Emotional robots as health promotion in dementia care
- *group activity with a seal robot in nursing homes*

Emosjonelle roboter som helsefremmende tiltak i demensomsorg
- *gruppeaktivitet med en selrobot på sykehjem*

Philosophiae Doctor (PhD) Thesis

Nina Jøranson

Section for Public Health Sciences
Department of Landscape Architecture and Spatial Planning
Faculty of Social Sciences
Norwegian University of Life Sciences

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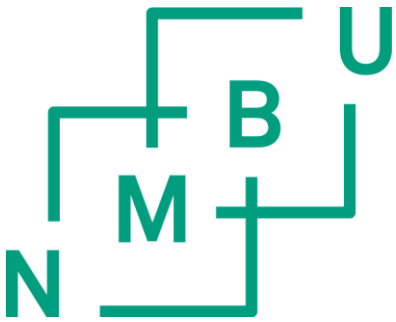

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Trust is not of our own making; it is given. Our life is so constituted that it cannot be lived except as one person lays him or herself open to another person and puts him or herself into that person's hands either by showing or claiming trust.

By our very attitude to another we help to shape that person's world.

Knud Ejler Løgstrup

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Summary

In recent years there has been shift in how to approach treatment of people with dementia towards stimulating social, personal and physical resources in order to promote health and well-being. Promoting health in nursing home (NH) residents with moderate or severe dementia is considered challenging for staff of several reasons. Often are challenges related to residents' behaviors, such as symptoms of restlessness, agitation and depression, but also inactive behavior, making motivation for conducting various activities in daily life challenging. Amongst Norwegian NH residents 80 % have dementia with agitation and depression as the most common symptoms. Due to limited effects from medical treatment, but also harmful side-effects, non-pharmacological treatment is recommended as first choice worldwide. The increasing number of people with dementia and the inverse development of number of care staff, has led to development of a variety of welfare technology mainly for enhancing independent living at home and produce effective execution of health-related tasks for care staff. In addition, welfare technology as an alternative way to assist people socially and emotionally is developed. Robots resembling pets are made for interaction for elderly with dementia, in order to provide comfort and enhance well-being.

The overall aim of the thesis was to investigate possible effects from an intervention with the baby harp seal robot Paro in a group activity for people with dementia aiming to promote health in this patient group. We investigated effects on symptoms of agitation, depression, use of psychotropic drugs and on quality of life (QoL). In addition, behaviors shown by participants during Paro-activity was investigated in terms of prevalence and development during the intervention period. We also investigated differences according to dementia severity. The trial was conducted as a cluster randomized controlled trial and was conducted in three periods during 2013 and 2014: Ten special care units (SCU) from the three Norwegian counties Østfold, Vestfold and Akershus were recruited to participate. Each SCU recruited up to six participants forming a group allocated to receive Paro-activity or being a control group having "treatment as usual". Paro-activity was conducted biweekly during 12 weeks.

One activity session in week two and one in week ten in each intervention group were video-recorded in order to analyze occurring observations during Paro-interaction and change in these behaviors (paper I). 23 participants attended both sessions. A theoretical framework describing creation of engagement in people with dementia was used to explain the findings. Paro caught attention in all participants from the start, and observing Paro was the most common behavior in both groups. However, participants with mild/moderate dementia observed Paro significantly more than those with severe dementia. Participants with severe dementia observed other things significantly more than participants with

mild/moderate dementia. During the course of the intervention, we found an increasing development of social interactions observed as significantly increase in smiles and laughter towards other participants, although a decrease in conversations while having Paro on the lap.

In the main study (paper II and III), the cluster-randomized controlled trial, we included 53 participants in the analysis (drop-out of 7 participants). Effects on symptoms of agitation, depression and QoL were investigated by using psychometric assessment scales before baseline (T0), after intervention (T1), and three months after end of intervention (follow-up)(T2). We found effects on reduced symptoms of both agitation and depression when comparing the groups from T0 to T2. Symptoms in the intervention group declined, while symptoms on agitation remained almost stable and symptoms of depression increased in the control group. We found no effects at T1. There were no effects of the intervention on QoL in the total sample. However, when investigating development of QoL according to dementia severity, we found significant effects for participants with severe dementia as the intervention group maintained their QoL while the corresponding control group worsened. Additional analysis showed that a model with the Paro-intervention in combination with reduction in use of psychotropic drugs best explained the variance in change in QoL. The positive development of social interactions and engagement has most likely affected this participant group positively. The intervention did not seem to influence QoL in participants with mild/moderate dementia showing higher and stable measures of QoL.

The overall conclusion of this thesis is that Paro-activity created engagement and improved social interactions in the group resulting in positive effects which are considered to promote health in participants with dementia.

Sammendrag

I de senere år har det vært en endring i behandling av personer med demens mot stimulering av deres sosiale, personlige og fysiske ressurser for å fremme helse og velvære. Å fremme helse i sykehjemsbeboere med moderat og alvorlig demens vurderes som krevende av ansatte av ulike grunner. Ofte er utfordringene forårsaket av beboerens adferd, som kan være symptomer på uro, sinne (agitert adferd) og depresjon, men også inaktivitet, som utfordrer motivasjon til å gjennomføre daglige aktiviteter. Blant norske sykehjemsbeboere har 80 % demens, mange av disse med symptomer på agitert adferd og depresjon. Grunnet begrenset behandlingseffekt av medisiner ved siden av skadelige bivirkninger er ikke-medisinsk behandling anbefalt som førstevalg over hele verden. Et økende omfang av personer med demens og den motsatte utviklingen av helsepersonell fremover har medført utvikling av velferdsteknologi med mål om økt selvstendighet og trygghet for hjemmeboende og effektivisering av oppgaver for helsepersonell. Velferdsteknologi er også sett som en alternativ måte å gi sosial og emosjonell støtte overfor eldre med demens med målsetning om å skape trøst og økt velvære.

Det overordnede målet i denne avhandlingen var å undersøke mulige effekter fra en intervensjon med selunge-roboten Paro i en gruppeaktivitet for personer med demens for å fremme helse i denne pasientgruppen. Vi undersøkte effekter på agitert adferd, depresjon, bruk av psykotrope medisiner og livskvalitet. I tillegg ble adferder hos deltakerne under Paro-aktiviteten undersøkt for å avdekke forekomst av og utvikling av adferd gjennom intervensjonsperioden. Forskjeller relatert til alvorlighetsgrad av demens ble også undersøkt. Vi utførte en cluster-randomisert kontrollert studie gjennom tre intervensjonsperioder, to i 2013 og en i 2014: Ti skjermede enheter fra Østfold, Vestfold og Akershus fylke ble rekruttert til deltakelse. Hver skjermede enhet rekrutterte inntil seks deltakere til en gruppe. Enhetene ble trukket til å motta Paro-aktivitet eller være kontrollsted med «treatment as usual». Paro-aktiviteten ble gjennomført to ganger i uka gjennom 12 uker.

En gruppesesjon i uke to og en i uke ti i hver Paro-gruppe ble filmet for å analysere adferder som oppsto under samspill med Paro og hvordan disse adferdene endret seg (artikkel I). 23 deltakere møtte til begge sesjoner og ble inkludert. Et teoretisk rammeverk som beskriver utvikling av engasjement hos personer med demens ble brukt for å forklare funnene. Paro tiltrakk seg oppmerksomhet hos alle deltakere fra begynnelsen, å observere Paro var den vanligste adferden i begge grupper. Allikevel var det deltakerne med mild/moderat demens som observerte Paro signifikant mer enn de med alvorlig demens. Deltakerne med alvorlig demens observerte derimot andre ting signifikant mer enn deltakerne med mild/moderat demens. Gjennom hele intervensjonsperioden fant vi en økende utvikling av sosialt

samspill observert som signifikant økning av smil og latter overfor hverandre, samtidig som vi fant redusert kommunikasjon mens deltakerne hadde Paro på fanget.

I hovedstudien (artikkel II og III), med cluster-RCT, inkluderte vi 53 deltakere i analysen (7 deltakere gikk ut av studien). Effekter på symptomer på agitert adferd, depresjon og livskvalitet ble undersøkt gjennom psykometriske tester før intervensjonsstart (T0), etter intervensjonens slutt (T1) og tre måneder etter intervensjonens slutt (T2). Vi fant effekter på reduserte symptomer på både agitert adferd og depresjon ved sammenligning av gruppene fra T0 til T2. Symptomer målt på intervensjonsdeltakerne gikk ned, mens symptomer på agitert adferd forble uendret og depresjonssymptomer økte i kontrollgruppa. Vi fant ingen effekter ved T1. På hele gruppa fant vi ingen effekt av intervensjonen på livskvalitet. Derimot, ved å undersøke utvikling av livskvalitet relatert til alvorlighetsgrad av demens, fant vi en signifikant forskjell mellom gruppene for deltakere med alvorlig demens der intervensjonsdeltakere beholdt nivå på livskvalitet mens kontrollgruppa fikk forverret sin livskvalitet. Tilleggsanalyser viste at en modell med Paro-intervensjon sammen med redusert bruk av psykotrope medisiner best forklarte variansen i endring av livskvalitet hos de med alvorlig demens. Den positive utviklingen av sosialt samspill og engasjement har mest sannsynlig påvirket intervensjonsgruppedeltakerne positivt. Intervensjonen så ikke ut til å påvirke livskvalitet for deltakerne med mild/moderat demens som i utgangspunktet hadde bedre skår på livskvalitet.

Den overordnede konklusjonen i denne avhandlingen er at Paro-aktivitet skapte engasjement og forbedret det sosiale samspillet i intervensjonsgruppa og resulterte i positive effekter, som vi mener kan fremme helse i deltakere med demens.

List of papers

I. Jøranson, N., Pedersen, I., Rokstad, A. M. M., Aamodt, G., Olsen, C. & Ihlebæk, C. Group activity with Paro in nursing homes: Systematic investigation of behaviors in participants. *International Psychogeriatrics, (in press)*, 1-10.

II. Jøranson, N., Pedersen, I., Rokstad, A. M. M., & Ihlebæk, C. (2015). Effects on Symptoms of Agitation and Depression in Persons With Dementia Participating in Robot-Assisted Activity: A Cluster-Randomized Controlled Trial. *Journal of the American Medical Directors Association, 16*(10), 867-873.

III. Jøranson, N., Pedersen, I., Rokstad, A. M. M., & Ihlebæk, C. Change in quality of life in elderly with dementia participating in Paro-activity: A cluster-randomized controlled trial *(submitted)*

Abbreviations

NH	Nursing Home
Paro	Personal assistive robot
QoL	Quality of Life
SCU	Special Care Unit
RCT	Randomized controlled trial
T0	Baseline
T1	After end of intervention
T2	Follow-up (3 months after end of intervention)
WHO	World Health Organization
NPS	Neuropsychiatric Symptoms
PCC	Person-centred care
HAI	Human-animal intervention
SAR	Socially assistive robots
CDR	Clinical Dementia Rating scale
CDR 1+2	Participants with mild and moderate dementia
CDR 3	Participants with severe dementia
AL	Activity Leader
BARS	Brief Agitation Rating Scale
CSDD	Cornell Scale for Depression in Dementia
QUALID	Quality of Life in Late-Stage Dementia
ANOVA	Analysis of variance
χ^2	Chi-square

1. Introduction

The World Health Organization (WHO) report the worldwide number of people with dementia estimated to 47.5 million people today, and the number is growing with 7.7 million new cases every year (WHO, 2015a). The prevalence worldwide will be doubled every 20 years estimated to 115.4 million people in 2050 due to an increasing aging population (Prince *et al.*, 2013) making dementia a public health issue worldwide. In Norway today, it is assumed that about 77.000 people live with dementia, an estimated number based on European studies due to lack of precise Norwegian estimates, and the numbers will be doubled in 2040 (Ministry of Health and Care Services, 2015). There is an increasing incidence in the future due to increased population and ageing, the latter being the most important risk factor (Strand *et al.*, 2014).

People with dementia living in Norwegian nursing homes have high prevalence of symptoms like agitation, depression and apathy (Selbaek *et al.*, 2007). Severity of dementia, symptoms of agitation and depression are associated with lower quality of life (Mjorud *et al.*, 2014b; Roen *et al.*, 2015). Due to little effect from medical treatment, facilitated activities are recommended as the best approach to treat these symptoms (Gauthier *et al.*, 2010; Salzman *et al.*, 2008). Performance of activities are facilitated by staff, although staff still consider personal care as a more important task (Kjøs and Havig, 2015). Living a positive life in residential care include performing meaningful occupations (O'Sullivan and Hocking, 2006) and the Norwegian care plan emphasize the significance of facilitated activities in dementia care (Ministry of Health and Care Services, 2007).

There is still no cure for dementia, and in recent years there has been shift in how to approach treatment of dementia described in research and in white papers towards both preventing dementia and promoting health in people with dementia (Ministry of Health and Care Services, 2015; WHO, 2015b). Promoting health in people with dementia includes a focus towards use of residual functions through participation in meaningful activities producing physical, mental and social well-being (Wilcock, 2005). This view is also in line with a growing person-centred care approach in dementia care during the last decades (Edvardsson *et al.*, 2008).

One of the actions towards the growing number of people with dementia and the inverse development of health care workforce is development of welfare technology aiming to facilitate life at home longer, but also development of robotic pets made for entertainment and interaction as substitutes for human-animal interactions (Ministry of Health and Care Services, 2011). The most used robotic pet in intervention studies is the baby harp seal Paro (Chang and Sung, 2013). Although Paro is considered as

an activity in dementia care in white papers, there is a need of further investigation in terms of health effects, but also towards ethical issues (Ministry of Health and Care Services, 2011). The recently launched Norwegian Care Plan describes development of and an enhanced focus on environmental therapeutic methods through tutorial programs for staff (Ministry of Health and Care Services, 2015). Facilitated activities, such as with robotic pets, could create engagement during the interactions in people with dementia (Cohen-Mansfield, 2013) aiming to promote health in this patient group.

The purpose of interventions with Paro and other robotic animals is to provide social, psychological and physiological benefits (Shibata *et al.*, 2004). The growing focus on using robotic animals towards people with dementia has resulted in several studies, although there is little evidence of effects requiring further investigation (Broekens *et al.*, 2009; Kolling *et al.*, 2013; Mordoch *et al.*, 2013).

The main aim of this thesis is to investigate how an activity-based intervention stimulate engagement and promote health in elderly with moderate and severe dementia living in nursing homes after participation in a group activity with the seal robot Paro. We investigate how Paro-activity affected the participants during the activity (paper I) and how the intervention influenced participants during the course of the intervention (paper II and III). Although ethical issues are out of the main scope of this thesis, it is elaborated on in a separate chapter in the thesis

Based on the described issues in the introduction, the thesis will investigate the following research questions:

1. How could Paro affect behaviors in participants during group activity, and are there differences related to dementia severity? (paper 1)
2. Are there any effects on symptoms of agitation and depression after intervention with Paro-activity? (paper 2)
3. Are there any effects on quality of life and use of psychotropic drugs after intervention with Paro-activity, and are there differences related to dementia severity? (paper 3)

2. Background

2.1 Dementia

2.1.1 Definition, diagnosis and prevalence

The term “dementia” is an umbrella term for a variety of pathological conditions in the brain characterized by acquired and chronic cognitive impairment, impairment of emotional control and reduced functioning concerning daily living functions (Engedal and Haugen, 2009). It is a clinical syndrome caused by a detected or assumed organic brain disease being characterized by a progressive decline in cognition and level of function. Cognitive impairment includes disturbances in short-term and long-term memory, perception, language, intellectual, visuospatial and executive functions. Decline in functioning includes reduced capacity in performing daily tasks which leads to a challenge in maintaining an ordinary level of activity and change in behavior (Engedal and Haugen, 2009).

