 43.6 % had moderate dementia, and 47.4 % had severe dementia. By contrast, the respective percentages for home-dwelling PWDs were 43.5 %, 47.0 %, and 4.3 % (Table 1).

QoL, sleep patterns, physical activity, light exposure, and medication

In the whole sample, PWDs living in nursing homes showed a significantly lower QoL than home-dwelling PWDs (Table 1). They also scored significantly lower on all sleep parameters, except for 'Wake > 5 min'. PWDs living in nursing homes experienced almost four times less light exposure compared with home-dwelling PWDs. The actigraphy results showed that PWDs living in nursing homes were less active than and showed significantly more sedentary and less active behaviour than home-dwelling PWDs (Table 1). There were also a significant difference in use of psychotropic medication between PWDs living in nursing homes and home-dwelling PWDs, both in the prevalence and number of medications used (Table 1).

Because of the substantial differences in the severity of dementia between the two populations, a stratified analysis on CDR was conducted to look at differences between the two groups with regard to their cognitive levels (Table 2). PWDs living in nursing homes showed a significantly lower QoL for all three categories of severity of dementia and for the category moderate dementia, they had significantly more use of walking aids, less

Table 1 Demographic data, quality of life (QUALID), and ActiGraph data relating to persons with dementia in nursing homes (PWD NH) and persons with dementia living at home (home-dwelling PWDs)

	PWD NH	Home-dwelling PWDs	<i>p</i> -value
Demographic data			
Women (%)	52 (66.7) (<i>n</i> = 78)	74 (64.3) (n = 115, 1 missing)	0.877
Age Mean (SD)	84.6 (6.50) (n = 78)	82.6 (6.84) (n = 103, 12 missing)	0.803
Education (%)	n = 78	n = 115	0.226
Below upper secondary school	40 (51.3)	43 (37.4)	
Upper secondary school	10 (12.8)	21 (18.3)	
Above upper secondary school	12 (15.4)	28 (24.3)	
Missing	16 (20.5)	23 (20.0)	
Quality of life	(n = 77)	(n = 109)	
QUALID (SD)	24.06 (7.13)	15.99 (4.33)	< 0.001
Clinical Dementia Rating (CDR) scale (%)	n = 78	n = 115	< 0.001
Mild	7 (9.0)	50 (43.5)	
Moderate	34 (43.6)	54 (47.0)	
Severe	37 (47.4)	6 (5.2)	
Missing	0 (0)	5 (4.3)	
Walking aids (%)	n = 78	n = 115	< 0.001
None	24 (30.8)	69 (60)	
Walking sticks/Cane/Crutches	7 (9)	19 (16.5)	
Rollator/High walker	37 (47.4)	21 (18.3)	
Wheelchair	9 (11.5)	0 (0)	
Needs support walking	1 (1.3)	0 (0)	
Missing	0 (0)	6 (5.2)	
Social contact with family/friends (%)	n = 78	n = 115	< 0.001
Every day	5 (6.4)	39 (33.9)	
Several times per week	20 (25.6)	48 (41.7)	
Once per week	31 (39.7)	14 (12.2)	
Once every other week	8 (10.3)	2 (1.7)	
Rare	11 (14.1)	5 (4.3)	
Never	0 (0)	0 (0)	
Missing	3 (3.8)	7 (6.1)	
Sleep patterns	(n = 71)	(n = 105)	
Sleep during night-time, Mean (SD)	75.89 (15.46)	80.01 (11.88)	0.048
Total sleep time in hours, Mean (SD)	5.31 (1.08)	5.60 (0.08)	0.046
WASO in minutes, Mean (SD)	93.24 (59.47)	73.36 (42.48)	0.011
Wake > 5 min	4.67 (2.80)	4.18 (2.12)	0.190
Activity pattern	(n = 71)	(n = 107)	
Sedentary % (SD)	51.87 (19.78)	43.51 (14.62)	0.001
Light % (SD)	45.78 (17.70)	50.20 (11.69)	0.045
Moderate % (SD)	2.35 (4.31)	6.29 (5.98)	< 0.001

Table 1 Demographic data, quality of life (QUALID), and ActiGraph data relating to persons with dementia in nursing homes (PWD NH) and persons with dementia living at home (home-dwelling PWDs) (Continued)

Light exposure (lux av. counts)	(n = 71)	(n = 107)	
	43.63 (51.40)	165.88 (254.36)	< 0.001
Psychotropic medication	(n = 68)	(n = 88)	
Use of (%)	69.1	35.2	< 0.001
Number (SD)	1.12 (0.97)	0.43 (0.64)	<0.001

Notes: p < 0.05 (level of significance)

social contact, lower levels of moderate activity, lower levels of light exposure, and higher use of psychotropic medication (Table 2). The same pattern was found for the categories mild and severe dementia, although few differences were found to be significant.

Regression analysis

The analysis showed that for PWDs with moderate dementia residency was significantly associated with lower QoL after controlling for age, gender, social encounters, use of walking aids, moderate physical activity level, light exposure, and medication. The model explained 28 % of the variance in QoL (Table 3).

When looking at change in QoL over time, residency explained 25 % of the change in QoL among participants with moderate dementia (F(2,16) = 3.993, p = 0.039, R^2 Adjusted = .25). Nursing home PWDs' mean change in QoL was 1.73, while home-dwelling PWDs' mean change was -0.38. The analysis shows that both baseline score on QUALID and institutionalization did significantly predict change in QUALID during 6 months (Beta = -0.63, t(19) = -2.66, p < .05) and (Beta = -0.51, t(19) = -2.16, p < .05) (data not shown).

Discussion

PWDs living in nursing homes showed significantly lower QoL for all three categories of severity of dementia compared to home-dwelling PWDs. In the group with moderate dementia, PWDs living in nursing homes had significantly more use of walking aids, less social contact, lower level of moderate activity, lower levels of light exposure, and a higher use of psychotropic medication. Living in nursing homes was significantly associated with low QoL, even after controlling for several possible confounders, and associations seem to be consistent over time.

Severity of dementia is known to be highly associated with QoL [27, 30]. We found significantly higher prevalence of severe dementia in nursing home residents than in persons living at home, and similar findings have been reported previously [11, 52]. Decrease in cognitive functioning such as loss of abilities in memory, judgment, and abstract thinking will lead to need for assistance in

many activities of daily life [53], and residential care might be necessary in order to provide the care needed. However, in our study, PWDs living in nursing homes showed lower QoL than PWDs living at home, even after stratifying for severity of dementia. This finding is in line with that of a small study that compared QoL among PWDs with mild dementia living in nursing home or at home and found a significant difference in QoL and social contact between the two groups [54].

Several other factors showed significant differences between home-dwelling PWDs and PWDs living in nursing homes after stratifying for severity of dementia, and this finding might be associated with the differences in QoL. For PWDs with moderate dementia, we found that those who were home-dwelling had significantly less use of walking aids and higher level of moderate activity than those living in nursing homes. These differences might indicate that even though the degree of dementia was the same, the PWDs living in nursing homes had poorer physical function. Poor physical function and dependency has been found associated with low QoL [55], but is also a predictor for nursing home admission [9, 13, 14, 56]. In our study, PWDs living in nursing homes had a lower frequency of social contact, and lack of social support is also known to be a predictor for institutionalization [7]. The higher use of psychotropic medication found among PWDs living in nursing homes compared with home-dwelling PWDs is in line with previous studies [57, 58]. Halvorsen et al. suggest that such differences in medication could be explained by more prevalent behavioural and psychiatric symptoms (BPSD) in PWD NH [58]. We did not have any measurements on BPSD for the home-dwelling population and therefore could not compare the two groups on these factors. This constituted a weakness in our study, as BPSD is known to affect patients' quality of life (QoL) [40, 52] and might also be associated with institutionalization [13, 56].