In Norway dementia is normally diagnosed by the Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems, ICD-10, classifying dementia as a syndrome caused by diseases from trauma affecting the brain, characterized by a chronic and progressive development. The following criteria for the dementia syndrome are extracted from the comprehensive description of the criteria for research (WHO, 1993):

A. Evidence of each of the following:

1. A decline in memory, which is most evident in the learning of new information. The decline should be objectively verified by an informant, or, if possible, by neuropsychological tests.
2. A decline in other cognitive abilities characterized by deterioration in judgement and thinking, such as planning and organizing, and in the general processing of information.

   The severity of the decline should be assessed as follows.

   Mild: The decline in cognitive abilities causes impaired performance in daily living.

   Moderate: The decline in cognitive abilities makes the individual unable to function without assistance of another in daily living.

   Severe: The decline in cognitive abilities is characterized by an absence, or virtual absence, of intelligible ideation.

B. Preserved awareness of the environment (i.e. absence of clouding of consciousness).

C. There is a decline in emotional control or motivation, or a change in social behavior manifest as at least one of the following:

   1. emotional lability;
   2. irritability;

3. apathy;
4. coarsening of social behavior.

D. For a confident clinical diagnosis, the symptoms described in A should have been present for at least 6 months; if the period since the manifest onset is shorter, the diagnosis can be only tentative.

Different brain diseases cause dementia of which Alzheimer's disease is the most common with a prevalence of about 70 % (Engedal and Haugen, 2009). Alzheimers disease, Vascular dementia, Dementia with Lewy Bodies, Parkinson's disease dementia, Frontotemporal dementia and dementia caused by alcohol abuse, constitutes more than 95 % of the dementia diagnoses for people older than 65 years (Engedal and Haugen, 2009).

Several factors could influence observed symptoms of dementia such as anatomical damage in the brain, personality, coping skills, stressors in the environment, somatic disease and progression of dementia (Engedal and Haugen, 2009). People with dementia have various capacities in how they master such symptoms, which also will appear differently related to dementia severity.

2.1.2 Symptoms describing dementia

Observed regular symptoms in people with dementia will vary according to type of dementia and dementia severity. These symptoms are characteristic and describe daily challenges and struggles in people with dementia. Engedal and Haugen (2009) divide these symptoms into three major groups describing cognitive, behavioral and motoric impairment:

Symptoms of cognitive impairment

Several symptoms describe cognitive impairment, such as impaired awareness, which include cognitive abilities as focused awareness and divided awareness. Impaired learning ability and memory mean that in general, memory requires previous learning. Memory is divided into short term and long term memory. Impaired language skills, also called aphasia, is seen as motoric aphasia (impaired production of words and speaking), sensory aphasia (producing too much words perceived as meaningless to others, in addition to strive with understanding oral and written language) and anomic aphasia (striving with denominations). Impaired executive function is lack of ability to perform practical actions despite remaining physical abilities and an understanding of the action, such as failing in planning order of actions or to raise the arm holding a glass towards the mouth to drink. Agnosia is seen as lack of ability to recognize a known object despite remaining sensory functions. Impaired intellectual capacity includes

impaired ability to reason and to think abstractly, but also in figuratively speaking, such as understanding irony, idioms and ambiguous remarks (Engedal and Haugen, 2009).

Behavioral symptoms

There are several symptoms of behaviors in dementia, often based on emotional changes in people with dementia. Such symptoms could be difficult to detect precisely through use of scales due to different methods and criteria resulting in various prevalence in different studies. Behavioral symptom of depressed mood is described with prevalence from five to 80%. Other symptoms are anxiety, catastrophic reactions, delusions, hallucinations, change in personality and change in diurnal rhythm. Several factors contribute to explain behavioral symptoms, such as delirium, personality, anxiety, lack of insight into own situation, disturbances in physical environment, interactions with others, dementia severity and type of dementia (Engedal and Haugen, 2009). Symptoms of agitation and depression will be further described in 2.2.2.

Symptoms of motoric impairment

Damage in the brain also causes muscle rigidity entailing struggle to move. Impaired balance often increase fall rate. Lack of controlling mechanisms of urine, and later also incontinence of feces (Engedal and Haugen, 2009).

2.1.3 Factors influencing people living with dementia

Living with dementia includes reduced capacity to connect various incidents and interpret surroundings, in addition to keep track of occurring incidents due to having time-lag between previous life and present life (Engedal and Haugen, 2009). Gradually loss of memory and abilities to associate incidents will lead to losing overview of and track of life. Applying life experiences, which usually helps to construe, now rather consist of failing memories and difficulties in problem solving (Engedal and Haugen, 2009). People with dementia mourn over loss of abilities, experience reduced safety and reduced empowerment (Ministry of Health and Care Services, 2015).

Although people with dementia often will find themselves psychologically elsewhere in time and space, they still have capacities and remaining functions which could be stimulated. A holistic view on people with dementia includes both the cognitive impairment and the remaining functions and resources. The enriched model of dementia, introduced by Tom Kitwood (1997), takes several aspects of dementia into account to approach the person with dementia (Brooker and Surr, 2007; Kitwood, 1997) describing the following factors.

- *Neurological impairment* – will affect the brain function and higher psychological functions, such as short- and long term memory, ability to understand and use language, ability to interpret situations, master planning of activities and to view things from other people's point of view.

- *Health* – Elderly people living in nursing homes will, in addition to having dementia, also be affected by illness, which will exacerbate their frail condition, such as dehydration, delirium, urinary tract infections and side-effects from medication, in addition to undetected pain, lack of hearing aids or adjusted glasses. If such conditions are not identified and treated, they could easily worsen daily life for people with dementia, also affecting willingness to participate in social activities or even to get on their feet from the bed or chair.

- *Biography – life story.* People with dementia are no longer able to trust their experience to solve situations and find meaning in incidents and situations, often due to loss of short-term memory. Shifts in time-lag will be confusing when present surroundings no longer are in accordance with previous life experience, producing insecurity, anxiety and restlessness. Memories from the life story are essential resources and need various reminders and stimulation in daily living, such as listening to familiar music, be able to tell someone stories, see pictures of or meet family and friends, smell familiar fragrances, or to interact with a pet or animal-looking doll to be reminded of previous pets.

- *Personality* – represent both strengths and vulnerabilities, which will affect the ability to cope with having dementia and reduced cognitive capacities. A controlling personality will most likely need to experience control in everyday life with dementia and may result in many struggles. A person who still leaves decision making to others might adapt more easily.

- *Social psychology* – contains the social and psychological environment in which people with dementia live. The environment could be experienced as supportive or devastating. When people with dementia display major language impairments or severe loss of memory, they are in great need of support, which primarily is conducted through interactions with staff or others.

Understanding how these factors influence people with dementia in terms of how they behave, feel and probably think will enable surrounding people to better understand and help people with dementia to live well (Kitwood, 1997). People with dementia have remaining abilities and resources, which need to be seen, valued and encouraged to be used in various ways.

2.2 Challenges in dementia care in nursing homes

People with severe dementia are in need of diurnal care, most of them living in NH (Engedal and Haugen, 2009; Strand *et al.*, 2014). Norwegian studies describe more than 80 % of NH residents to have dementia according to dementia rating scales (Bergh *et al.*, 2011; Bergh *et al.*, 2012; Selbaek *et al.*, 2007), although about half of the participants lacked a dementia diagnosis (Selbaek *et al.*, 2007). Mild dementia is described in 20-23 %, moderate dementia in 27-37 % and severe dementia in 34-50 % of NH residents with dementia (Bergh *et al.*, 2011; Bergh *et al.*, 2012; Selbaek and Engedal, 2012)

Norwegian NH have a variety of physical designs of buildings and numbers of floors. NH units are organized in regular units and special care units (SCU). SCU is a small unit adapted for people with dementia often including 7-8 residents, although such units are provided for only 25.5 % of the residents. Care and social activities are mainly provided by professional staff (Gjora *et al.*, 2015) as recommended in national dementia care plan (Ministry of Health and Care Services, 2007).

Small and adapted NH units can provide spatial orientation and accessibility for people with dementia, and homelike environments, neutral designs and low stimulus are associated with less behavioral challenges and less medication (Landmark *et al.*, 2009). However, a review describe physical surroundings inside NH units to have a higher focus on stimuli reducing measures compared with measures promoting thriving and well-being (Bergland and Kirkevold, 2011). In addition, the traditional prioritizing of personal care from staff is still rated as more important towards residents despite the increasing governmental attentions towards increased performances of social and physical activities in Norwegian NH, a finding which is negatively correlated with lower staff competence (Kjøs and Havig, 2015). This underpin a need for higher focus on social and physical activities towards people with dementia in NH.

2.2.1 Challenges in doing meaningful activities

Human beings, in general, are created to be active. In general, people's activities sustain or undermine their health and well-being (Wilcock, 1993), and to be engaged in activities is important for everybody's health and quality of life (Christiansen and Townsend, 2014). To perform various occupations in daily living is a central aspect of the human experience (Wilcock, 1993). Independent of cognitive impairment, people with dementia in NH are in risk of being offered too little activities in their daily life, even though they are capable of doing more activities than what they are participating in (Egan *et al.*, 2006; Harper Ice, 2002; Holthe *et al.*, 2007; Perrin, 1997).

Apathy is one of the behavioral symptoms in dementia resulting from the brain damage and related to dementia severity, therefore quite common in NH (Brodaty and Burns, 2012). One observational study describes how residents were waiting to be asked to participate being dependent on the staff's invitations, participation was passive and with little engagement (Holthe *et al.*, 2007). Many NH residents have reduced capacity to concentrate and little energy left to participate in any group activity or even to motivate themselves to get up from the chair. Observational studies describe how most residents spend most of the time of the day unoccupied, many alone in their rooms, unfortunately a reality for decades (Harper Ice, 2002).

Inactivity could be seen in several aspects. It might be due to an attitude in the unit where staff mainly focus on the cognitive impairment in people with dementia rather than exploring potential abilities or interests in performing occupations (Kitwood, 1997). It could also be caused by staff lacking knowledge on how to detect individual possibilities and/or how to stimulate people with dementia in occupations. Little activity might also be caused by an inner fear in people with dementia to fail when performing activities and to risk being exposed to correction in front of an audience, which can explain why some residents hesitate to participate when being requested (Egan *et al.*, 2006; Holthe *et al.*, 2007). Nevertheless, all human beings, even when having dementia, have a wish to engage in various occupations through the day, the week, the year exist, and this willingness could depend on demands of the occupation, encouraging environment, personal skills and resources (Backman, 2014). Facilitated activities or social interactions are described to produce episodes of lucidity in people with severe dementia when staff are aware of the need of not making demands (Normann *et al.*, 1998).

2.2.2 Challenges in emotions and behaviors

There has been an increasing research on emotional changes and behavioral symptoms in dementia to understand the occurring symptoms and the treatment, to alleviate sufferings in people with dementia and reduce burden in care givers (Engedal and Haugen, 2009). Such symptoms are often described as Behavioral and Psychological Symptoms in Dementia (BPSD) (Finkel, 1997). In this thesis the term neuropsychiatric symptoms (NPS) is used comprising a variety of characteristics evolving over time as NPS is the most common term used in recent articles (Gauthier *et al.*, 2010; Selbaek *et al.*, 2013).

NPS, such as depression, agitation, anxiety, apathy are additional symptoms and diagnoses in people with dementia. Several studies describe NPS in people with dementia in NH to be consistently high (Brodaty *et al.*, 2001; Selbaek *et al.*, 2013; Zuidema *et al.*, 2007) and evolving over time due to development of dementia (Gauthier *et al.*, 2010; Margallo-Lana *et al.*, 2001; Selbaek *et al.*, 2007). Studies of NPS in Norwegian NH reveal presence of agitation in more than half of the residents and symptoms of

depression to be present in 20-40%. The findings are in accordance with international studies (Barca *et al.*, 2012; Bergh *et al.*, 2012; Selbaek *et al.*, 2007).

NPS are driven by biological, psychological, psychosocial and environmental factors (Gauthier *et al.*, 2010) which have different causes, such as various physical ailments, undetected illnesses and pain (Volicer and Hurley, 2003), discomfort, multiple unmet needs, person-environment conflicts, and stress responses (Cohen-Mansfield, 2001; Ragneskog *et al.*, 1998), but also inactivity, leading to boredom as a result of no or few activities in NH (Cohen-Mansfield, 2013). Staff perceive such behavior as difficult to handle and complicated to treat (Cohen-Mansfield, 1995; Zimmerman *et al.*, 2005).

People with dementia affected by NPS experience great sufferings and require treatment (Cohen-Mansfield, 2001). Psychotropic drugs are often used as first choice to alleviate symptoms (Volicer and Hurley, 2003), although the efficacy of such treatment is limited, and the side-effects are potentially harmful (Ballard and Corbett, 2012; Salzman *et al.*, 2008) including higher mortality rates (Gill *et al.*, 2007). Hence, reviews on management of NPS recommend non-pharmacological interventions as first choice to treat NPS (Gauthier *et al.*, 2010; Salzman *et al.*, 2008). Assessment of possible causes towards NPS in an individual should be performed in advance of any treatment, in order to assess reversible factors and possible treatments (Gauthier *et al.*, 2010). Treatment with non-pharmacological interventions through participating in activities or occupations should be tailored based on previous and present interests and be facilitated according the individual's unmet needs (Cohen-Mansfield, 2013).

Measuring agitation and depression in people with dementia

Tools for measuring NPS in people with dementia living in nursing homes are mainly based on information from staff. The advantage of this practice is provision of observations made by professional carers in the unit, a practical solution due to the described prevalence of dementia in NH. However, proxy-measures rely on the observational skills in the observer, which is a challenge.

Tools measuring symptoms of agitated behavior

The term agitation includes behaviors like agitation, irritability, lack of inhibitions and excitability (Bergh *et al.*, 2012; Selbaek and Engedal, 2012). Measurement for research on symptoms of agitation through assessment scales have been developed, such as The Neuropsychiatric Inventory (NPI) (Cummings *et al.*, 1994), further developed for assessment by staff on nursing home residents (NPI NH version). NPI-NH assess frequency and severity in 12 domains of NPS, such as delusions, hallucinations, agitation/aggression, depression, anxiety, euphoria, apathy, disinhibition, irritability/lability, aberrant motor disturbances, sleep and appetite disturbance (Wood *et al.*, 2000). NPI is widely used in studies with NH participants. Another widely used tool in studies is The Cohen-Mansfield Agitation Inventory (C-

MAI) (Cohen-Mansfield *et al.*, 1989) which specifically assess frequency of agitated behavior on a 29-item Lickert scale to be rated by professional caregivers based on observations during the preceding two weeks. Both scales are translated into Norwegian. The ten most frequent behaviors from the C-MAI are developed into a scale, The Brief Agitation Rating scale (BARS) (Finkel *et al.*, 1993), which is used in the thesis and described in 3.4.2.