One European study investigating how QoL varied according to living arrangements concluded that there were no clinically significant differences in QoL between PWDs living in nursing homes and home-dwelling PWDs [21]. However, in our study, living in a nursing

	Mild dementia			Moderate dementia		Severe dementia			
	NH	Home-dwelling	<i>p</i> -value*	NH**	Home-dwelling	<i>p</i> -value	NH	Home-dwelling	<i>p</i> -value
Quality of life	18.86 (6.41)	14.89 (3.74)	0.022	21.94 (6.22)	16.66 (4.37)	<0.001	26.95 (6.94)	18.67 (5.82)	0.009
Walking aids (%)	57.1	47.9	.265	70.6	25.5	< 0.001	70.3	33.3	0.004
Social contact weekly (%)	42.9	97.9	< 0.001	81.8	90.4	0.004	74.3	80.0	0.058
Sleep patterns									
Sleep during night-time (%)	76.68 (16.54)	79.43 (11.52)	0.579	76.77 (15.51)	79.22 (12.84)	0.453	75.95 (14.68)	86.86 (3.76)	0.111
Total sleep time in minutes	322.04 (69.45)	333.61 (48.37)	0.579	322.41 (65.16)	333.07 (53.96)	0.438	318.99 (61.64)	364.81 (15.77)	0.111
WASO*** (minutes)	92.84 (68.17)	75.71 (37.94)	0.323	89.75 (59.95)	75.02 (48.94)	0.242	93.84 (57.87)	53.47 (16.90)	0.135
Wake > 5 min	4.61 (2.78)	4.31 (1.74)	0.694	4.88 (2.61)	4.16 (2.50)	0.229	4.49 (3.04)	3.20 (1.83)	0.363
Activity pattern									
Sedentary (%)	41.44 (21.17)	43.01 (14.27)	0.800	47.63 (16.67)	43.71 (15.14)	0.281	58.06 (20.76)	48.2 (15.52)	0.317
Light (%)	52.55 (17.95)	50.26 (10.8)	0.634	49.74 (14.21)	50.12 (12.17)	0.900	40.62 (19.58)	49.15 (14.35)	0.357
Moderate (%)	6.01 (7.8)	6.73 (6.8)	0.797	2.63 (4.72)	6.17 (5.36)	0.003	1.32 (2.08)	2.65 (2.05)	0.191
Light exposure (lux av. counts)	93.49 (102.91)	142.55 (211.55)	0.551	39.12 (44.39)	171.84 (275.17)	0.010	37.28 (36.63)	300.15 (328.12)	< 0.001
Psychotropic medication	1.17 (0.98)	0.54 (0.61)	0.042	1.17 (1.09)	0.32 (0.60)	< 0.001	1.06 (0.88)	0.40 (0.89)	0.126

Notes: *p < 0.05 (level of significance); ** nursing home, *** wake after sleep onset

Page 8 of 11

Table 3 Association between age, gender, use of walking aids, social contacts, activity level, light exposure, medication, and residency with QUALID in persons with moderate dementia (N = 61)

Variables	β	р
Age	001	.991
Gender	.028	.806
Use of walking aids ^a	014	.922
Social contact ^b	.139	.266
Moderate activity ^c	070	.604
Light exposure ^c	145	.243
Psychotropic medication ^c	.090	.487
Residency ^d	394	.023

Notes:

- ^a Use of walking aids: 0 = No, 1 = Yes
- ^b Social contact: 0 = Less than once a week, 1 = Weekly
- ^c High score indicates to high level of moderate activity, high level of exposure to lux, and high use of psychotropic medication
- ^d Nursing home = 0, Home-dwelling = 1

Standardized beta was used

p < 0.05 (level of significance)

Adjusted R² .276 R² change .373

home was associated with a lower QoL than living at home for persons with moderate dementia, even after controlling for confounding or mediating factors. Being institutionalized might lead to loss of control and lack of autonomy (e.g. when and what to eat, when to sleep, and when to go for a walk), and Heggestad et al. found that many nursing home residents did not feel at home in their unit and missed their former homes [59]. Furthermore, nursing home residents do not often participate in activities and tend to be unoccupied for much of the day [60]. Several studies of institutionalized PWDs have shown that the residents' needs for meaningful activities are often unmet [15, 17, 61]. In the Netherlands it has been shown that small-scale settings provide better environments for social relationships than traditional nursing home settings, and one study revealed that residents had significantly higher scores on the QoL subscale 'positive affect' [62]. However, other studies have found mixed results on the effects of small-scale settings [63], and that residents perceived a more traditional nursing home environment as satisfactory and that being deprived of privacy was not a problem [64].

The longitudinal QoL data from the sub-group with moderate dementia enabled us to take unobserved heterogeneity into account and thereby detect developments or changes in the characteristics of the population. The fact that nursing home residents had a decrease in mean change of QoL, whereas homedwelling PWDs were stable over a 6-month period supports the findings that living in a nursing home affect QoL negatively.

Strengths and limitations

This study had several limitations. The institutions and the participants were all recruited to participate in two RCTs and might not have been representative of nursing home and home-dwelling populations in general. However, the recruitment procedure and inclusion criteria were the same for both patient groups, which made the groups comparable. Furthermore, the participants' characteristics and level of QoL were in line with findings in other Norwegian studies of persons with dementia [28, 57, 65], indicating that the sample was representative. All home-dwelling PWDs had activities at a day care centre at least once per week, which means that the sample was not representative of the home-dwelling PWD population as a whole. It should be noted that activities at Norwegian day care centres are usually offered to persons who exhibit higher levels or more severe symptoms of dementia, to ease the burden on the family carers.

Validated psychometric questionnaires were used to measure cognitive impairment (CDR) and QoL (QUA-LID), but proxy assessments always will have less validity than self-assessments. Assessing QoL in PWDs is often done with proxy assessments due to the assumption that the respondents will not able to complete a self-report. However, research has shown that especially those with mild or moderate dementia are capable of completing such reports, and interestingly PWDs in general report that they have a better QoL than their close relatives or care workers do [21, 26]. Therefore, we cannot know whether the scoring in our study truly reflected the participants' experience, but the QUALID assessment rates concrete and observable behaviour and is a validated tool for this patient group [45]. In our study the patients' primary nurses scored the psychometric measures, and primary nurses at nursing homes could be expected to have a broad understanding of their patients' cognitive level, behaviour, and mood. However, the nurses at the day care centre only saw their patients once or twice each week and might not have had the same insights into their patients' lives. This could have led to bias if the scoring relating to QoL in home-dwelling PWDs was systematically higher than for nursing home PWDs. However, a previous study found no clinically relevant differences in proxy-reported QoL between those in home care and those in institutional long-term care [21].

Actigraphy gives objective data on physical activity. The use of wrist ActiGraphs has been validated for the evaluation of sleep in patients with dementia [66], and the devices have been used to study motor activity patterns in elderly patients with dementia both living in nursing homes and living at home [67, 68]. A specific problem of using actigraphy in this particular patient group could be the removal of the wrist device. We

Page 9 of 11

excluded days that had less than 8 h recorded after applying ActiLife's Wear Time Validation tool (21.75 % of the total number of days); hence, removal of the wrist ActiGraph was not considered a substantial problem. Also, we had to rely on an arbitrary setting of 'time in bed,' which on the one hand allowed us to obtain a more standardized measure of the amount of sleep during more 'desirable' hours of the day or night, but on the other hand did not fully return a measurement of the participants' actual sleep efficacy. This would have to be taken into account if the findings were to be compared with those in the existing literature.