Tools measuring symptoms of depression
Several scales have been developed and translated into Norwegian. The Geriatric Depression Scale (GDS) (Yesavage *et al.*, 1982) developed as self-rated and widely used in research. The Norwegian version is recommended as structured interview of participants (Berentsen and Schimmer, 1995). GDS consist of 30 questions to be answered yes or no. In the thesis, we chose to use The Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos *et al.*, 1988), described in 3.4.2.

2.2.3 Challenges in sustaining quality of life and relative well-being

Symptoms of inactivity, apathy, depression and agitation are often related to dementia severity and of unmet needs in daily dementia care will influence QoL, as described above. Symptoms of agitation and depression are found to decrease QoL in dementia in several studies (Ballard and Margallo-Lana, 2004; Banerjee *et al.*, 2009; Beerens *et al.*, 2013; de Rooij *et al.*, 2011; Mjorud *et al.*, 2014b). Studies with NH residents describe contact with family and friends, participation in meaningful activities to influence QoL (de Rooij *et al.*, 2011; Drageset, 2004; Moyle and O'Dwyer, 2012; Moyle *et al.*, 2011). To be independent in daily living is also described as an important aspect to enhance QoL (Drageset, 2004; Moyle and O'Dwyer, 2012; Moyle *et al.*, 2011). When psychological and social needs are not being met in the daily living, people with dementia in NH will experience reduced well-being, more time socially withdrawn and lower QoL (Ballard *et al.*, 2001; Brooker and Duce, 2000; Kuhn *et al.*, 2005).

QoL is a subjective assessment of perceived quality of life on several areas in individuals including both positive and negative dimensions. World Health Organization (WHO) defined QoL as *"individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"* (WHOQOL, 1995), meaning that one has the capacity to carry out complex intellectual assessments relating to different areas in life. The concept of QoL is uniquely individual and is perceived as hard to measure. Measuring QoL is even more challenging in people with dementia due to them having cognitive impairment with deficits in attention, judgement and communication (Logsdon *et al.*, 2002).

Lawton (1994; 1997) explored QoL to include both subjective and social-normative criteria of the individual's behavioral and environmental situation. When taking dementia into consideration, four dimensions influence QoL in people with dementia:

- behavioral competence including social behavior, activities of daily living and cognitive performance,
- objective/external environment, including assessment of physical surroundings, the likings of or ability to orient in the living area,
- psychological well-being including both positive and negative affect states (emotions) such as ability to engage in positive pastime, and
- quality of life as perceived by the person with dementia.

This definition by Lawton (1994; 1997) is commonly accepted as a multidimensional concept of QoL and is used by most researchers investigating QoL in dementia (Logsdon *et al.*, 2002; Moyle and Murfield, 2013; Roen *et al.*, 2015).

Participation in different occupations as human beings is perceived as meaningful. Such activities will often provide interaction with others, experience of physical wellness, recreation of contact with life story, etc., which could promote health and thereby create well-being (Christiansen and Townsend, 2014). QoL encompasses residents' well-being (Kane, 2003), and an appropriate approach to better understand how people with dementia display satisfaction, such as during participation in an activity, could be a view through the term *relative* well-being (Hasselkus, 1998; Kitwood and Bredin, 1992). The term *relative* refers to morbidities like depression, anxiety and apathy (Kitwood and Bredin, 1992), additional diagnosis regularly affecting people with dementia (Engedal and Haugen, 2009). Although dementia involves a dismantling of the person, people with severe dementia can be in a state of relative well-being (Brooker, 2004). Indicators of relative well-being can be observed in people with dementia as self-confidence, relaxation, affective warmth, creativity and self-expression, showing evident pleasure, helpfulness, initiation of social contact, assertion of desire or will, social sensitivity, humor and ability to express a range of positive and negative emotions (Kitwood and Bredin, 1992). Other descriptions of relative well-being through occupations are observed in people with dementia as expressions of smiles, laughs, pleasant look or looking friendly, calmness, socializing, showing affection, etc. (Hasselkus, 1998). Focus on positive events promoting pleasant experiences and engagement in people with dementia increase arousal (Teri and Logsdon, 1991), which will influence well-being and increase QoL (Lawton, 1994).

Challenges with measuring QoL in people with dementia

Measurement through assessment scales have been developed for research on QoL in different cultures and address several facets of QoL in order to promote mental, social and physical well-being, in addition to investigate QoL in people with moderate to severe dementia through proxy measures (WHOQOL, 1995). Although research on QoL should be based on self-report measures (Banerjee *et al.*, 2009; Logsdon *et al.*, 2002), assessing affect states in measurement tools on QoL in dementia is challenging due to impaired memory, time perception, reduced capacity of having insights, in addition to impaired language skills (Banerjee *et al.*, 2009; Kane, 2003; Logsdon *et al.*, 2002). However, studies report satisfying results between self-report and proxy-measures of QoL in dementia (Logsdon *et al.*, 2002; Smith *et al.*, 2005). Proxy-based measures on QoL could provide valuable insights, but there are natural limitations regarding subjective aspects which implies careful use of such results (Bruvik *et al.*, 2012).

Measuring QoL in dementia should have higher priority in dementia care (Schölzel-Dorenbos *et al.*, 2007). There is a lack in NH studies of assessing QoL in dementia through formal scales which rather has been assessed through outcomes associated with QoL, such as level of depression or agitation (Ballard *et al.*, 2001; Cooper *et al.*, 2012; Moyle and Murfield, 2013). Symptoms of depression seem to have a clear pattern with poor QoL (Banerjee *et al.*, 2009; Logsdon *et al.*, 2002), and some studies describe agitation to be associated with lower QoL (Banerjee *et al.*, 2006; Mjorud *et al.*, 2014b; van de Ven-Vakhteeva *et al.*, 2013).

2.3 Health promotion in people with dementia

Health promotion was defined by World Health Organization (2009) in the Ottawa Charter in 1986 as *"..the process of enabling people to increase control over, and to improve, their health."* Although, in people having dementia, to control improvement of increasing health will be rather challenging. In this view, to stimulate social and personal resources in addition to physical capacities could improve health. The view of providing dementia care include strengthening various residual capacities in people with dementia, which is in accordance with present government priorities in society to deal with dementia as a great public health challenge (Ministry of Health and Care Services, 2007; WHO, 2015b). The present view in dementia care is to promote psychological and physical health in people with dementia by facilitating sense of empowerment, belonging and to experience meaning in life (Ministry of Health and Care Services, 2015).

People with moderate to severe dementia living in NH have capacities left in performing physical activities due to comprehensive impairment although being dependent on staff assistance. Activities focusing on strengthening remaining physical, psychological and cognitive functions contain a view of

adding meaning and support through health related interventions, as described above. Strengthening such aspects in the individual will promote health, as high-lighted in the Norwegian care plans on promoting dementia care (Ministry of Health and Care Services, 2007; 2015).

To promote health in people with dementia through meaningful activities, an individual care approach to value the individual's needs is necessary in addition to create engagement in daily activities. Theory on a person-centred care approach and a comprehensive approach towards creating engagement in people with dementia will add a foundation for caregivers in understanding how health promotion can be achieved in this patient group and will be used in this thesis to discuss findings associated with the Paro-intervention.

2.3.1 Person-centred care approach

In person-centred care (PCC) units in NH, staff will value people with dementia through focusing on the *person* having dementia, not through the traditional view with the disease and impairments. In PCC the person *itself* is of interest, containing a history of life, habits, personality and different interests (Kitwood, 1997). In a PCC approach the quality of the relations between staff and the person with dementia is of importance (McCormack, 2004). The late Tom Kitwood introduced PCC in dementia care by using the term "personhood", which is a value being given a person through interaction with others and characterized as recognition, respect and trust (Kitwood, 1997; Kitwood and Bredin, 1992). A PCC approach entails an enhanced focus on attitudes towards psychological needs of persons with dementia, and values the life history and preferences of the person having a dementia, to take the person's perspective in each situation, in addition to facilitate a socially stimulating environment (Brooker, 2004; Edvardsson *et al.*, 2008; McCormack, 2004).

Kitwood (1997) emphasized the caring environment's ability to stimulate well-being through meeting the person's psychological needs for comfort, occupation, attachment, inclusion and identity. This is of crucial importance for people with severe dementia, hence being core concepts in PCC (Brooker, 2004). People with dementia have a special need of love, and they often express a prominent need for care and trust, being emphasized in daily life relations. It is possible for people with dementia to experience a relatively high state of well-being if the caring environment is capable of meeting the person's psychological needs systematically and experience "personhood" (Kitwood, 1997). Having an overview of life history, remaining skills and preferences in each individual with dementia prepares the staff to facilitate and help the person to experience well-being. NH units rated with higher levels PCC seem to have significantly higher proportion of residents performing activities in daily living, in addition to keeping abilities longer (Sjögren *et al.*, 2013).

The quality of the psychosocial environment is pivotal in NH in terms of treating behavior, increase mood and create engagement, and is of significance in PCC (Brooker, 2004; Brooker, 2007; Edvardsson *et al.*, 2008; McCormack, 2004). To meet needs for comfort, the staff must ensure that all patients are cared for, feel safe, can relax and be calm, and are relieved from physical and emotional pain. And their need for activity be met by considering each patients remaining skills and interests, and facilitate appropriate activities in daily living. The need for inclusion can be met by appreciation, using humor and actively include patients in social settings for each feel belonging to the group. Intervention studies in NH units with PCC show improved QoL (Rokstad *et al.*, 2013) and decreased agitation in participants (Chenoweth *et al.*, 2009).

Several person-centred models or frameworks have been made through the years (Brooker and Surr, 2007; Edvardsson *et al.*, 2010; Edvardsson *et al.*, 2008; Kitwood, 1997; McCormack and McCance, 2006; White *et al.*, 2008). There is no single definition of a PCC approach, but researchers agree upon the following components being included in PCC for people with severe Alzheimer's dementia, summing up description of PCC:

> *…the recognition that the personality of the person with dementia is increasingly concealed rather than lost; personalization of the person's care and their environment; offering shared decision-making; interpretation of behavior from the viewpoint of the person; and prioritizing the relationship as much as the care tasks (Edvardsson et al., 2008), p 362).*

2.3.2 Stimulation of engagement in people with dementia

To promote health through a PCC approach, creation of engagement through occupations is of significance to create relative well-being in dementia (Hasselkus, 1998), and stimulation of engagement in dementia could be understood as a natural consequence of conducting PCC. The more impaired the more focus is essential in relations on waking up concealed functions in order to make the person try to keep contact with the inner self to feel valued. To participate in pleasant activities is valued as beneficial for people with in dementia and must be facilitated individually (Teri and Logsdon, 1991). People with dementia can be engaged with various, but facilitated and tailored stimuli (Cohen-Mansfield *et al.*, 2010a), and previous interests or past role identities in an individual are stimuli shown to impact engagement (Cohen-Mansfield *et al.*, 2010b).

Based on the relationship between adequate stimuli and reduced agitation, it is assumed that engagement must have been produced in order to affect an emotional change in people with dementia. This mechanism of engagement was investigated by Jiska Cohen-Mansfield et al. (2009) and engagement

defined as "*the act of being occupied with or interested with an external stimulus"* (p. 300). Dimensions of engagement were described in a theoretical framework launched in the model "*The Comprehensive Process Model of Engagement"* (Cohen-Mansfield et al., 2009). The model describes relations between attributes in constructs interacting and affecting the experience in an activity, which create engagement and changes in affection, which in turn influence expressed behaviors in the person (figure 1).

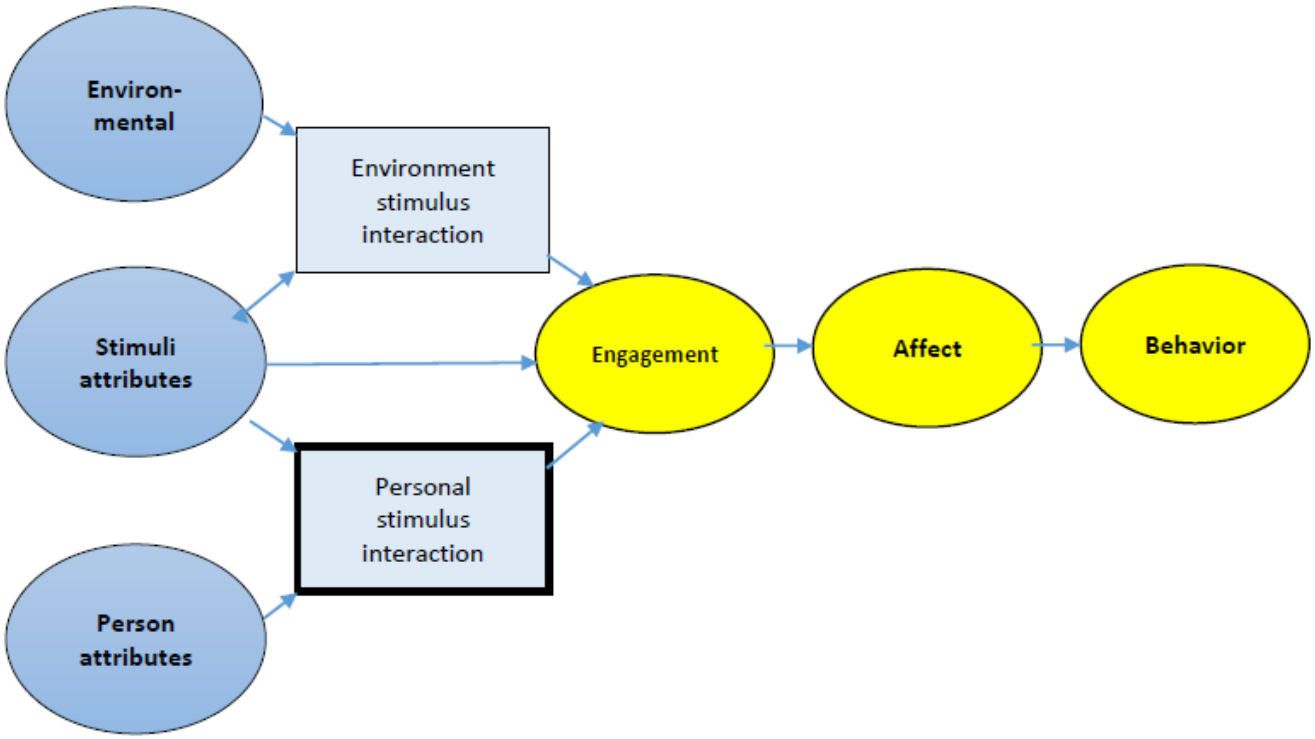

Figure 1: The conceptual framework concerning engagement of persons with dementia in "The Comprehensive Process Model of Engagement"

In the model interaction with a stimulus for a person with dementia will be affected by attributes in the environment (characteristics in the location, time of day, noise, social setting, how the stimulus is presented, etc.), in the person (how present and previous interest relate to level of engagement) and in the stimulus (level of social qualities, possible to manipulate, resembles previous work roles, etc.) (figure 1). There could also be an interaction between the environment and the stimulus, such as if an activity makes noise. During interaction with the stimuli, attributes of the chosen stimuli will create engagement in the person, particularly when using person-tailored stimuli, i.e. interaction with a visitation dog would most likely create engagement if the participant has premorbid likings for pets. The stimulus itself could

also create engagement. Interactions perceived meaningful will create engagement in the person, which in turn will influence the person through a change in affect, which in turn will influence the presentation of behaviors in the person (figure 1).