The model explained 28 % of the variance in QoL, which indicates that other factors not included in the study affected QoL in the patient group. It is reasonable to assume that the PWDs living in nursing homes had poorer health in general, and more comorbid somatic diseases, as might be indicated by the significant differences between the groups in medication and use of walking aids. However, comorbidity and number of diagnoses were not found associated with QoL in another Norwegian study of patients with dementia in nursing homes [31], and earlier research has shown inconsistent associations between medication and QoL in PWDs [21, 31, 40].

Finally, the cross-sectional design of the study restricted the possibility of drawing any conclusions on causality, and the only conclusion that could be derived from the regression model is that living in nursing home is associated with lower QoL. However, the results of the longitudinal analysis conducted on the subgroup population could suggest that residential care contributes in a causal way toward lower QoL.

Conclusion

The results of our study indicate that living at home as long as possible is not only desirable for economic and/ or health political reasons but also is associated with a higher QoL for patients with moderate dementia. More studies are needed to investigate how QoL could be increased for PWDs living in nursing homes.

Abbreviations

QoL, quality of life; PWDs, persons with dementia; PWD NH, persons with dementia in nursing homes; CDR, The Clinical Dementia Rating scale

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Availability of data and materials

Data supporting the findings is available upon request. Please contact the first author Christine Olsen (christine.olsen@nmbu.no) for data availability.

Authors' contributions

CO, CI and IP contributed to the study design, CO, IP, GC and NJ contributed to data collection, CO, IP, GC, and CI contributed to data analysis and data interpretation. All co-authors contributed to the writing process. The first author took part in the whole process. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable

Ethics approval and consent to participate

The project was performed in accordance with the Helsinki Declaration, and the project was approved by the Regional Committee for Medical Ethics in south-east Norway. Associated health staff allocated eligible participants, provided information about the study, and gathered written consent. Written and verbal information about the study was given to potential participants and their relatives by their primary caregivers. A procedure for care workers was developed for evaluating potential 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, their care workers and/or their next-of-kin took the decision on their behalf and gave written consent when appropriate.

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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.

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Paper II



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

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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.

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

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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

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2 C. Olsen et al.

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 OoL 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

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

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.

4 C. Olsen et al.

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 $(T_0, T_1 \text{ and } T_2)$.

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

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

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

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. To 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

6 C. Olsen et al.

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 minimental 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

T₁ and T₀ to T₂ (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 individualbased 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

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

Estimates of main effects ¹									
Denondent	Control-	-intervention	T.	₁ – T ₀	T;	$_{2}-T_{0}$			
Dependent variables	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI			
CSDD BARS QUALID	1.78 0.67 1.00	-2.88, 6.44 -9.65, 10.99 -5.05, 7.06	1.16 -1.25 -0.33	-1.38, 3.70 -5.35, 2.86 -3.74, 3.08	0.89 -0.03 -0.63	-1.29, 3.08 -3.24, 3.17 -3.27, 2.00			

CSDD, Cornell Scale for Depression in Dementia; BARS, Brief Agitation Rating Scale; QUALID, Quality of Life in Late-stage Dementia; T₀, pre-test; T₁, post-test; T₂, follow-up; CI, confidence interval..

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

				Estimates of fixed effects ¹							
Dependent	Pre-test	Doot	Follow-	$T_1 - T_0$						$T_2 - T_0$	
Dependent variables	(T_0)	Post- test (T ₁)	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.

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

¹A mixed model was used to estimate main effects.

¹A mixed model was used to estimate time trends between the groups.

²Significance level 0.05.

8 C. Olsen et al.

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

				Estimates of fixed effects ¹							
				$T_1 - T_0$ $T_2 - T_0$						$T_2 - T_0$	
Dependent variables	Pre-test (T ₀)	Post- test (T ₁)	Follow- up (T ₂)	Estimate	t	p ²	95% CI	Estimate	t	р	95% CI
CSDD mild/n	noderate de	mentia									
Control	6.36 ± 5.56 (<i>n</i> = 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 (<i>n</i> = 13)	9.36 ± 6.02 (n = 11)	8.55 ± 6.64 (<i>n</i> = 11)								
CSDD severe		,	,								
Control	11.25 ± 6.74	12.92 ±8.08	16.70 ± 11.72	-5.04	1.99	0.054	-10.17, 0.09	-11.00	3.67	0.001	-17.01,-5.00
AAA	(n = 12) 13.50 ± 5.28 (n = 10)	(n = 12) 11.00 ± 6.91 (n = 11)	(n = 10) 7.91 ± 5.43 (n = 11)								
BARS mild/m			(1 – 11)								
Control	21.43	21.71	21.79	0.48	017	0.866	-5.23, 6.20	-0.09	0.03	0.980	-7.40, 7.21
Oontroi	± 10.09	± 12.63	± 11.40	0.40	017	0.000	-3.20, 0.20	-0.03	0.00	0.500	-7.40, 7.21
	(n = 14)	(n = 14)	(n = 14)								
AAA	21.92	22.69	21.92								
, , , , ,	± 6.13	±5.92	± 8.80								
	(n = 13)	(n = 13)	(n = 12)								
BARS severe		()	(/								
Control	25.25	28.08	26.82	-3.68	1.02	0.317	-11.04, 3.67	-0.95	0.24	0.811	-8.89, 6.99
	± 12.88	± 15.17	± 15.27				, , , ,				,
	(n = 12)	(n = 12)	(n = 11)								
AAA	25.08 [^]	25.00 [^]	28.09 ´								
	± 8.99	± 8.47	± 6.77								
	(n = 12)	(n = 11)	(n = 11)								
QUALID mild	/moderate	dementia									
Control	20.36	23.07	23.00	1.05	-0.40	0.692	-4.27, 6.38	1.47	-0.47	0.643	-4.85, 7.79
	± 5.96	± 9.50	± 6.56								
	(n = 14)	(n = 14)	(n = 14)								
AAA	21.46	25.23	25.83								
	± 7.00	± 5.10	± 8.08								
	(n = 13)	(n = 13)	(n = 12)								
QUALID severe dementia											
Control	25.91	27.92	30.91	-5.08	2.33	0.035	-9.79, -0.37	-9.79	3.15	0.003	-16.03, -3.54
	± 10.21	± 10.90	± 12.15								
	(n = 12)	(n = 12)	(n = 11)								
AAA	26.58	24.27	23.18								
	± 6.17	± 6.72	± 4.40								
	(n = 12)	(n = 11)	(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.

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.

¹A mixed model was used to estimate time trends between the groups.

²Significance level 0.05.

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 No change	-3.00 -2.00 -1.00 0.00	0 (0) 2 (4.1) 4 (8.2) 11 (22.4)	1 (2.0) 2 (4.1) 4 (8.2) 11 (22.4)	0 (0) 0 (0) 3 (6.4) 13 (68.4)	0 (0) 8 (17.0) 3 (6.4) 6 (31.6)
Worse	1.00 2.00 3.00	7 (14.3) 1 (2.0) 1 (2.0) $\chi^2 = 3.16$	5 (10.2) 0 (0)	5 (10.6) 3 (12) 1 (2.1)	3 (6.4) 2 (4.3) 0 (0) 4, 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 animalassisted intervention group compared with the control group.
- Animal-assisted activity may be effective in dementia care.