Engagement should be considered on the basis of five dimensions: *Rate of refusal* of the stimulus, *duration* of the interaction, *attention* towards the stimulus, positive or negative verbal, physical, expressive *attitude* towards the stimulus, and how the participant's *actions* was towards the stimulus. The latter dimension includes items to be observed, such as how the participant held, manipulated, talked to and talked about the stimulus, but also if the stimulus led to disruptive behavior or inappropriate manipulation of the stimulus. The most important dimensions of engagement of clinical interest seem to be refusal, attention and attitude (Cohen-Mansfield *et al.*, 2009).

Regardless of activity, the attitude of and skills in staff is essential when performing activities (Vatne, 2006) in addition to individually consider how often and for how long each activity should be performed (Cohen-Mansfield *et al.*, 2010a; Marx *et al.*, 2010). Activities performed to stimulate and engage could strengthen capacities in people with dementia and promote health.

2.4 Health promoting activities for NH residents

Environmental treatment is in general conducted in residential settings as kind of an activity-based treatment aiming to improve cognition, social skills and practical abilities in the patient, in addition to support sense of self and experience of mastering. The environmental milieu is created through interactions and relations between staff and residents (Vatne, 2006). Purposes in dementia care are to create meaning in daily life, distracts from sorrow and pain, physical exercise, curb unrest, etc. through individually and facilitated occupations (Brooker and Surr, 2007). Reducing NPS through non-pharmacological interventions aim at providing comfort and enhancing QoL (Kverno *et al.*, 2009).

Individually tailored activities are described to be the most suitable non-pharmacological treatment in this target group (Cohen-Mansfield, 2013; Gitlin *et al.*, 2008) which includes a wide range of approaches. Despite various research quality and possibilities of comparing the nature of interventions, several studies show positive outcome in addressing improved QoL and quality of care, in particular when interventions target social contact and meaningful stimuli or activity, and tailor the intervention to the individual (Cohen-Mansfield, 2001). Interventions are perceived beneficial when conducted in social settings making participants able to connect with others and the nature of the activity demands little need for instructions towards participants (Lawrence *et al.*, 2012).

Several psychosocial interventions have shown to reduce agitation and depression (Vernooij-Dassen *et al.*, 2010), interventions with music therapy have shown to reduce agitation (Cohen-Mansfield, 2013; Livingston *et al.*, 2014), interventions with sensory stimulation (Cohen-Mansfield, 2001; Livingston *et al.*, 2014) and massage (Cohen-Mansfield, 2013) have shown to reduce agitation, interventions with music reduced agitated behaviors (Cohen-Mansfield, 2001), while aromatherapy (Cohen-Mansfield, 2013; Livingston *et al.*, 2014) and light therapy (Livingston *et al.*, 2014) showed no evidence of efficacy. Reminiscence therapy show promising results regarding cognition and mood, although requiring stronger research design (Woods *et al.*, 2005). Doll therapy seems to have beneficial effects towards agitation and well-being, although stronger evidence is needed (Cohen-Mansfield, 2013; Fernandez *et al.*, 2014; Higgins, 2010). Towards people with severe dementia most studies examined sensory stimulation, although a majority with low quality. In this target group aromatherapy seems to produce evidence in reducing agitation, and music therapy seems to give some evidence of reducing agitation and apathy, while the positive results on light therapy had low evidence quality (Kverno *et al.*, 2009).

Reducing stress in residents with severe dementia is of high importance in NH and highlight the need in staff for strategies to reduce distress in daily care (Kverno *et al.*, 2009). Reviews describe a variety of interventions with staff care training in communication to produce increased QoL and improved communication skills (Vernooij-Dassen *et al.*, 2010), and PCC and communicative training to improve agitation (Livingston *et al.*, 2014).

However, there is still a need for well-designed interventions to strengthen the evidence base for psychosocial interventions in dementia care (Vernooij-Dassen *et al.*, 2010). In addition, there is scarce evidence regarding long-term effects of non-pharmacological interventions (Livingston *et al.*, 2014), and studies often lack measures on long-term effects (Cooper *et al.*, 2012).

Non-pharmacological interventions can be performed individually or through group activity, depending on the social capacity of the participant and the nature of the activity (Cohen-Mansfield, 2013; Vernooij-Dassen *et al.*, 2010). Group activities with several participants enables development of social interactions as additional effects of an activity (Engedal and Haugen, 2009), such as during dancing or in a reminiscence group activity.

2.4.1 Group activities as intervention in NH

Some activities, such as aromatherapy or hand-massage, are by its nature a one-on-one activity, while music, reminiscence and training are well suited as group activities. Facilitating an activity in a group setting can stimulate conversations and social interactions in participants, which is an important added

value from an activity. In order to master such a setting, communicative skills and engagement in staff are valued as factors of success (Lawrence *et al.*, 2012; Vatne, 2006).

Group based activities are common in NH and considered as practical and effective when several residents can be included simultaneously. Most resident-oriented interventions are described to encourage participants to interact with each other and express emotions or from life story, perceived as being meaningful, but also in producing beneficial side-effects of an activity (Lawrence *et al.*, 2012). In addition, perception of thriving in social groups stimulates secretion of the hormone oxytocin producing stress-reducing effects in human beings (De Dreu and Kret, 2015; Heinrichs *et al.*, 2003; Uvnäs-Moberg, 1998) working as a silent, but significant consequence of social stimulation.

Several non-pharmacological interventions have been conducted in recent years as treatment in people with dementia in NH. One kind is human-animal intervention (HAI), which has been conducted in NH for many years. Previous research in HAI and robot-assisted intervention are presented in the following.

2.5 Previous research on human-animal and human-robot interventions

2.5.1 Human-animal interventions in nursing homes

Interaction with robotic animals is based on HAI. Contact with animals has long been known to be emotionally beneficial to people and have therefore been used in health care institutions for centuries (Brodie and Biley, 1999; Levinson, 1962). Intervention-studies including dog-related stimuli on engagement of elderly with dementia, like using a plush dog (toy) or a puppy video in addition to real dogs reveal increased engagement (Marx *et al.*, 2010).

Studies involving HAI conducted in NH on residents with dementia have shown reduced symptoms of agitation and increased social interaction, (Churchill *et al.*, 1999; Richeson, 2003) and reduced symptoms of depression (Moretti *et al.*, 2011; Mossello *et al.*, 2011). A calming effect is seen, and also reduced anxiety and depression (Allen *et al.*, 2002; Barak *et al.*, 2001; Barker and Dawson, 1998; Bernstein *et al.*, 2000; Cole *et al.*, 2007; Colombo *et al.*, 2006; Crowley-Robinson *et al.*, 1996; Enders-Slegers, 2007; Kramer *et al.*, 2009). The calming effect is explained by increased oxytocin-levels altering the stress-response in humans producing reduced blood-pressure from both tactile stimulation and social interactions during the intervention (Odendaal and Meintjes, 2003; Uvnäs-Moberg, 1998). Few studies have investigated the effect of animal-assisted interventions on mood in dementia (Bernabei *et al.*, 2013), although one study reports that it reduces apathy, but with no effect on depression (Motomura *et al.*, 2004), while another study suggests it reduces sadness and increases pleasure (Mossello *et al.*, 2011). One recent study report effects on depression at follow-up after intervention and long-term effect on

QoL from intervention in NH with visitation dogs (Olsen *et al.*, 2016), one study report effect on reduced loneliness (Banks and Banks, 2002). Reviews on HAI for elderly with dementia conclude that it could reduce aggression and agitation, and promote social behavior (Filan and Llewellyn-Jones, 2006; Perkins *et al.*, 2008; Williams and Jenkins, 2008) and one conclude with influence on psychological well-being and reduced loneliness (Brodie and Biley, 1999).

Evaluations from HAI paved the way for developing and introducing robotic animals towards people with dementia in NH.

2.5.2 Robot-assisted interventions

An alternative to the human-animal approach among elderly is the use of welfare technology, such as robotic animals, suggested as replacement for living animals, due to challenges with residential animals and animal welfare, allergic reactions towards animals and fear of live animals (Libin and Cohen-Mansfield, 2004). These robots are developed as socially assistive robots (SAR) or emotional robots (Kolling *et al.*, 2013) aiming to bring emotions forward during interactions. Interactive human-oriented robots are, in general, developed to facilitate the person's positive experiences through technological tools in order to influence life skills, such as mediate communication, stimulate the person physically and mentally, be an interactive device and be a human companion in special situations and in life circumstances (Libin and Libin, 2005). This will be further described in 2.5.3.

In recent years, several SARs have been developed for this purpose and potential effects been investigated, such as on the metal robotic dog AIBO (Kramer *et al.*, 2009; Shibata and Wada, 2011; Tamura *et al.*, 2004). Robot-assisted therapy seem to have similar effects on people with dementia as with animal-assisted activity/therapy. Intervention studies using AIBO compared with a real dogs describe both interventions to have effects like general attachments and improvements in loneliness (Banks *et al.*, 2008) and increased social contact among patients with severe dementia (Tamura *et al.*, 2004). Another SAR is the robotic cat NeCoRo having a fur, and sounds and looks like a real cat. An intervention study with both NeCoRo and a toy cat shows a decreased agitated behavior and increased pleasure and general interest (Libin and Cohen-Mansfield, 2004). A robotic dog and cat are shown in figure 2.

Figure 2: The robotic dog, AIBO and the robotic cat, NeCoRo.

2.5.3 The emotional seal robot Paro

One of the most popular robotic animals to be used in dementia care is the robotic baby seal Paro (Paro is an acronym for personal assistive robot) (Chang and Sung, 2013)(figure 3). It was developed to substitute a pet, but was further developed in order to appeal towards and maintain long-term interactions with people with dementia (Shibata *et al.*, 2004). Paro's characteristics include the shape and size of a baby harp seal, length about 50 cm and weighs 2.7 kg. It has actuators moving the swiveling head, two eyelids, two front flippers and a rear flipper, and speakers that make the authentic sound of a real baby harp seal. Paro is a highly advanced, adaptive robot with artificial intelligence software. Light sensors captures external movements, and microphones receive verbal communication, making Paro able to interact and recognize voices and respond to repeated words. Its artificial and anti-biotic fur contains sensors capturing tactile stimulation and create interactivity between users and the robot as it responds to the user's repetitive motions, such as stroking (Shibata *et al.*, 2004).

Figure 3: The robotic seal, Paro, and an example of interaction with Paro.

Benefits from of Paro-activity

According to the Japanese inventor of Paro, Takanori Shibata, Paro-activity is based on human-animal interactions aiming to provide social, psychological and physiological benefits (Shibata and Wada, 2011;

Shibata *et al.*, 2004) which are described in several studies (see 2.5.1). *Social benefits* could be provided through social activities, verbal/non-verbal communication (Chang *et al.*, 2013; Robinson *et al.*, 2015a; Robinson *et al.*, 2013; Takayanagi *et al.*, 2014). *Psychological benefits* could be provided through experience comfort and joy in the activity (Chang *et al.*, 2013; Shibata *et al.*, 2004) and experience of engagement in an activity (Cohen-Mansfield *et al.*, 2010a). *Physiological benefits* could be provided through sensory stimulation, such as petting, kissing and hugging Paro, resulting in stress-reduction measured as decreased levels in cortisol (Shibata *et al.*, 2004) and in blood pressure and heart rate (Robinson *et al.*, 2015b) in participants. These three described benefits are in line with the overall theoretical approach in the thesis; to promote health and create engagement in people with dementia through influencing residual capacities (WHO, 2009).

The use of Paro

Paro is recommended to be used in limited periods of time, and staff should be present when people with dementia interact with it to reduce potential misinterpretations of the robotic animal (Shibata and Wada, 2011). There are several ways of having Paro, such as a pet at home, or as an engagement tool in daily life in NH (Calo *et al.*, 2011; Shibata and Wada, 2011).

Paro looks like a baby seal and is classified as a non-familiar animal (Shibata *et al.*, 2004). A cross-cultural test concluded with widely acceptance of Paro, particularly in Western countries, where animals as pets have been common through centuries (Shibata *et al.*, 2009). Paro resembles a pet, but not a common pet, such as a cat or a dog. The seal robot will therefore not give an illusion of expected behaviors from people interacting with it, in contrast to expectations from robotic animals resembling familiar pets, such as dogs and cats. Most users have scarce experience with or knowledge of seals, hence, people usually are unable to compare it with real animals, which is why Paro is given higher evaluations compared with robot cats or dogs (Shibata and Wada, 2011).

Paro is an emotional robot developed to affect people during interactions (Kolling *et al.*, 2013) and it gives the *illusion* that it is responding to its environment during interactions, such as through talking or petting (Shibata and Wada, 2011). This illusion is also meant to make people with dementia develop a kind of companionship with Paro, hence ethical issues will arise. Ethical issues are dealt with in 4.1.

2.5.4 Previous research on Paro

In general, studies investigating psychological, physiological and social impact from the seal robot Paro used in interventions on elderly with dementia in NH show corresponding findings. Many of the studies that will be presented in this thesis were found through reviews (Bemelmans *et al.*, 2012; Broekens *et*

al., 2009; Mordoch *et al.*, 2013) published at the start of this project, in addition to looking through studies included in the reviews ("snowball effect"). Book-chapters and conference proceedings were also read to establish an overview of the research field. Literature searches were made in several databases: PubMed, Web of Science, PsychNET, in addition to Google Scholar. Key words for search were: *dementia, Paro, robot, robot/robotic seal, robot therapy, nursing home, intervention, group activity*. The further presentation of intervention studies with Paro in this chapter, is narrowed to include only peer-reviewed studies aiming to ensure satisfying quality of the previous research, regarding methods and results in particular. Studies with both group setting and individual interaction are included. No design was excluded due to the expected limited amount of peer-reviewed studies with Paro. In general, studies have various sample size, frequency of sessions during the intervention period and duration of the intervention, making comparisons of findings quite difficult. The studies are presented in table 1 divided into RCTs, studies without control group, and studies including staff-participation. The last page of table 1 present reviews on SARs including studies on Paro.

Reviews including studies on Paro

Reviews of interventions with social robots, including Paro, contain peer-reviewed articles, but mostly non-peer-reviewed papers or conference proceedings, and are presented on the last page of table 1. An early review including several SARs focuses on the companion function and describes positive effects on health and psychological well-being of elders, such as improved mood, loneliness and social connections (Broekens et al., 2009). Other reviews describe findings on SARSs, such as AIBO, NeCoRo and Paro, to be positive findings on increased social interaction, improved communication (from Paro), reduced anxiety, depression, agitation and stress (Bemelmans *et al.*, 2012; Kachouie *et al.*, 2014; Mordoch *et al.*, 2013). The most recent review describe SARs in general to potentially enhance well-being and decrease workload for nurses (Kachouie *et al.*, 2014). However, studies with more robust research design and larger samples in order to create evidence-based knowledge in this field are requested (Bemelmans *et al.*, 2012; Broekens *et al.*, 2009; Kolling *et al.*, 2013). Long follow-up measures after implementation studies in dementia are in general needed (Wang *et al.*, 2012)

Paro-studies investigating behaviors associated with NPS

Several studies have been conducted to investigate different behaviors, which could be associated with neuropsychiatric symptoms in dementia. These studies often describe psychological and social effects or changes in the participants.