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

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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*: ClinicalTrial.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, 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. Functional ability is the key for living good independent lives throughout the life course and obtaining a high quality of life (QoL).

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}

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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).

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 wellbeing, 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 AAIs and PWDs' need for meaningful activities, ³⁹ research on the effect of AAIs on the physical outcome 'balance' would be of great interest. Moreover, there has been a lack of research on the effect of AAIs in homedwelling 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 ClinicalTials.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 AAIs 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

C. Olsen et al. / Geriatric Nursing xx (2016) 1-8

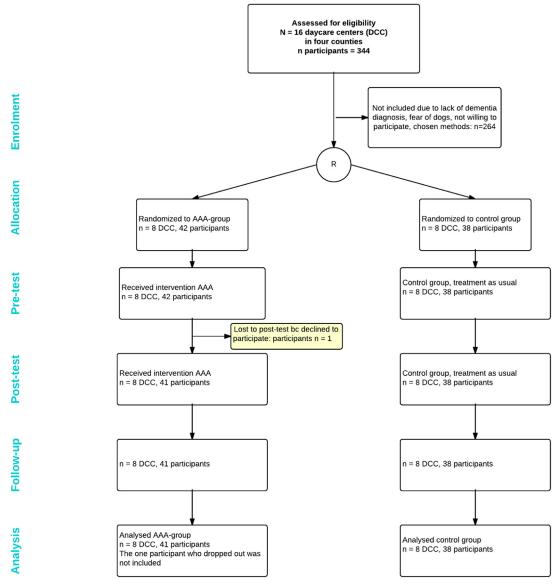


Fig. 1. Consort flow diagram of participants.

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. All Range of motion exercises 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).

		J ()	
	Control	AAA	p-value
	(n = 38)	(n = 41)	
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 =)	0.99
None	19 (51.4)	22 (53.7)	
Spouse	18 (48.6)	18 (43.9)	
Other relatives	0	1 (2.4)	
Missing	1		0.50
Social contact (%)	12 (27 1)	12 (22 2)	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) 3	2 (5.1) 2	
Missing	3	2	0.80
Hobbies (%)	10 (22 2)	0 (22.0)	0.80
Cognitive activities	10 (32.3)	8 (22.9)	
Physical activities Other	12 (38.7)	19 (54.3) 0	
Combination	3 (9.7)		
	6 (19.4) 7	8 (22.9)	
Missing	1	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.).

C. Olsen et al. / Geriatric Nursing xx (2016) 1-8

Table 2Scores in Berg Balance Scale (BBS) and Quality of life in Late-Stage Dementia (QUALID) for control and animal-assisted activity (AAA) (mean ± 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).
- $^{\mathrm{c}}$ 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.
- $^{\mathrm{f}}$ 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 (T_0) .

A mixed model was used to investigate changes over time (T_0 , T_1 and T_2) and differences between the groups (intervention and control group). 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. T_0 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 pretest 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 T_0 , with an increase to 44.71 at T_1 , and a score of 44.28 at T_2 . The control group scored 45.31 at T_0 , 45.50 at T_1 , and 46.57 at T_2 . On balance, the AAA intervention was a significant positive effect from T_0 to T_1 (p=0.03) (Table 2). No effect was found at follow-up, even though the improvement experienced by the intervention group remained constant after T_1 .

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 T_0 , 16.52 at T_1 , and 15.23 at T_2 , 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 T_0 to T_1 or from T_2 (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 (T_0) to post-test (T_1) , but not from pre-test to follow-up (T_2) . 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 par-

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

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 al⁵⁸). 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 daycare 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

C. Olsen et al. / Geriatric Nursing xx (2016) 1-8

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 OoL of the study population.

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C. Olsen et al. / Geriatric Nursing xx (2016) 1-8

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Engagement in elderly persons with dementia attending animal-assisted group activity.

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Abstract

The need for meaningful activities that enhance engagement is very important among persons with dementia (PWDs), both for PWDs still living at home, as well as for PWDs admitted to a nursing home (NH). In this study, we systematically registered behaviours related to engagement in a group animal-assisted activity (AAA) intervention for 21 PWDs in NHs and among 28 homedwelling PWDs attending a day care centre. The participants interacted with a dog and its handler for 30 minutes, twice a week for 12 weeks. Video-recordings were carried out early (week 2) and late (week 10) during the intervention period and behaviours were categorized by the use of an ethogram. AAA seems to create engagement in PWDs, and might be a suitable and health promoting intervention for both NH residents and participants of a day care centre. Degree of dementia should be considered when planning individual or group based AAA.

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Keywords

dementia, engagement, animal-assisted activity, video-recording, ethogram

Background

Worldwide estimates count 47.5 million persons with dementia (PWDs) today (World Health Organization (WHO), 2015). A range of health care services is needed for this group, from home-based services and respite care such as attending a day care centre (DCC) to residential care at a nursing home (NH). In Norway, about half of the total population of PWDs live in their own home (Lystrup, Lillesveen, Nuygård, & Engedal, 2006) and the most frequent unmet need for home-dwelling PWDs are daytime activities (Miranda-Castillo et al., 2010). DCCs are established to provide meaningful activities for home-dwelling PWDs and, at the same time, provide relief to family carers (Norwegian Ministry of Health and Care Services, 2015; Söderhamn, Aasgaard, & Landmark, 2014; Söderhamn, Landmark, Eriksen, & Söderhamn, 2013). About 20% of the dementia population in Norway who live at home attend a DCC once or twice a week (Vossius et al., 2015). Experience of attending a DCC is found to provide social fellowship, meaningful engagement, a sense of meaningful life and well-being (Brataas, Bjugan, Wille, & Hellzen, 2010). For PWDs at NHs, the need for meaningful activities that enhance engagement is equally important, as NH residents are frequently reported as participating in few activities and to be unoccupied most of the day (Smit, de Lange, Willemse, Twisk, & Pot, 2015). A high prevalence of inactivity, apathy and sedentary behaviour is commonly reported (Bates-Jensen et al., 2004; MacRae, Schnelle, Simmons, & Ouslander, 1996), and having an opportunity to participate in activities and activities that amount to something is important for increasing a sense of independence and positive self-image (Allen, 2011). During periods of activity, NH residents with dementia express positive affects much more often than during the periods of inactivity (Schreiner, Yamamoto, & Shiotani, 2005).

Engagement may be defined as "the act of being occupied or involved with an external stimulus" (Cohen-Mansfield, Dakheel-Ali, & Marx, 2009). For both home-dwelling PWDs and PWDs in NHs, engagement may prevent and improve behaviour problems and increase alertness, reduce boredom and agitation, increase positive emotions (Cohen-Mansfield, Thein, Dakheel-Ali, & Marx, 2010) and enhance quality of life (QoL) (Smit et al., 2015).

Animal-assisted interventions (AAIs) have become a regular activity in NHs and among dementia patients (Bernabei et al., 2013; Cohen-Mansfield, 2001). AAI is "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" (International Association of Human-Animal Interaction Organizations (IAHAIO), 2014). Animal-assisted activities (AAAs) is a sub-discipline of AAI, e.g. visits by dogs and their handlers for 'meet and greet' activities (IAHAIO, 2014). AAAs are usually conducted on a voluntary basis by individuals who do not have an education in health or a degree in human services, but they may also work formally and directly on specific documentable goals (IAHAIO, 2014).