Table 1: Overview of peer-reviewed studies with Paro

Study	Sample/N	Design	Intervention/duration	Outcome measures	Main findings
Randomized controlled trials (RCT)					
Moyle et al (2013)	1 NH, 2 groups, Australia, n=18	Pilot randomized cross-over design, Quantitative data.	Group activity with Paro, compared with reading group.	Assessments of QoL scale, anxiety scale, apathy scale, depression scale, wandering scale.	Moderate to large clinical influence on QoL in Paro compared with reading groups, in addition to higher pleasure scores.
Robinson et al (2013)	Hospital and rest home, New Zealand, n=40	Randomized controlled trial. Quantitative data.	Free interaction with Paro or visitation dog for 1 hour/twice a week/12 weeks.	Assessments of loneliness scale, depression scale, self-rated QoL scale and proxy-rated QoL. Behaviors noted.	Participants had significantly decrease in loneliness after intervention with Paro, and they talked to and touched Paro significantly more than dog. Conversations of Paro occurred more than with the dog. Discussion of Paro involved more participants than of the dog.
Takayanagi et al (2014)	2 NH units, Japan, n=30	Randomized controlled trial, control group with stuffed toy Lion. Time sampling method produced quantitative data.	Individual interaction in participant's room. Video recording of the 6 first minutes of interaction, behavioral analysis of used.	Frequencies of responses to Paro or Lion. Stratified analysis on dementia level (mild/moderate, n=19 = M-group, and severe, n=11 = S-group).	All: Highest frequency of talking to and laughing with Paro, more positive changes in emotional expressions with Paro. M-group showed more negative emotional expressions towards Lion than Paro, significantly higher frequencies of touching/stroking, frequencies of talking to staff, response to staff initiative when with Lion. S-group showed most neutral expressions with Lion. All participants showed greater interest for Paro than Lion.
Valentí Soler et al (2015)	NH, n=211 and day care center, n=37, Spain.	Pilot RCT with 3 arms. Units randomized to one of the three parallel arms, 2 fases. Blind raters.	2 days/week/3 months. Intervention in 2 fases: Fase 1 with Paro, NAO (humanoid robot) or control. Fase 2 with Paro, dog or NAO. Day care center: Fase 1 with NAO and Fase 2 with Paro.	Assessments from dementia deterioriation scales, agitation scale, apathy scales and QoL scale.	NH fase 1: Paro group had improvement in apathy, NAO group some decline in cognition. Fase 2: Decrease in QoL. Day care center fase 1: Improvement in NPI irritability and total score. No differences in fase 2.

Study	Sample/N	Design	Intervention/duration	Outcome measures	Main findings
Published studies without control group					
Bemelmans et al (2015)	6 different units from 3 NH, Netherlands, n = 71 (inclusion criteria of aggressive behaviors)	A multicenter quasi-experimental time series ABAB-study, within-subject comparison. Quantitative data. Short-term assessments.	1. Therapeutic purpose + 2. Facilitate daily activities (A-study) or usual care (B-study), one month in each phase, total duration 4 months. 86 interventions conducted (69 with therapeutic intervention)	Goal attainment scale (IPPA) and Mood scale (Coop/Wonca).	Therapeutic-related intervention showed effect, while the care support-intervention did not. Combined measures show significant effect from the ABAB-study. No differences associated with dementia severity.
Shibata et al (2004)	2 units, health service facility, Japan, n=23	Between-subject. Quantitative data.	Free interaction for 1 hour/4 days a week/3 weeks. Comparing Paro and placebo toy seal.	Face scale, Profile of moods (POMS).	Both groups report improved mood. Scores of depression-dejection decreased. Group with placebo Paro kept interest in the seal toy.
Wada & Shibata (2008)	2 units in NH, Japan, n= 12	Observation study. Case studies. Within-subjects repeated measures. Qualitative and quantitative data.	Free interaction with 2 x Paro, placed on a table through 9 hours daily (08.30-18.00)/2 months. Video recordings during 6 days pre intervention, early and late during intervention time.	Observations from video recordings. Urine tests of stress-related hormones.	Social interactions increased through interaction with Paro. Two residents broke barriers in communication through Paro. Urine tests 4 weeks after interactions ended show statistically significant stress reduction.
Shibata et al (2009)	7 countries, n=1400	Survey. Questionnaire offered after contact with Paro up to 30 minutes.	Subjective evaluation of Paro (displayed at exhibitions in 7 countries) worldwide (Europe, Asia and North-America).	Survey resulted in a component analysis.	Women and people liking animals rated Paro highest. Two factors, 1) Comfortable feeling like interacting with real animals, and 2) Favorable impression to encourage interaction. UK, Sweden and Italy rated factor 1 highest, while Japan and South Korea on factor 2. US and Brunei rated both factors highly.

Study	Sample/N	Design	Intervention/duration	Outcome measures	Main findings
Chang et al (2013)	NH, Indiana, USA, n=10	Observational study. Qualitative data.	Weekly interactions in group with Paro and therapist for 8 weeks.	Behaviors analyzed after video recordings.	Significant factors that support the successful use of PARO are mediation of the therapist, the individual interpretations of PARO by different participants, and the context of use.
Klein & Cook (2012)	NH units, Germany (DE), n=62 and United Kingdom (UK), n=5	Ethnographic study (UK), observations and interviews, video recordings/ protocols (DE). Qualitative data.	Group discussions of Paro through 5 sessions with therapist (UK). 5 groups with Paro (n=38) and 1 group (n=24) with toy dinosaur (Pleo) with social work students (DE)	Observations and participant expressions into findings.	Maintained observation of Paro through sessions. Positive interactions led to lucid moments. Emotional robots (Paro & Pleo) revealed reactions, such as touching, mimic expressions, verbalization – also similar to how people talk to babies, stimulation of social interactions – also reminiscence of pets, caring behavior.
Klein et al (2013)	NH units, Denmark (DK), Germany (DE) and UK	Single-case reports. Qualitative data.	DK: Questionnaire to staff after Paro-course. DK: Observations of video recordings of group activities. UK: Observations of group interactions.	Characteristics of Paro-experiences in three EU-countries.	Common findings in three studies, according to Klein & Cook, 2012. Suggested principles for utilizing Paro activity in groups or individually: Facilitator skilled in dementia and in communication. Small groups of max. 5. Quiet location, etc., in addition to principles in how to use Paro. Basic knowledge in organization.
Robinson et al (2013)	1 NH, SCU, New Zealand, n=10	Cross-sectional study. Video recording. Quantitative and qualitative data.	Paro or humanoid robot (Guide) introduced to participant alone or with relative, encouraged to interact with robot.	Coding/counting numbers of smiles, touches and talking to robot. Coding of open-ended questions from video rec.	Favorable reactions to Paro. Residents smiled, touched and talked to Paro significantly more than Guide. Paro found to be more acceptable among participants, relatives and staff. Paro's noise found to be distressing for residents.

Study	Sample/N	Design	Intervention/duration	Outcome measures	Main findings
Robinson et al (2015)	NH, New Zealand, Observation: n=20 (residents) Interviews: n=16 (residents) n=21 (staff)	One group, observational study Interview with most participants and staff. Qualitative data.	Free interactions in group with Paro or visitation dog for 1 hour/twice a week/12 weeks. *(ref. Robinson et al, 2013, RCT-study)*	Characteristics on engagement, treatment of Paro and social attributes of Paro.	Six out of 20 refused Paro. Some residents found to relate emotionally with Paro, treated Paro as agent. Paro also treated as a robot, an artificial object. Paro worked as a social facilitator, served as an ice-breaker in and generated communication. Staff found residents to enjoy sharing, interacting with and talking about Paro.
Sung et al (2015)	NH, Taiwan, n=12	One-group pre- and posttest design. Quantitative data. Pilot study	30 minutes group therapy twice a week for 4 weeks.	Assessment of communication and interaction skills (ACIS-C) and the Activity Participation Scale.	Skills in communication and interaction and activity participation significantly improved after 4 weeks.
Robinson et al (2015)	NH, New Zealand, n=21	Repeated measures within-group design. Quantitative data.	Blood pressure (BP) measured 3 times: Before, during and after group interaction with Paro.	Blood pressure (systolic and diastolic) and heart rate?	Both systolic and diastolic BP and heart rate changed significantly over time. Systolic and diastolic BP decreased significantly from baseline to during interaction, while diastolic BP increased significantly after withdrawal of Paro.
Studies including staff-participants on Paro					
Gelderblom et at (2010) Bemelmans et al (2013)	Staff from 3 NH, Netherlands, n=30 Staff from one additional NH participated in the same study from Gelderblom et al (2010).	"Metaplan" session, focus group approach. 3 meetings in each NH, totally 9 or 12 meetings. Qualitative data.	Staff should specify goals, target groups and environments for intervention. To collect intended effects and added value from Paro intervention	RCT-preparations, defining goals for intervention with Paro. Description of goal, target group, environment and how care-staff should act to pursue effective application of a robot system.	Expectations from staff regarding prioritized goals in use of Paro as interventions: 1. Could be used to apply therapeutic purposes (outcome=behavioral change, depression, medication), 2. To facilitate daily care activities. 3. To support social visits (outcome for intervention 2+3= goal attainment scale + change in behaviors). Application of and supporting activities practically described for staff.

Bemelmans et al (2016)	3 small scale psychogeriatric care units, NH, Netherlands, n=23 residents (Based on results described above)	Three arms study: 1. Therapeutic purpose 2.Facilitate daily activities 3. Support social visits. Interview with staff. Qualitative data.	Individual sessions of 10-15 min., qualified participants interacted once or twice/week for 3 weeks. Individual goals. Totally 71 sessions. Registration form for each session, interviews with care staff.	Registration of experienced added value described in forms by staff, transforming experiences to a scale. Statements from care staff.	Staff rated practical applicability high and strongly correlated with added value. Therapeutic intervention (1) most promising intervention (activate, liven up, relaxation), to support of family visits (3) least. Interventions considered to be of added value for the provided care. Aims having therapeutic effects could be well implemented in daily care. Ethical issues were raised by staff and family members.

Reviews on interventions with SARs including Paro				
Study	**Papers & quality**	**Study selection**	**Main findings from Paro-studies**	**Conclusions**
Broekens et al (2008)	43 papers including 23 papers on Paro. None peer-reviewed papers.	No RCTs found. All studies reporting effects were included. Aim: Focus on health- and psychological well-being on elderly.	Patterns: Majority of papers on Paro and AIBO, most studies conducted in Japan. Most studies on elderly in NH. Many studies indicate positive effects on mood, loneliness and social connections with others. Some evidence of positive effects from companion robots towards elderly.	Lack of robust methodology (control conditions, long-term measures, small samples, poorly described experiment) and difficult to conclude on findings. Limited strength of evidence. Methodological problems: Need for control groups, replication, clearer study design, larger samples, long-term effects.

Study	Papers & quality	Study selection	Main findings from Paro-studies	Conclusions
Bemelmans et al (2012)	17 studies on 4 robotic pets. 30 papers on Paro: 26 papers divided into 5 Japanese studies on Paro. 2 peer-reviewed papers.	No RCTs on Paro. Aim: To investigate what is published, no studies excluded. Formal assessments of methodological quality found to be of little value.	2 typical studies found (Wada&Shibata): One with 14 elderly interacting 1h/twice a week up to one year. Other study: 12 elderly interacting with Paro 9h/day during 2 months. Paro stimulated communication, social interaction, psychological improvements. Physiological stress reduction. Findings described in several papers. Three other studies, small samples, qualitative data from observations. Paro described to stimulate conversations, be a social mediator, bring out emotions.	Effects/effectiveness not proven comprehensively. Much positive findings reported, although lack of methodological quality (small samples, short durations, no control group, no randomization). Added value must be clarified. Many explorative studies. The development seems to provide a potential for provision of care and QoL. Legal and ethical issues needs investigation.
Mordoch et al (2013)	21 studies on robotic pets. Paro: 11 papers, 3 peer-reviewed papers.	No RCTs on Paro. Aim: Review literature and determine efficacy within elderly with dementia. Determine future directions in area.	There is potential for using commitment robots towards elderly with dementia. Paro demonstrated specific effects in areas of affect regulation, social interactions, decrease in psychological stress and physiological stress. Indication of less burnout in staff.	Difficult to understand study design in papers, overlapping studies and papers. Robust studies are required, often small samples, lack of controls, difficult to replicate. Need for peer-reviewed publications of studies and of ethical considerations
Kachouie et al (2014)	86 papers from 37 studies on 13 socially assistive robots (SAR). Paro: 9 studies published in 43 papers, 5 peer-reviewed papers.	No RCTs on Paro. Aim: Overview of published studies with a holistic viewpoint on SARs. Effectiveness evaluated according to constructs of well-being.	Mostly Japanese studies found on Paro. In general, SARs could potentially enhance well-being and decrease workload for nurses. Need for construct to map physical and physiological well-being of elderly participants.	Various quality of studies making comparison and generalizability difficult, ten areas described regarding quality, such as low samples and lack of controls. Need for triangulation to improve understanding. Most studies did not pay attention to novelty or Hawthorne-effects. Welfare technology should be developed in a person-centred perspective.

The first two RCTs with Paro were published in 2013. One of these found participants in the Paro-group to have more social interactions with other participants compared with a visitation dog, but found no effect on symptoms of depression (Robinson *et al.*, 2013). The other, a pilot RCT, showed increased pleasure scores and less anxiety in the intervention group compared to a social group activity, but found no effect on depression (Moyle *et al.*, 2013). The next RCT, published in 2014, describe effects from individual interaction with Paro on frequent talking, positive expressions, and laughing from individual interaction with Paro compared to interaction with a stuffed toy lion. This study is one of the few which stratified analysis according to severity of dementia finding participants with severe dementia to have more active interaction with Paro (Takayanagi *et al.*, 2014). In 2015, a large multicenter three-armed RCT including both day care centers and NH found participants in the Paro-group in NH to have improvements in apathy, while participants from the day care center showed improvement in irritability and total score investigating NPS (Valentí Soler *et al.*, 2015).

A study comparing interaction with Paro in one group with a toy baby seal (placebo) in the other group found improved mood and decreased depression in both groups during three weeks (Shibata *et al.*, 2004). Another observation study including repeated measures had explored longer time of interaction for participants when Paro was placed on a table for 9 hours during 2 months. Video analysis revealed increased social interactions and two participants broke communication barriers through talking to Paro (Wada and Shibata, 2008). Another descriptive study found participants to express reminiscence of pets, touch and mimic, and increased social interactions also included lucid episodes, a phenomenon only described in this study. Paro was also described to enhance communicative skills through being a trigger to start conversations and interactions which would not otherwise take place (Klein and Cook, 2012). Studies without control of Paro in group settings in NH demonstrate increased interactions between residents and Paro, but also increased interaction among individuals in group settings, which are additional outcome from group settings with Paro (Chang *et al.*, 2013; Klein and Cook, 2012; Robinson *et al.*, 2015a; Sung *et al.*, 2015).

In HAI, physiological effects are described, such as increased oxytocin levels produce stress-reducing effects, as described in 2.5.1. In Paro-studies, physiological changes in participants have been investigated only in a few studies and without control group. One study showed significantly reduced stress levels through reduced cortisol-levels in urine, even 4 weeks after end of intervention (Wada and Shibata, 2008). This study differs from other studies due to having an intervention of 9 hours duration displaying Paro on a table in the unit available for free interaction of residents, four days a week during 4 weeks. Such a design produce an intensive interaction compared with most other Paro-interventions, as

described in table 1. Another recent study measured systolic and diastolic blood pressure and heart rate (pulse) in participants before, during and after interaction, found a significant decrease from baseline to during interaction. Diastolic blood pressure increased significantly after end of interaction (Robinson *et al.*, 2015b).