Research in the AAI field is increasing, and studies have already documented the beneficial effects of AAI for elderly persons and PWDs in relation to agitation, depression, QoL, social interaction, loneliness, balance, etc. (Bernabei et al., 2013; Filan & Llewellyn-Jones, 2006; Friedmann et al., 2015; Majic, Gutzmann, Heinz, Lang, & Rapp, 2013; McCabe, Baun, Speich, & Agrawal, 2002; Olsen, Pedersen, Bergland, Enders-Slegers, & Ihlebæk, in press; Olsen, Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press; Perkins, Bartlett, Travers, & Rand, 2008; Richeson, 2003).

The conceptual framework devised by Cohen-Mansfield et al. "the Comprehensive Process Model of Engagement" (2009) may be used to understand some of the aspects of AAI, and to provide a link between the activity and the outcomes seen in studies of this group. The model claims that engagement with a stimulus is affected by environmental characteristics, the participant and the stimulus itself.

Environmental characteristics are described as surroundings, such as time, place, number of people present and temperature, as well as the manner of stimulus presentation. In an AAI intervention, this can refer to the design of the intervention, including group vs. individual intervention, as well as how the sessions are utilised. Participant characteristics constitute cognitive function, demographic characteristics, general level of activity and interest. These are all aspects that influence interaction with the dog as well as its handler in an AAI. Stimulus characteristics such as social vs. non-social, and human vs. non-human may influence the level of engagement. In an AAI, the dog serves as an adjunct for the handler, who represents the social human dimension in addition to the live, social, non-human attributes of the dog. The model further explains how environmental characteristics, participant characteristics and stimulus characteristics create engagement and have an impact on the participants' affect and behaviour (Cohen-Mansfield et al., 2009). By reducing boredom and loneliness and increasing interest and positive emotions, the change in the level of engagement is found to influence problem behaviours such as agitation (Cohen-Mansfield et al., 2009; Cohen-Mansfield, Libin, & Marx, 2007).

Direct observation of engagement has been used to assess levels of engagement among PWDs (Cohen-Mansfield et al., 2009; Cohen-Mansfield, Marx, Dakheel-Ali, Regier, & Thein, 2010; Cohen-Mansfield, Thein, Dakheel-Ali, Regier, & Marx, 2010). In the Comprehensive Process Model of Engagement, engagement is measured according to five dimensions, which are: rate of refusal of the stimulus; duration of time the participant was occupied or involved with a stimulus; level of attention to the stimulus (e.g. facial feedback, eye tracking); attitude towards the stimulus (e.g. smiles, laughs, negative facial expressions); action towards the stimulus (e.g. holding it or talking to the stimulus itself or another resident) (Cohen-Mansfield et al., 2009). A few observational studies have reported on behaviours occurring among the participants during human-animal interaction (Cohen-Mansfield, Thein, Dakheel-Ali, Regier, & Marx, 2010; Hauge, Kvalem, Pedersen, & Braastad, 2013; Marx et al., 2010; Pedersen, Nordaunet, Martinsen, Berget, & Braastad, 2011), but there is still a need for more knowledge about AAI in terms of engagement among PWDs. The main objective of this study was to systematically register behaviours related to engagement in a group AAA intervention for PWDs in NHs and among home-dwelling PWDs attending a DCC, and a second aim was to investigate possible differences between the two populations.

Methods

Design and research sites

The study was conducted as part of two cluster randomized controlled trials (RCTs) (Olsen, Pedersen, Bergland, Enders-Slegers, & Ihlebæk, in press; Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press). In the RCT trials, the intervention was found to have a positive effect on depression, balance and QoL (Olsen, Pedersen, Bergland, Enders-Slegers, & Ihlebæk, in press; Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press). In the present study, only data from the intervention groups were used, as no observational data from the control

groups were collected. The project is registered in ClinicalTials.gov (identifier: NCT01998490 and NCT02008630), a service of the US National Institutes of Health.

Out of 90 eligible NHs, 10 adapted NHs for PWDs in the Norwegian counties: Østfold, Vestfold, Oslo and Akershus agreed to participate in the project. In addition, 16 (out of 108) adapted DCCs for home-dwelling PWDs were recruited to the project. The institutions included had to ensure that they had the facilities required to carry out this kind of intervention. They had to abstain from any dog-visiting activities for three months prior to the intervention, as well as any other dog-visiting activities during the intervention period and three months after the end of the intervention.

After randomisation, each institution was given the opportunity to recruit 5–8 participants. The inclusion criteria were: being 65 years of age or older, having dementia or a cognitive deficit measured as a score of less than 25 on the Mini-Mental State Examination (MMSE) (Folstein et al., 1975; Strobel & Engedal, 2009). The exclusion criteria were: people afraid of dogs or with an allergy to dogs.

The possible benefits of a 12-week intervention with AAA for PWDs were studied. Groups of AAA were videotaped early and late in the intervention, and different behaviours that occurred during the filming were systematically mapped.

Sample

A total of 58 NH participants and 80 DCC participants agreed to participate in the RCT project. The control group included 30 NH participants and 38 DCC participants while 28 NH participants and 42 DCC participants were included in the intervention group, which is the population in this study. The deaths of three NH residents excluded them from the analyses. One of the DCC participants withdrew from the intervention and was therefore excluded. Participants who were only present at one of the video-recordings were also excluded from the analyses (n=4 NH participants and n=13 DCC participants). Thus, the study population consisted of 21 NH participants and 28 DCC participants.

Intervention and intervention content

The intervention consisted of 30-minute AAA sessions twice a week for 12 weeks in groups of 3–7 participants. The AAA sessions were led by a qualified dog handler. A protocol for conducting AAA sessions ensured equal intervention sessions between units. The protocol was deliberately designed to be able to standardise the intervention as much as possible, both across sessions and across the different institutions. The time span of 30 minutes was chosen due to the short attention span typical of dementia.

For each session, the participants were randomly seated in a semicircle. Every session started with a greeting round, where each participant got to pet the dog and give it treats. The handler then started the different activities, which could be: petting the dog, giving the dog a treat or throwing a toy for the dog to fetch. The programme theory underpinning the protocol was based on several principles, such as dementia knowledge, AAI competence and health care workers' knowledge of the patients. Even though the sessions were designed to follow the protocol, they could also be individually tailored. No activities were mandatory, and the sessions included activities that naturally occurred between the participants, and between each participant and the dog. A health care worker was present during all sessions.

Dogs and their handlers

In an AAI the dog serves as an adjunct to the dog handler. Therefore, both the dogs and their handlers, who were also the dogs' owners, were carefully selected for the study.

The dogs had to conduct and pass a screening test containing different elements according to their suitability. Different traits, such as aggressiveness, sociability, anxiety and the dog's behaviour when handled, were assessed by dog trainers and ethologists at the Norwegian Centre of Anthrozoology. In this study, all the handlers were female, and most of them had either a bachelor's degree or prior experiential learning in biology or social care. Both dogs and handlers then had to complete at least one course in AAI for visiting dogs. All the handlers were informed both orally and in writing about the protocol for the sessions in order to increase similarity between sessions and institutions.

Several different breeds of dogs were involved, most of them were large breeds: Standard Poodle (N=2), Collie (N=2), Flat Coated Retriever (N=1), Golden Retriever (N=1), Alaskan Malamute (N=1), Border Collie (N=1), Springer Spaniel (N=1), Portuguese Water Dog (N=1), Pomeranian (N=1) and Shetland Sheepdog (N=1), Mix (N=4). There were seven male (one neutered) and nine female dogs. Their ages varied between 2.5 and 13 years old, with an average age of 5.6 years. The dogs were kept both on and off a lead, depending on the interaction. No dogs were forced to do anything they were not comfortable doing and no activities were mandatory for the participants.