Paro-studies investigating QoL

Several review studies consider robotic pets as possible tools to enhance QoL based on findings which can be associated to influence QoL (Bemelmans *et al.*, 2012; Huschilt and Clune, 2012). The pilot RCT of Moyle et al. (2013) using the seal robot Paro revealed a moderate to large clinical improvement on QoL, while the RCT of Robinson et al. (2013) report a non-significant improvement of Paro on QoL, although this study found effect on decreased loneliness. Additionally, a large RCT, published in 2015, with group-activity with Paro found decreased QoL compared with control group (Valentí Soler *et al.*, 2015). There is still little knowledge of the mechanisms in how SARs influence QoL (Broekens *et al.*, 2009; Mordoch *et al.*, 2013). Although several non-pharmacological interventions aiming to enhance QoL in dementia have been conducted, more knowledge and further research in general is needed (Cooper *et al.*, 2012).

Staff evaluations of Paro

A Dutch study has focused on staff expectations towards using Paro in interventions in dementia care. Two papers describe preparations for a RCT including staff from 3 NH (Gelderblom *et al.*, 2010) or with one additional NH, totally 4 NH (Bemelmans *et al.*, 2013). Staff described interventions with Paro to be applied in therapeutic purposes, to facilitate daily care provision and to support social visits. In addition, application of and supporting activities with Paro were practically described for staff (Bemelmans *et al.*, 2013; Gelderblom *et al.*, 2010). These three described intervention types resulted in a three-arms study. Interviews with staff rated therapeutic interventions as most promising intervention, and possibilities with Paro to activate, liven up and relax participants were described to produce most added value from the intervention towards participants (Bemelmans *et al.*, 2016).

2.5.5 Research gaps and aims of the thesis

The review of peer-reviewed published studies of Paro reveals several gaps in the research. Studies with RCT-design were scarce on robotic pets in general. No RCTs were published on Paro-interventions when the Paro-intervention in this thesis started in 2013. However, various conference papers and proceedings provide professional insights into the field, although bearing the mark of poor research quality, as stated above. Finally, almost no studies have follow-up measures for investigating long-term effects of the interventions.

One of the aims of non-pharmacological interventions is to enhance QoL, although no RCTs yet have succeeded in demonstrating effects on QoL from Paro-interaction. There are only a few RCTs reporting effects on outcome measures, such as on reduced symptoms of agitation and depression from Paro-studies in dementia care. There is also a lack of systematic descriptions of all occurring behaviors during interactions with Paro, in addition to describe how Paro-interaction create engagement in people with dementia.

Although some RCTs have been published the last three years, there is still need for more evidence in this field to investigate how and if Paro has any effect on frequent behaviors in NH residents, such as agitation and depression. Such knowledge is necessary when considering Paro as a possibly favorable non-pharmacological treatment compared with pharmacological treatment in dementia. Taking the present view on dementia care from white papers, there are no Paro-studies describing potential health promotion in participants, which is the overall aim in the thesis.

The main aim of this thesis is to investigate how an intervention with Paro in a group activity could promote health in elderly with dementia in nursing homes.

The objectives of the individual papers were as follows:

1. To investigate what mood, engagement and social interactions arise in Paro-groups and differences in behaviors related to severity of dementia in addition to explore changes in behaviors during the course of the intervention.
2. To investigate whether there was an effect on agitation, depression or optional medication among elderly persons with dementia at nursing homes participating in robot-assisted interventions compared to a control group.
3. To investigate whether there was an effect on quality of life and use of psychotropic drugs among elderly persons with dementia at nursing homes participating in robot-assisted interventions compared to a control group, also related to severity of dementia.

3. Material and methods

3.1 Research approach and research methods in the papers

This intervention project was planned as a prospective study collecting baseline data ahead of response from the exposure from the intervention (Laake *et al.*, 2007). The study methodology is mainly positivistic by collecting quantitative data to be analyzed statistically for detecting effects of an intervention (Laake *et al.*, 2008; Polit and Beck, 2004).

The thesis contains two empirical, quantitative studies to investigate an intervention of group activity with Paro conducted in SCUs in several NH. The overall research strategy for this project was an experimental study with a cluster-randomized controlled trial (RCT) design to study effects on individuals in intervention groups to be compared with control groups. A cluster-RCT design is applied in paper II and III, a design chosen in order to minimize systematic differences between the treatment groups (Polit and Beck, 2004; Skovlund and Vatn, 2008). Having several clusters in a RCT could strengthen the validity in terms of generalization of the outcome (Benestad and Laake, 2008; Klepp, 2007). Measures on behaviors in the intervention group during activity sessions with Paro was explored through systematic quantitative observations of video recordings, a method applied in paper I.

A combination of methods was chosen in the thesis to enable a broad approach in how the intervention would influence the participants. Findings on change in behaviors obtained from repeated observations of the sessions could contribute to explain effects in symptoms from repeated measures from psychometric assessment scales. Combining research methods produce different aspects of a research field and contributes to overcome bias that occurs when data are obtained from a single research method (Benestad and Laake, 2008; Polit and Beck, 2004). Combining methods also produces the possibility of receiving multiple viewpoints into a complex reality and enhance the understanding of phenomenon in a research field (Polit and Beck, 2004), like human-robot interaction for elderly with dementia, a research field still demanding further investigation (Klein *et al.*, 2013).

3.2 Recruitment of nursing home units and participants

Development centers for NH and day care centers in Vestfold, Østfold and Akershus in the eastern part of Norway were responsible in recruiting NH during 2012 and 2013. NH with SCU adapted for elderly people with dementia were contacted. The first ten NH to have capacity and willingness were offered participation, see flowchart in figure 4. Some NH declined, some did not respond, while other NH did not have capacity due to other ongoing projects.

A procedure was developed by the project group describing how to assess residents' ability to perform informed consent, and how staff should perform recruitment. Research ethics is discussed in 4.2. The project group asked the nurses attached to the project to invite residents who most likely would be able to complete the intervention of seven months, which was as an attempt of trying not to exceed the drop-out rate of 20 %. In terms of possible differences between NH, all SCUs were characterized by having a range of dementia severity and frailty in residents.

Inclusion criteria:

- Age over 65 years
- Dementia diagnosis or cognitive impairment
- Show interest for Paro when demonstrated during recruitment (only to intervention group)

To assess cognitive impairment in participants without diagnose, The Norwegian version of the Mini-Mental State Examination, MMSE (Folstein *et al.*, 1975) was used. Score lower than 25/30 qualified for inclusion. Residents who met the inclusion criteria were offered participation.

All units were requested to put visits from visitation dogs on hold from three months before intervention start, as a "wash-out period" before the intervention (Pedersen and Vollset, 2007), lasting through the follow-up period. Other animals, such as cats living in the unit, poultry as a part of the outdoor milieu, or fish tanks were considered not to bias assessments of the participants.

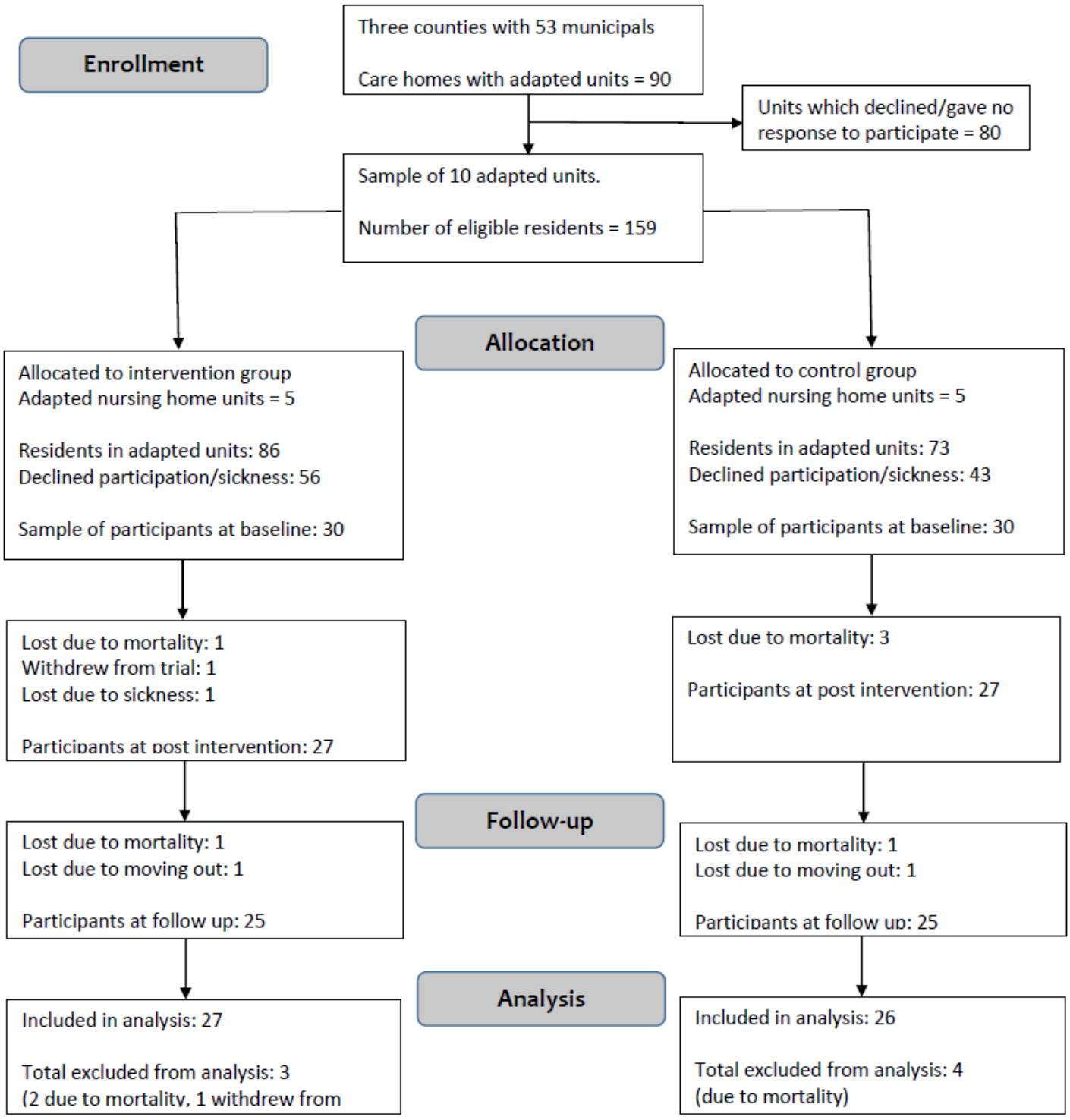

Figure 4: Consort flow-diagram describing the recruitment process and drop-out during the course of the intervention.

3.2.1 Participants in the cluster-randomized controlled trial

In the cluster-RCT the units were randomly allocated to intervention group with the seal robot Paro or to control group having treatment as usual. The random allocation of the units was conducted at the University of Bergen by external researchers, who were blind to the participating nursing home units.

The trial was conducted during three periods of practical reasons due to having only two available seal robots in the project for implementation. Three months before start of the intervention, the units were randomly allocated. The first intervention period was in Spring 2013 including the first two units, thereafter four units were allocated for the next intervention in Autumn 2013, and the last intervention period was conducted in Spring 2014.

Each unit recruited up to six participants, which formed a group in each of the ten units, treated as a cluster. A total of 60 participants were recruited resulting in 30 participants in each group at baseline. All but one had diagnosed dementia (MMSE score of 7/30). One participant was younger than 65 years, although considered suitable for the project due to having a severe dementia. In our sample CDR-rating showed primarily moderate to severe dementia, which is a normal prevalence in Norwegian NH (Bergh and Selbaek, 2012). Background information at baseline for the included participants in the analysis of the RCT are assembled in table 2.

Table 2: Personal characteristics at baseline for included participants in RCT

	Intervention group n = 27	**Control group** n = 26	*p-value*
Mean age (standard deviation)	83.9 (7.2)	84.2 (6.6)	.889
Women	70.0 %	63.3 %	.584
Number of participants with dementia diagnosis	27	25	
or having cognitive impairment	0	1	
CDR-rating:			.716
- 1 = Mild	7.4 %	7.6 %	
- 2 = Moderate	48.1 %	46.2 %	
- 3 = Severe	44.4 %	46.2 %	
Participation in activities:			.449
- Prefer cognitive activities	20.0 %	30.0 %	
- Prefer physical activities	40.0 %	40.0 %	
- Prefer both types of activities	13.3 %	13.3 %	
- Do not participate in activities	10.0 %	6.7 %	
- No information	16.7 %	10.0 %	
Previous animal/pet ownership:			
- Yes	46.7 %	46.7 %	
- No	13.3 %	13.3 %	
- No information	40.0 %	40.0 %	
Enjoy animal contact:			.493
- Yes	73.3 %	93.3 %	
- No	10.0 %	6.7 %	
- No information	16.7 %	0 %	

The total drop-out rate in the Paro group was 10 % (n=3), in the control group 13 % (n=4), which was lower than the estimated drop-out rate of 20 %. A total of six participants died during the course of the intervention and one participant withdrew from the intervention group, and these participants were not included in the statistical analysis. Participants who moved before end of intervention period or follow-up measures were included in the analysis by using a multiple imputation model in SPSS (described in 3.5). See flowchart for overview of the process of recruitment of units, allocation, participants, drop-outs and number included in the analysis (see figure 4 in 3.1).

Data on several outcome measures were collected at several time points and are described in 3.4.

The study is registered in Clinical Trials, and checklist from CONSORT (Consolidated Standards of Reporting Trials) for cluster interventions is applied in paper II and III, adhering to the CONSORT statement.

3.2.2 Participants in the observation study of activity sessions

In the study of change in behaviors during Paro group sessions, all included participants from the intervention group participated. Included participants had to be present during the video recordings of the group activity conducted once in week two and once in week ten, producing a total of ten recorded sessions. Only participants that had been video recorded in both weeks were included, resulting in a total of 16 women and seven men, age range 62-92 years (n = 23). Background information in table 3.

Table 3: Personal characteristics at baseline, included participants in observation study

		n = 23
Mean age (standard deviation)		84.7 (7.0)
Women		69.6 %
Dementia diagnosis		100 %
CDR-rating	1 Mild	8.7 %
	2 Moderate	47.8 %
	3 Severe	43.5 %
Prefer cognitive activities		17.4 %
Prefer physical activities		34.8 %
Prefer both types of activities		21.7 %
Do not participate in activities		8.7 %
No information of activities		17.4 %
Previous animal/pet ownership:	Yes	46.7 %
	No	13.3 %
No information of pet ownership†		40.0 %
Enjoy animal contact:	Yes	73.9 %
	No	10.5 %
No information of animal contact		17.4 %

To film the group sessions the video camera was placed to record all participants in the camera eye simultaneously and for as much of the time as possible. The same project member conducted the

recordings during all ten sessions. The recordings were uploaded in the software program Solomon Coder beta 14.03.10 (Péter, 2014), which is an ethogram program used to define and distinguish different predefined behaviors in participants and to map duration of behaviors in analysis of the video recordings, as demonstrated in figure 5.

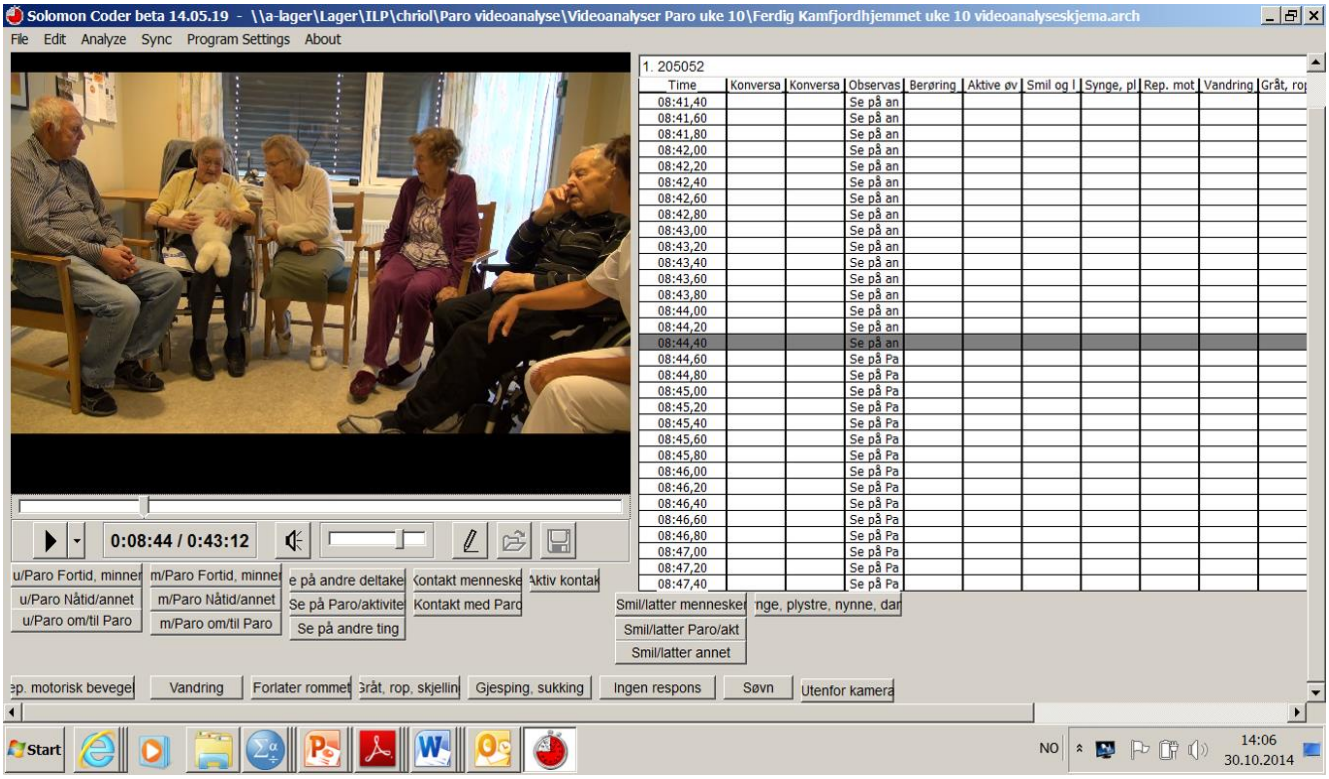

Figure 5: Print screen of the ethogram with video recording and all variables from the software program Solomon Coder beta 14.03.10 (Péter, 2014) .

An ethogram is a catalog of descriptions of relevant behaviors of the subjects of the study (Troisi, 1999). In cooperation with an expert center in human-animal interventions, Norwegian Center of Anthrozoology, members of the project group defined relevant behaviors to be observed in the ethogram in this study based on previewing the first video recordings of the Paro-group. One project member conducted the video analysis. An overview of behaviors included in the ethogram and how duration of the variables were calculated are described in 3.4.6.

3.3 Research setting and the intervention

3.3.1 The nursing home units

Norwegian SCU have various number of residents, although the majority have 7-8 residents (Gjora *et al.*, 2015) which also was the majority of participating SCUs in this study. Only NH run by the municipality, as most of Norwegian NH, were offered participation. The participating NH were representing both urban

and rural areas, different sizes and of architectural design, and the units with SCU were located on different floors. One SCU had 6 residents where all participated, and three SCUs had 7-10 residents, whilst four SCUs consisted of 2 groups, each with 7-8 residents, and recruited from both groups. One large SCU consisted of four groups with 6-7 residents in each and distributed recruitment from all groups, resulting in two participants from two groups and one participant from two other groups. One SCU with 6 residents recruited three participants and recruited three other participants from a dementia unit not classified as SCU.

Most units had plans for regular activities to be performed in the unit or in common areas in the NH, and planned activities were usually conducted. Half of the units had daily activities, others had activities two or three times a week. Activities were various, although common activities were singing, listen to music, physical group exercises, games, and most of the participants in our study participated regularly in offered activities. Only a few reported focus on activities based on individual preferences. Based on the abovementioned according to activities for the participants, the units seem to be in line with descriptions of environment treatment conducted in Norwegian SCU (Fermann, 2012).

In the first intervention period, including two clusters, SCU from two of the counties were allocated. In the second period, including four clusters, three SCUs from one county and one from another county were allocated. In the third and last period, all counties were represented in the allocated units. In total, one county had five participating units, another had three units, whilst one county had two participating units. However, the three counties are considered to be representative in Norwegian terms, and therefore comparable in terms of population and socioeconomic factors.

3.3.2 The intervention with Paro-activity

The project group developed a protocol for the Paro program. The protocol stated that sessions should take place in a separate, quiet room, all participants to sit close together in a half circle without a table in front of them and all sit in their usual seats to create predictability for the participants. During all sessions, the activity leader (AL) should sit in front of the group. An additional staff member was always present in the background if participants needed assistance during the session or wanted to leave the room. These considerations are in accordance with recommendations for conducting group activity with Paro (Klein *et al.*, 2013).

Staff members connected to the project from each SCU participated in a mandatory Paro training course prior to the intervention period. AL was one of the trained NH staff, while another staff member observed the session. Staff leading the Paro-sessions were supervised post sessions during the first two

weeks by one member of the project group, aiming to make sessions in all intervention units as similar as possible for the sake of comparison.

Up to six participants from a unit formed one of the five local Paro groups. During the intervention period 14 participants attended 22-24 sessions. The activity sessions lasted for about 30 minutes and were conducted twice a week over the course of 12 weeks. Sessions should be performed during the daytime, preferably at noon, on weekdays, aiming the participants, mainly with moderate to severe dementia, to have the best possible ability to concentrate on the activity.

Sessions were semi-structured and facilitated by AL, who started with presenting Paro as an articulated doll. This was important to reduce misinterpretations of Paro in the participants. The AL distributed Paro

to participants' laps for an equal period of time, preferably during two rounds to reduce waiting time. Sessions involved activities naturally occurring between participants and Paro and between participants. AL should promote all participants to interact with Paro and try to include participants in conversations through themes, such as their perception of Paro, of previous pets or through other related themes. When participants seemed to be engaged or entertained in the activity, the interaction should be free. AL would encourage participants to interact with Paro, such as to pet or cuddle it. All sessions were closed by AL, who should encourage participants to tell Paro good-bye before turning it off.

3.4 Measures on participants

To collect data on patients in NH, tools used for assessments are usually based on observations and information from staff. All psychometric tests require thorough observations during the preceding week(s). Scales used in this study are all developed for use in NH participants with dementia and validated for their purpose. Each scale will be presented in the following.

Assessments were conducted three times, at baseline (T0), after intervention (T1) and at follow-up (3 months after end of intervention) (T2), an interval chosen based on expected changes on these outcome measures. See table 4 for overview of all collected data.

Table 4: Time points of measure of assessments in participants in NH. Data above line was only collected at baseline.

Baseline T0	**Week 2**	**Week 10**	**At end of intervention T1**	**Follow-up (3 months after end of intervention) T2**
-Demographic data -CDR-rating				
-QUALID -Regular psychotropic medication -BARS -CSDD -1 week reg. extra psychotropic drugs	- Video-recording of one session in the intervention groups	-Video-recording of one session in the intervention groups	-QUALID -Regular psychotropic medication -BARS -CSDD -1 week reg. extra psychotropic drugs	-QUALID -Regular psychotropic medication -BARS -CSDD -1 week reg. extra psychotropic drugs

Several of the units in our study had never participated in a research study previously, hence not being used to the informed strict rules during the course of the intervention, such as to set visitation dogs on hold, to perform the intervention activity in the time stated, to assess the participants during the weeks stated, collect all data for all participants in due time, etc. These challenges were given attention by the project group by sending out e-mails to remind participating staff and leaders in the units/NH of the next time for assessments. To keep track of time points for all measures and avoid mixing of sheets and participant numbers, a separate binder containing copied scales including prefilled participant number and time points in addition to separate sheets between all measurement points, was made for each participant and distributed to the units ahead of the intervention period.

To ensure common understanding on how to conduct the assessments, a three-hour training course in how to use the scales was arranged. In addition, inter-rater-reliability test in all units on the main outcome measure was conducted producing a confident result (see 3.5).

3.4.1 Background information of participants

Staff connected to the project obtained background information, including information about activity level and animal contact from each participant in a form, as presented in table 3 (3.2.1) for participants included in the analysis.

Assessing level of dementia

In order to distinguish if severity of dementia could be related to findings from the trial, level of dementia was measured at baseline through an assessment tool, the Clinical Dementia Rating scale, CDR (Hughes *et al.*, 1982). The CDR scale is used to assess cognitive impairment and possible dementia based on observations by care personnel during the last 4 weeks and was conducted by the project staff in the units. The CDR scale rates cognitive functions as memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care. The scale has 5 levels on each rating area, rating from 0 (no impairment), via 0.5 (questionable impairment), 1 (mild dementia) and 2 (moderate dementia) up to 3 (severe dementia). The rater should consider the persons function in relation to their cognitive ability and last performance. The Norwegian version of the CDR scale is considered as an instrument to be readily applied by nurses knowing the participant (Nygaard and Ruths, 2003).

3.4.2 Assessing symptoms of agitation and depression in dementia

Assessing symptoms of agitation

For measuring agitated behavior, The Brief Agitation Rating Scale (BARS) was used. The scale is derived from the 29 point assessment scale of behaviors in dementia, The Cohen-Mansfield Agitation Inventory (called C-MAI). BARS contain ten frequent behaviors from the C-MAI (Finkel *et al.*, 1993; Rabinowitz *et al.*, 2005). Assessments with BARS are based on health personnel's observations of the participant during the preceding two weeks. BARS is used to assess frequency and level of severity of physically aggressive and physically non-aggressive behaviors in addition to verbal agitation in elderly nursing home residents.

The validated Norwegian version of BARS has nine frequent behaviors dementia to be assessed on a seven-point Lickert scale according to occurrence and frequency during the preceding two weeks. Items to be assessed are pacing/aimless wandering, repetitive questions or statements, hitting, grabbing, pushing, making strange sounds, complaining, repetitious mannerisms or general restlessness. Each symptom is assessed from "never" (score 1) to "many times during an hour" (score 7), and a sum-score is constructed (range: 9-63). BARS has been used to assess agitation in several studies on people with dementia (Sommer and Engedal, 2011). A low score indicates low symptoms of agitation.

Assessing symptoms of depression

To measure symptoms of depression in dementia, the Cornell Scale for Depression in Dementia (CSDD) was used. It includes 19 questions on a three-point scale assessing different behavioral symptoms during the preceding week (Alexopoulos *et al.*, 1988). There are five areas of depressive symptoms, described as mood-related signs, behavioral disturbance, physical signs, cyclic functions (during diurnal) and ideational disturbance. Each of the 19 items is rated for severity on a scale from 0-2 (0 = absent to 2 = severe), score range 0-38. The Norwegian version of CSDD is tested to be a valid and reliable tool

towards people with dementia in Norwegian NH (Barca *et al.*, 2010). A low score indicates low symptoms of depression.

Baseline assessments for both scales are presented in table 5.

3.4.3 Assessing quality of life in dementia

The Quality of Life in Late-Stage Dementia scale (QUALID) (Weiner *et al.*, 2000) was chosen as outcome measure for assessing the participants' QoL by the Norwegian version. QUALID consists of 11 items regarding different aspects of proxy-rated assessments of QoL in people with severe dementia, reflecting observations from staff during the last two weeks. Items to assess are if the person smiles, appears sad, cries, shows facial expression of discomfort/appears unhappy/in pain, appears physically uncomfortable, complains/groans/screams, is irritable/aggressive, enjoys eating, enjoys touching/being touched, enjoys social interactions or appears calm and comfortable. Each item is assessed between the score 1 and 5. The minimum scale score is 11, indicating good QoL, and maximum score is 55, reflecting a poor QoL. Baseline assessments are presented in table 5.

The Norwegian version is a reliable and validated tool in studies of elderly with dementia (Roen *et al.*, 2015), but it has also been found to be highly associated with the Cornell Scale for Depression in Dementia (CSDD) (Mjorud *et al.*, 2011; Roen *et al.*, 2015).

To explore various aspects in the items in the QUALID scale, component analysis have been conducted to explain which items loading on the factors, making clusters of items with joint affiliation. Studies with component analysis of QUALID items have resulted in various numbers of factors, although one large Norwegian NH study produced three factors explaining 53 % of the variance (Mjorud *et al.*, 2014a). The three factors were found to be relevant towards the psychometric outcomes in our study and was therefore chosen. The first factor, "Tension", includes the items facial expression of discomfort, appears physically uncomfortable, verbalizes expression of discomfort, being irritable and aggressive, and appears calm. The second, "Well-being", includes items as smiles, enjoys eating, enjoys touching/being touched, and enjoys social interaction. The third, "Sadness", includes items as appears sad, cries and shows facial expression of discomfort. Crohnbach's α for the three subscales were on "Tension" = 0.607, on "Well-being" = 0.614 and on "Sadness" = 0.750 suggesting questionable to acceptable internal consistency, however being in accordance with values reported in Mjorud et al (2014a).

3.4.4 Prescribed regular and additional medication

Based on medical treatment towards agitated behavior and depression in dementia, as described in 2.2.3, an overview of prescribed regular medication associated with treating NPS would be valid

information when considering and explaining effects from Paro-activity. Overview of or change in medication has not yet been investigated in Paro-studies. In this study, we only collected overview of the drugs, not if the dose was changed at any time point, only if the drug was prescribed or not. Additionally, extra medication is given to treat behavior occurring in periods, which also could be of interest to collect information on in this study.

Overviews of regular medication in accordance with the Anatomical Therapeutic Chemical (ATC) Classification System (WHO, 2014) on the second level N (nervous system) with 6 subgroups: Strong analgesics (N02A), antipsychotics (N05A), antidepressants (N06A), anxiolytics (N05B), hypnotics and sedatives (N05C) and anti-dementia drugs (cognitive enhancers)(N06D) were collected at baseline, at end of intervention and at follow-up. A drug was recorded with 1, if prescribed. To narrow the investigation towards treatment of NPS, four of the subgroups were merged into one variable of psychotropic drugs, containing antipsychotics, antidepressants, anxiolytics and hypnotics/sedatives, making a score from 0-4. Baseline assessments are presented in table 5. For all medication, a drug was recorded if present in a subgroup regardless of the dose. This means that we did not register high or low or change in doses of a drug, only if the drug was prescribed or being given as additional medication.