Assessments and procedures for data collection

The MMSE was used if a dementia diagnosis had not been made, the Clinical Dementia Rating (CDR) Scale and sociodemographic characteristics on age, gender, education, use of walking aids, social contact, hobbies and animal contact were collected at baseline by pretrained health care workers working in the units. The video-recordings were carried out early (week 2) and late (week 10) during the intervention period.

The MMSE was used to assess global cognition for patients not yet diagnosed with dementia. The MMSE consists of 20 items concerning orientation, word registration and recall, attention, naming, reading, writing, following commands and figure copying. Scores between zero and 30 are assigned, where a higher score indicates better performance (Folstein et al., 1975). A cut-off score of 24–25 is related to cognitive impairment and is said to provide a reliable diagnosis of dementia. Although this cut-off score is not valid for younger individuals and highly educated individuals, where a higher cut-off should be applied (O'Connor, Pollitt, Treasure, Brook, & Reiss, 1989), it should be considered valid for our population of older adults with a moderate level of education and it was therefore applied.

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

The video-recordings were standardised, using a camera Sony HXR-NX30E, a camcorder recording full HD with Balanced Optical SteadyShotTM and a tripod VCT-PG11RMB. The camera was placed in the room before the participants arrived to avoid interference with the intervention. The recordings were done by members of the project

group, who were all trained in where to place the camera in the room and how to behave and introduce the camera to the participants. All of the participants were told that the camera was on, and they had signed a written consent beforehand. The camera was placed in the room so the camera eye could record participants, the dog and the handler at all times.

An ethogram, which is a catalogue of behaviour descriptions (Martin & Bateson, 1986), was used to categorise the different behaviours from the video-recordings. The ethogram provides an objective description of the different behaviours that occur in the intervention, and has previously been used in other studies of human—animal interaction (Berget, Skarsaune, Ekeberg, & Braastad, 2007; Hauge et al., 2013; Pedersen et al., 2011).

Ethics

The project was conducted in accordance with the Helsinki Declaration and was approved by the Regional Committee for Medical Research Ethics. Participants were aware of the conditions for their participation, since the randomisation was done at institutional level. A procedure was developed to evaluate the participants' capacity to provide informed written consent, which was obtained by pre-trained health care workers. PWDs with sufficient capacity were informed about the project and asked to provide written consent. For participants with reduced capacity, health care workers and/or the next-of-kin made the decision on behalf of the elderly and provided proxy written consent. The written consent contained information about the project, the intervention, different assessments (including the fact that they would be videotaped) and the possibility to withdraw from the project at any time. In addition, participants were informed about the video-recordings the day before recording and on the day the session was to be recorded.

Video analyses

The videos were analysed using the behaviour coding software Solomon Coder, version beta 14.10.04, by five pre-trained observers. Solomon Coder provides an opportunity to quantify behaviour. By defining behaviours of interest in an ethogram, we calculated the duration (length of time a single occurrence of the behaviour pattern lasted) and frequency (number per unit time) of different behaviours (see Table 1). The frequency and/or duration of conversations, head orientation, touching, activities, smiles and laughter and singing, whistling or dancing, as well as stereotyped behaviour, wandering around, agitated behaviour, yawning or sighing and whether they fell asleep or left the session was registered (Table 1).

The videos were randomised between the observers, and then analysed in a random order, so there was no dependence on whether the recordings were done early or late in the intervention.

For one recording of a group of five participants, the video was analysed five times, registering behaviours for each participant at a time.

Intraclass correlation coefficient. To test the level of agreement between those rating the videorecordings, they all blindly analysed the same two videos. The intraclass correlation coefficient with a Two-Way Mixed model and Absolute Agreement showed a mean average measure of 0.9, range 0.76–1.0. The mean single measure was 0.71, range 0.45–0.98. Values between 0.75 and 1.0 are considered excellent inter-rater reliability (Hallgren, 2012).

Table 1. Ethogram.

Behaviour	Description	F/D
Conversation	Conversations with the therapist, dog handler, other	F&D
Look at other people	participants or the dog Faces the therapist, dog handler, other participants who are not handling the dog	F&D
Look at the dog activity	Faces the dog or activities involving the dog	F&D
Look at other things	Faces other things than the dog, therapist, dog handler or other participants	F&D
Touch people	Physical contact with the therapist, dog handler, other participants (more than 2 seconds)	F&D
Touch dog	Physical contact with the dog (more than 2 seconds)	F&D
Do activities	Throws the ball, gives treats, brushes the dog	F&D
Smile or laugh at people	Smiles or laughs with face oriented towards the therapist, dog handler or other participants	F&D
Smile or laugh at dog	Smiles or laughs with face oriented towards dog or activities with dog	F&D
Smile or laugh at other things	Smiles or laughs with face oriented towards other things than the dog, therapist, dog handler or other participants	F&D
Sing, dance, clapping hands, etc.	Sings, whistles, hums, dances, claps hands	F&D
Stereotyped behaviour	Repetitive behaviour that occurs for minimum 5 seconds	F&D
Wandering around	Wanders around in the room without leaving the room	F&D
Agitated behaviour	Cries, yells, swears, aggressive sounds	F
Yawn and sigh	Yawns or sighs	F
No response	Doesn't respond when contacted by the therapist, participants, dog handler or dog	F&D
Asleep	Sleeps, sits still with eyes closed for minimum I minute	F&D
Leaving the room	Leaves the room and doesn't come back	F
Off camera	Off camera	F&D

F: scored in frequency; D: measured duration.

Statistics. All analyses were computed using the statistical software IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp. An analysis of variance (ANOVA) was used to test the differences in means between groups.

Descriptive statistics were used to present demographic data using frequency distribution. Video registrations in Solomon Coder were imported into SPSS for further calculation. Time was registered in seconds. Time off camera was subtracted from the total time for each participant, and, due to differences in the total time of each session, the percentage of total time for each behaviour was calculated. Since there were only minor differences in durations or frequencies of the behaviour from early to late in the intervention period, a mean value for both recordings was calculated and serves as descriptive data for this study (Table 3).

The degree of dementia was previously found to influence the effects of AAA in PWDs (Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press). Consequently, we stratified all participants into level of CDR (0, 0.5 and 1 = mild, 2 = moderate and 3 = severe), and compared means.

Results

There were no significant differences between NH participants and DCC participants regarding age, gender, education level, use of walking aids, or whether the participants enjoyed having contact with animals (Table 2).

Table 2. Sociodemographic characteristics.

	NH (n=21)	DCC (n = 28)	p value
Age mean (SD)	84.8 (5.9)	84.08 (6.2)	.691
Missing	1 ` ′	2 ` ´	
Women (%)	13 (61.9)	13 (46.4)	.425
Missing	0 ` ′	2 `	
Education level (%)			.880
Below upper secondary school	8 (38.1)	12 (42.9)	
Upper secondary school	3 (14.3)	I (3.6)	
Above upper secondary school	2 (9.6)	7 (25.0)	
Missing	8 (38.1)	8 (28.5)	
Clinical Dementia Rating (CDR) Scale (%)			<.001
0	0	I (3.6)	
0.5	0	2 (7.1)	
I	2 (9.5)	10 (35.7)	
2	8 (38.1)	15 (53.6)	
3	11 (52.04)	0	
Missing	0	0	
Mean use of psychotropic medication	.93	.41	.046
Missing	7	6	
Walking aids (%)			.405
None	9 (42.9)	11 (39.3)	
Walking sticks	0	2 (7.1)	
Cane	I (4.8)	2 (7.1)	
Crutches	0	I (3.6)	
Rollator	10 (47.6)	9 (32.1)	
High walker	0	0	
Wheelchair	I (4.8)	0	
Needs support walking	0	0	
Missing	0	3 (10.7)	
Social contact (%)			.014
Daily	2 (9.5)	11 (39.3)	
Several times a week	6 (28.6)	11 (39.3)	
Once a week	11 (52.4)	5 (17.9)	
Every other week	0	0	
Rare	I (4.8)	I (3.6)	
Missing	I (4.8)	0	
Hobbies (%)			.061
Cognitive activities	3 (14.3)	6 (21.4)	
Physical activities	7 (33.3)	15 (53.6)	
Combination	8 (38.1)	4 (14.3)	
Missing	3 (14.3)	3 (10.7)	
Enjoy animal contact (%)	15 (71.4)	21 (75.0)	.709
Missing	4 (19.0)	3 (10.7)	

Only four of the NH participants did not have a dementia diagnosis, and the mean MMSE for these participants was 15.3 (SD=6.7, range: 7–23). For DCC participants, the mean MMSE for the eight participants without a dementia diagnosis but with a MMSE score was 18.4 (SD=6.2, range: 8–26). Around 40% of participants in both groups did not use any walking aids, however, 47.6% of NH participants used a rollator (32.1% of DCC participants), and one NH participant used a wheelchair. The participants were somewhat engaged in hobbies, but DCC participants were more engaged than NH participants in physical activities. The majority of the participants reported that they enjoyed contact with animals (>70%) (Table 2).

There was a significant difference in the degree of dementia between NH participants and DCC participants (p < .001), as the majority of NH participants had a score of severe dementia (52%), while none of the DCC participants were assessed as having severe dementia, and the majority of DCC participants had moderate dementia (53.6%) (Table 2). NH participants showed significantly higher use of psychotropic medication than DCC participants. Most participants had regular social contact, with over 90% of both populations meeting family or friends at least once a week. However NH participants still had significantly less social contact.

Behaviours targeting either the dog or other people had the highest mean percentage times. These behaviours were: Look at dog-activity; Smile or laugh at dog; Conversation; Look at other people; Touch dog; Do activities with dog; Touch people; Smile or laugh at people. Mean values showed that actions towards the dog, such as observing it, smiling, talking to it or petting it, were the behaviours with the longest duration in AAA sessions in both populations (Table 3). Since this intervention was conducted as a group activity, time spent in contact with the dog had to be equally divided between the participants, which

Table 3. Mean time spent as percentage of total time of the session on Different Behaviours (SD).

Variable	NH (n=21)	DCC (n = 28)	p value
Look at dog-activity	70.41 (19.99)	77.35 (10.70)	.129
Smile or laugh at dog	16.21 (14.45)	25.55 (16.17)	.042
Conversation	12.31 (14.44)	20.72 (13.81)	.044
Look at other people	11.46 (9.63)	14.22 (9.28)	.316
Touch dog	9.81 (7.20)	10.64 (7.11)	.690
Look at other things	9.26 (6.25)	6.76 (5.49)	.143
Asleep	8.55 (18.96)	0.70 (2.19)	.034
Do activities	6.26 (4.61)	5.15 (5.19)	.439
Touch people	4.00 (10.26)	1.59 (7.53)	.346
Stereotyped behaviour	2.22 (4.04)	2.81 (8.75)	.776
Smile or laugh at people	2.20 (2.89)	2.83 (1.89)	.360
Sing, dance, clap hands, etc.	0.22 (0.59)	0.18 (0.27)	.757
Yawn and sigh	0.05 (0.06)	0.08 (0.11)	.333
Smile or laugh at other things	0.03 (0.08)	0.05 (0.07)	.222
Agitated behaviour	0.02 (0.05)	0.00	.069
No response	0.01 (0.03)	0.00	.169
Wandering around	0.00	0.00	.111
Leaving the room	0.00	0.00	.131

limited direct contact with or being able to do activities with the dog to 5–6 minutes for each participant. Most of the participants utilised that time to the full, and the mean time spent petting the dog was around 10% of the total time for participants at both NHs and DCCs. There was a small amount of stereotyped behaviour, and some of the NH participants occasionally slept during the session (Table 3). There were surprisingly few differences between the two populations; NH participants spent significantly less time smiling or laughing, and engaged less in conversation. They also spent more time asleep compared to DCC participants (Table 3).

When comparing the participants stratified by degree of dementia (CDR), we also found only a few differences in behaviours. Participants with severe dementia slept (mean = 15.3 %, SD = 24.7) significantly more (F = 6.60, p = .003) than those with mild (mean = .3%, SD = .99) or moderate (mean = 1.2%, SD = 2.61) dementia, and they spent significantly less time (F = 6.74, p = .003) looking at the dog-activity (mean = 60.7%, SD = 22.63) than those with mild (mean = 77.7%, SD = 10.3) or moderate (mean = 78.8%, SD = 10.42) dementia (stratified data not shown in table).

Discussion

In this study, few behavioural differences were found between NH participants and DCC participants during AAA, even though there was a significant difference in the degree of dementia between NH participants and DCC participants. There were also significant differences in the use of psychotropic medication and social contact, where NH participants had higher use of psychotropic medication and significantly less social contact than DCC participants. Behaviours targeting either the dog or other people had the highest mean percentage times, and actions towards the dog, such as observing it, smiling, talking to it or petting it, were the behaviours with the longest duration in AAA sessions in both populations. NH participants spent significantly less time smiling or laughing and engaged less in conversation. They also spent more time asleep compared to DCC participants. Participants with severe dementia slept significantly more than those with mild or moderate dementia and they spent significantly less time looking at the dog-activity than those with mild or moderate dementia.

According to the Comprehensive Process Model of Engagement by Cohen-Mansfield et al. (2009), environmental characteristics are one of three dimensions affecting the impact of a stimulus. In this study, the team of dog and handler constitute the stimulus, and the group activity design was an important environmental factor that could influence the participants' attention towards the dog. One of the purposes of the group activity design was to facilitate social interaction between the participants. It is suggested that group activities in which the participants themselves can influence the development of the activity are most effective (Cattan, White, Bond, & Learmouth, 2005). In AAA, voluntary participation is a key factor, as no activities are mandatory. The participants interact with the dog, the dog handler and the other participants in whatever way and to the extent they choose. They can sit and simply observe, they can respond to the contact initiated by the dog, they can try to engage the dog themselves, they can observe the social interaction between the other group members or they can choose to actively interact with the others. Group activities are found to create a sense of belonging, and the group represents a secure environment that contributes to strength, inspiration and joy (Sundsteigen, Eklund, & Dahlin-Ivanoff, 2009). The results show that in addition to being engaged with the dog, social interaction

with the dog handler and other participants also had high durations. The participants looked at other people, smiled to them and talked with them. The dog in AAA has previously been reported to have a social catalyst effect (Beetz, Uvnas-Moberg, Julius, & Kotrschal, 2012), and reviews on AAI on PWDs have concluded that this kind of intervention may increase social behaviour and interaction (Bernabei et al., 2013; Filan & Llewellyn-Jones, 2006; Perkins et al., 2008). Other environmental characteristics that could be important in this study were time and place. To ensure predictability for the participants, the institutions were asked to make a room available for the intervention away from other activities or people, and that the same room be used for all sessions. The location was therefore familiar to the participants. Predictability was also ensured by sessions always being held from between 12:00 and 13:30, just before dinner time.

The second factor influencing a stimulus according to the Comprehensive Process Model of Engagement (Cohen-Mansfield et al., 2009) is personal attributes. Important attributes that may affect stimuli and the level of engagement in this study could be interest in animal contact, degree of dementia and use of medication. The overall level of interest in the dog probably reflects the fact that the majority of the participants stated that they enjoyed contact with animals before the intervention period started. Participants with severe dementia slept significantly more than those with mild or moderate dementia, and were less attentive towards the dog. It has previously been reported that persons with severe dementia engage less in activities than those with mild or moderate dementia (Smit et al., 2015). Furthermore, the use of psychotropic medication is known to be associated with apathy (Tripathi & Vibha, 2010). Moreover, all participants with severe dementia were NH residents, and it is reported that institutionalised PWDs are sedentary most of the time (Król-Zielińska, Kusy, Zieliński, & Osiński, 2010; Salguero, Martinez-Garcia, Molinero, & Marquez, 2011).

The last important factor in the model is stimulus attributes. In this intervention, the social attributes of the dog may affect the participants' level of engagement. Dogs and humans share prosocial qualities of social competence, and some aspects of dogs' social competence can be considered to function similarly to that of humans (Miklosi & Topal, 2013). For instance, dogs can recognise human emotions (Albuquerque et al., 2016), and humans represent dogs' emotions in a somewhat similar way to their own (Konok, Nagy, & Miklósi, 2015). In this study, we deliberately chose to use different breeds of dogs. This was done to reduce the individual effect of the dog, as it has been found that participants show different levels of engagement towards the dog depending on the size/breed (Marx et al., 2010). The level of engagement has been found to be highest in responses to live social stimuli (Cohen-Mansfield, Marx, Thein, & Dakheel-Ali, 2011), and compared to a similar study with the social robot seal Paro (Joranson et al., 2016), participants looked at the dogactivity 1.4 times more than participants looked at Paro. In AAA, the dog serves as an adjunct, so it is actually the dog and handler dyad that acts as a stimulus. In many ways, the qualities of the handler are as important as the qualities of the dog. In a group activity, the dog handler has to be attentive to the needs of each individual, and not only the participants, but also the dog. This requires major skills and experience, as the dog handler must be able to identify the needs and mediate the intervention to be suitable for all participants involved, while also ensuring it is individually tailored. Appropriate guidance on interacting with stimulus is important to be able to benefit from the activity, and individual tailoring increases the effectiveness of the stimuli even more (Leone, Deudon, Piano, Robert, & Dechamps, 2012).

All the factors discussed above interact to create engagement during an activity and one of the model measurement dimensions is duration of time, i.e. how long the participant was occupied or involved with a stimulus. In this study, the behaviours; Look at dog-activity; Smile or laugh at dog; Touch dog; Do activities with dog could be regarded as involvement with a stimulus. Thereby demonstrating that the participants were able to engage in the AAA. The dog clearly had the participants' attention, as they spent six times as much time looking at the dog than other people or other things. As the abovementioned behaviours showed the longest duration in the AAA sessions, it could be claimed that the activity creates engagement. The high degree of involvement, as well as indications of a positive attitude (high level of smiles and laughter) which is another dimension in the model, further implies that the intervention created engagement among all participants. There are a few notable exceptions however; DCC participants showed more behaviours like smiling or laughing at the dog, were engaged in more conversation and slept less during the session. This may be related to the significantly lower degree of cognitive loss and less use of medication.

The conceptual framework model declares that engagement can subsequently result in a change in affect that may influence the presentation of behavioural problems (Cohen-Mansfield et al., 2009). Consequently, the engagement shown in this study can be associated with the results of our previous study (Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press), where we, in line with other studies, found AAA to have an effect on depression in NH participants with severe dementia (Friedmann et al., 2015; Majic et al., 2013; Olsen, Pedersen, Bergland, Enders-Slegers, Patil et al., in press). In the current study, the registered data show that participants smiled about 20% and 30% of the time. Although we did not investigate differences in mood over time, improved mood through interaction with a dog has been found earlier (Marcus et al., 2013).

Engagement in activities beyond routine care is an important indicator of QoL in NHs. Having the possibility to participate in activities and activities that amount to something is important for increasing a sense of independence and positive self-image in NH residents (Allen, 2011). Change in affect and behaviours as stated in the model are key factors related to QoL among elderly PWDs, and it is plausible that an activity that enhances engagement could influence QoL as seen in the study by Olsen, Pedersen, Bergland, Enders-Slegers, Patil (in press). Improving QoL has been identified as one of the primary goals of dementia treatment (Logsdon, McCurry, & Teri, 2007), and a significant improvement in QoL among NH residents was also previously found after being part of an AAI (Nordgren & Engstrom, 2014). Both NH residents and home-dwelling PWDs have been found to have a series of unmet needs, such as a need for social contact, sensory stimulation and a need for a meaningful activity (Cohen-Mansfield, Dakheel-Ali, Marx, Thein, & Regier, 2015). It is likely that an intervention such as AAA answers these kinds of needs to some extent, as these data show that the participants from both residences spend a lot of time displaying social behaviours, including touching the dog or other people. Furthermore, there is a need for new and innovative approaches to traditional health care, and activities that enhance engagement may have a great impact on PWDs' QoL (Smit et al., 2015). Our study indicates that AAA could be a basis for creating such engagement.

Strengths and limitations

This study has several strengths and weaknesses that need to be taken into consideration when interpreting the results. Using ethograms provides an opportunity to objectively study

the behaviours that occur in an intervention. The behaviours that were to be measured were clearly and unambiguously defined after pre-watching the videos, making them easily understood by the different observers. A detailed description was written before the analysis started. However, a limitation of ethograms is that not all members of a group studied behave in the same way (Martin & Bateson, 1986), making it possible to miss some important information that may have been picked up using qualitative methods. Using video-recordings could constitute a limitation if the participants' awareness of the camera made them more self-conscious and that this influenced their behaviour. However, study participants are generally found to forget the camera and behave normally as soon as the activity has started (Malterud, 2011).

Another limitation to the study is that we had limited knowledge on comorbid somatic diagnosis, which may affect behaviour. Furthermore, we had no information on behavioural and psychiatric symptoms, such as agitation and depression among DCC participants. It is reasonable to assume that the NHs residents had poorer health in general, as indicated by the significant differences between the groups in psychotropic medication and use of walking aids, and the few differences in behaviour reported may be due to this. It could be that the groups of participants should be more homogenous regarding gender, age, physical and cognitive function, in order for the AAA to be better suited for all participants in the group. Or it may be that severe dementia patients would benefit more from individually based AAA, as one-on-one socialising is found to give the highest ranking for duration, attention and/or attitude towards a stimulus (Cohen-Mansfield, Marx, Dakheel-Ali, Regier, & Thein, 2010). The significant standard deviation found for time spent on the different behaviours within the two populations could also indicate that AAA needs to be tailored to the individual patients. However, the few differences in behaviour seem to indicate that the group AAA created engagement in both groups.

Conclusion

Based on the high duration of behaviours related to the dog activity, and indications of positive attitudes with a high level of smiles and laughter, AAA seems to create engagement in PWDs both among NH residents and among participants of DCCs. AAA may be a suitable and health promoting intervention for both NH residents and users of DCCs. The degree of dementia should be considered when planning individual or group-based AAAs. Activities should be tailored to the participants' needs and interests. A flexible schedule and provision of resources and accommodation are also imperative to engage participants in their preferred activities despite limited functioning.

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