Overviews of need for extra psychotropic drug/sedatives from ATC-group N from four of the subgroups (strong analgesics, antipsychotics, anxiolytics and hypnotics/sedatives) were registered in a separate form in the same weeks as assessments of BARS and CSDD (baseline, at end and at follow-up). Antidepressants and anti-dementia drugs are not being prescribed as additional medication, only used as regular medication.

Table 5: Overview of measures at baseline for outcome measures (for included participants)

	Intervention group n = 27	**Control group** n = 26	*p-value*
Mean agitation, BARS (SD)	22.4 (7.7)	23.2 (11.4)	.759
Mean depression, CSDD (SD)	9.0 (4.9)	6.9 (4.7)	.116
Mean QoL, QUALID (SD)	23.5 (5.9)	22.9 (8.5)	.754
Regular medication prescribed			
- Analgesics	26.9 %	23.1 %	.749
- Antipsychotics	7.7 %	23.1 %	.248[a]
- Anxiolytics	23.1 %	26.9 %	.749
- Hypnotics and sedatives	34.6 %	30.8 %	.768
- Antidepressants	38.5 %	42.3 %	.777
- Cognitive enhancers	30.8 %	30.8 %	
No information (n=1)	1.9 %	0 %	
Mean psychotropic medication (SD)	1.04 (1.1)	1.23 (0.9)	.505

SD = standard deviation *[a] Fisher's exact test (2-sided) due to expected count <5.*

3.4.5 Behaviors observed from video recordings

The ethogram from the video recordings included both positive and negative behaviors, as presented in table 6. Behaviors related to both having and not having Paro on the lap was obtained to identify nuance in behaviors. In addition, this was an attempt of distinguishing between behaviors connected directly to Paro-activity or towards social activity with other participants.

In the ethogram, several behaviors could be registered in parallel, such as "Observing Paro", "Smile/laughter towards Paro" and "Contact with Paro". Two behaviors in the ethogram had mutually exclusive subcategories; category c) with observation of different objects and category d) with smiles and laughter (table 6). The subcategory in observation of different objects, c), was changed if the participant changed spot of observed object in more than two seconds.

The behavior "Conversation with Paro" was only registered when the participant communicated and simultaneously had Paro physically on the lap. The behavior "Contact with Paro" was registered when the participant physically had Paro on the lap or touched Paro on the next lap. Percentage of time for these behaviors will be low compared with the other behaviors due to the distribution of Paro for equal time among participants. Percentage of time with Paro on the lap when Paro was distributed among six attending participants in a session of 30 minutes would result in about 5 minutes for each participant, which corresponds with 16.7% of total occurrence. To catch engagement in the interaction with Paro, the behavior "Active with Paro" was registered simultaneously as "Contact with Paro". The total in this behavior, describing engagement with Paro, would therefore always have a lower percentage of time compared with the behavior "Contact with Paro".

Table 6: Observed behaviors recorded with time duration in seconds

a)	Conversation with Paro **Take initiative to converse or answer when having Paro on the lap.*
b)	Conversation without Paro **Take initiative to converse or answer when not having Paro on the lap.*
c)	Observations **Face towards Paro or other participants/*activity leader (*AL) or other things.* Mutually exclusive subcategories: - Observing Paro - Observing other participants/AL - Observing other things in the room
d)	Smile or laughter **Smile or laughter appearing simultaneously when face is towards Paro or other participants/AL.* Mutually exclusive subcategories: - Smile/laughter towards Paro - Smile//laughter towards other participants/AL
e)	Physical contact with Paro **Having Paro on the lap, or have physical contact with Paro on the next lap.*

f)	Activity with Paro **Showing engagement for Paro by hugging, petting, caring for, playing with, investigating) when having Paro on the lap. Recorded in addition to "Physical contact with Paro".*
g)	Singing, whistling, clapping, humming, dancing **Sing a song, declare poems, clap hands, dance, etc.*
h)	Napping **Close eyes in more than 10 seconds.*
i)	Walking around. **Raise from the chair and move in the room.*
j)	Repetitive movement **Movement without a cause, such as shaking legs.*
k)	Time out of recording. **No ability to observe participant on video due physical obstacle or blocking of camera*
l)	Physical contact **Take physical contact with participants or activity leader.*
m)	Signs of discomfort **Crying, shouting, swearing, yawning etc.*
n)	Leaving the group **Canceling the activity, leaving the group.*
o)	No response on contact **Passive behavior during physical contact with Paro, participants or AL, no motoric movements.*

**Description of observed behavior in the participant.*

Behaviors only with registrations on most participants were included to avoid biased results, in terms of the limited sample, resulting in a total of nine variables, from a) to f). The variables g) to o) were therefore excluded from the analysis.

3.5 Statistical analysis

All statistical analysis were performed by members of the project group and reviewed by an internal statistician.

Power calculation

To estimate the necessary number of participants included in a study in terms of drawing valid conclusions, the required difference in efficacy between the treatment groups must be defined in advance (Skovlund and Vatn, 2008). The Brief Agitation Rating Scale (BARS) (Finkel *et al.*, 1993) was chosen as the primary outcome measure in this study. A power calculation for change of means in BARS with 80 % probability of detecting differences between groups of 7.0 in a RCT, a standard deviation of 8.4 was used (Sommer *et al.*, 2009), a significance level: $\alpha = 0.05$, and a drop-out rate set to 20 %. This indicated a necessary number of participants in each group estimated to 30, a total of 60 in the RCT.

Missing data

Statistical data were analyzed using the Statistical Program for Social Sciences (SPSS) version 23.0. To reduce possible bias, loss of precision and power caused by missing data, multiple imputation methods are recommended (Sterne *et al.*, 2009). Missing items were handled in the following manner: If an assessment scale (BARS, CSDD and QUALID) lacked one, two, or three items at a time point, the mean

score of the remaining items in the scale was imputed. If four or more items were missing, the whole scale was treated as missing. There were few cases of single items missing and never more than two items in one scale. If an assessment was missing (the whole scale) at any time point, it was imputed using a multiple imputation procedure (in SPSS) including all outcome measures for all participants (Sterne *et al.*, 2009). Out of 477 scales (three scales (BARS, CSDD, QUALID) at three time points for 53 included participants) included in the analysis, a total of 13 scales were imputed for, which were for one participant missing three scales at T1 and T2 due to sickness, one participant missing three scales at T2 due to moving out, and one participant was overlooked resulting in two scales missing at T1 and one at T2, and one was overlooked with one scale at T0.

Analysis according to severity of dementia

To explore differences according to dementia severity, a dichotomous variable was established to separate mild + moderate dementia (CDR 1 + 2) and severe dementia (CDR 3) (applied in paper I and III). Creation of these subgroups divided the intervention group and control group into almost equal number of participants.

Analysis in paper I

Participant characteristics were presented in descriptive statistics. Variables were inspected by histograms for investigating potential skewness and out-layers.

To examine changes from week two to week ten, analysis of continuous variables with paired t-tests were performed. A variable was included in the analysis if it contained data registered from a minimum of 15 participants, in order to avoid bias due to the limited sample.

The stratification resulted in two groups of 10 and 13 participants, difference in duration of behaviors between the two CDR-groups were analyzed in terms of occurrence in week two with one-way ANOVA. Change in behaviors from week two to week ten for all participants was analyzed by paired t-tests.

Analysis in paper II and III

The participating NH units were treated as clusters. Participant characteristics were presented in descriptive statistics, and the differences between the intervention group and control group were assessed by one-way ANOVA (analysis of variance) for continuous variables and χ^2-tests for categorical variables. Variables were inspected by histograms for investigating potential skewness and out-layers.

Due to the chosen RCT-design of within-subjects with repeated measures and comparing groups of clusters, regression models for hierarchical data, also called linear mixed models, is recommended and was chosen for the outcome measures with continuous variables (Benestad and Laake, 2008; Skovlund

and Bretthauer, 2007). Such models are robust, in terms of preventing false significant findings by taking possible correlations between members of the same cluster, handling several time points, in addition to take missing data into account during statistical analysis (West, 2009). This model was used to test effects of the intervention for BARS, CSDD and QUALID. Time point was modelled as a repeated variable, an autoregressive covariance structure (AR1) was used to accommodate dependencies between the three time points (T0, T1 and T2). Nursing home was set as a random factor nested within intervention type, intervention type was used as fixed factor. To accommodate different time trends between the groups we also included an interaction term between intervention group and control group and time points, set as fixed effect, which was the effect of interest in this study. Results from the multiple imputation are pooled values derived from five imputed files, in addition to results presented from the original data.

Prevalence of medication at each time point in the six subgroups, as described in 3.4.5, was analyzed by χ^2-tests for categorical variables (applied in paper II).

Prevalence of psychotropic medication was analyzed according to CDR-groups by one-way ANOVA (applied in paper III).

In paper III, change in development for CDR 3 in QUALID total and the three subscales of QUALID (Tension, Well-being and Sadness) from baseline until follow-up, was calculated as change in mean (T2 minus T0). A linear regression models was used to test the different variables' predictive value on QUALID total and the subscales. We constructed four linear regression models using the variable for change in mean for QUALID total scale and the three subscales set as dependent variable in the separate models. Due to low number of participants the independent variables, "sex" and "age" in addition to "intervention/control", were applied in turn. When exploring predictive values on change in QUALID total we also included the variable "psychotropic medication" as one of the independent factors.

4. Ethical issues

Use of robotic animals towards frail elderly with dementia could produce value issues caused by various reasons demanding ethical deliberations (Calo *et al.*, 2011; Coeckelbergh, 2009; Kahn *et al.*, 2004; Klein *et al.*, 2013; Misselhorn *et al.*, 2013; Mordoch *et al.*, 2013; Sullins, 2011; Vallor, 2011). Criticism forces health care professionals to rethink their practice of care, and challenges philosophers and researchers to develop appropriate frameworks for ethical deliberations regarding practice. The value issues of emotional robots in dementia care is not straightforward (Sharkey and Sharkey, 2010), and investigation of concerns are also being requested in Norwegian whitepapers (Ministry of Health and Care Services, 2011). The most frequent ethical issues concerning emotional robots and dementia will be discussed in this chapter.

4.1 Issues regarding Paro and people with dementia

Literature on ethical issues regarding use of emotional robots in dementia is characterized by dichotomy: Some researchers have overly optimistic visions of how welfare technology can rescue arising challenges from the growing gap between increasing numbers of elderly with dementia and shortage of staff, while others rather describe use of emotional robots mostly as a deception towards people with dementia and therefore unethical (Calo *et al.*, 2011; Misselhorn *et al.*, 2013). Other concepts are technology conceived as cold care versus health care staff conceived as warm care (Pols and Moser, 2009). Robotic animals valued as companions and offering social support for people with dementia is one of the core dilemmas put forward in the ethical deliberations.

One common issue is Paro replacing care staff caused by the future increase in prevalence of people with dementia and the decrease in available staff (Misselhorn *et al.*, 2013; Sparrow and Sparrow, 2006). Welfare technology is developed through the recent years to meet this worldwide challenge (Ministry of Health and Care Services, 2011), although this is viewed as only the humble beginning (Sullins, 2011). Paro is seen as a means towards cutting costs and reduce workloads in carers for people with dementia, which will produce loss of human contact and increase objectification (Sharkey and Sharkey, 2010). Robots substituting human contacts is also considered as detrimental to well-being for this patient group (Sparrow and Sparrow, 2006).

Relevant aspects in this ethical deliberation are questions of who is controlling the robots, and considerations of how the robots are used, not simply the use of them (Sharkey and Sharkey, 2010). The inventors of Paro argue that it is so easy in use and can keep engagement in residents with dementia, indicating that staffs presence is not necessary in terms of producing benefits from the interactions

(Shibata and Wada, 2011). This argument is based on results from one study without staff, only Paro placed on a table for everybody to interact with it during 9 hours, showing increased social interactions among residents in addition to Paro mediating two participants to break communication barriers (Wada and Shibata, 2008). This study, conducted by the inventors of Paro, is in contrast with studies describing staff's attitudes and actions towards Paro activity. One study describe Paro to provide comfort, facilitate the provision of care and support social contact (Gelderblom *et al.*, 2010). Health professionals regard effects from Paro as a tool to provide diversion and facilitate attention in people with dementia (Bemelmans *et al.*, 2013). Findings on staff opinions support concerns towards emotional robots to replace care staff (Borenstein and Pearson, 2010; Misselhorn *et al.*, 2013; Sharkey and Sharkey, 2010). Paro is not a panacea towards engaging people with dementia, nor can it replace human contact (Rabbitt *et al.*, 2015). Paro could be well implemented and contribute as added value in daily care (Bemelmans *et al.*, 2016).

Another common issue is Paro being perceived living by people with dementia causing deception (Calo *et al.*, 2011; Sharkey and Sharkey, 2010; Sparrow and Sparrow, 2006), a consequence of impaired interpreting ability, but also impaired remembrance of Paro only being a doll. Paro is developed as a social companion for interaction towards people with dementia and gives an illusion of responding to its user (Wada and Shibata, 2008). Interaction with Paro is therefore argued as not appropriate, a profound disrespect and infantilization of people with dementia which threaten their dignity. According to Sparrow and Sparrow (2006) people could never be companion with technological items because people use and control the technology. In principle, it will be ethically wrong to interact with Paro as a companion and create emotions towards such a doll. According to Kant (1724-1804), persons are human beings with absolute dignity because of their rational nature making them capable of moral deliberation (Storheim, 1980). Nevertheless, people with dementia have reduced capability of making moral deliberations due to cognitive impairment making them vulnerable in such considerations.

However, several studies describe interaction with Paro to create engagement in participants observed as increased communication, mood, smiles and laughter towards Paro, staff and other participants (Chang *et al.*, 2013; Klein and Cook, 2012; Robinson *et al.*, 2015a; Sung *et al.*, 2015; Wada and Shibata, 2008). Paro could mediate communication in some residents with severe language impairment (Marti *et al.*, 2006; Wada and Shibata, 2008). Creation of mood, engagement and social relations are of significance in all people, indeed in people with dementia who live in the present time and show strong feelings despite their cognitive impairment (Brooker, 2004; Kitwood and Bredin, 1992). Due to progression of dementia resulting in lack of language, distress, short term memory and inactivity,

creation of engaging activities are challenging for caregivers. Regarding happiness as a purpose for all human beings seeking well-being, in addition to *happiness for others* as one of Kant's Categorical Imperatives, Paro could be interpreted as a means towards an end of happiness for others, which is a moral responsibility (Storheim, 1980). This imperative could not be universal and will most likely only succeed towards people who enjoy Paro.

Safeguarding dignity from Paros possible violation of it in people with dementia enforces a special awareness among caregivers. Preserving dignity in dementia is a cornerstone in person-centred core values (Brooker, 2004; Edvardsson *et al.*, 2008; Kitwood, 1997). Meeting of various needs in people with dementia are also core values in PCC, while absence of activities and occurrence of several unmet needs could produce agitated behaviors treated with medication (2.2.3) which is not in accordance with a person-centred view. Research describe several positive results and effects after interaction with Paro (2.5.3) and the significance of Paro activity should not be underestimated in people with dementia who enjoy interaction with Paro.

Another viewpoint is Paro supporting a need for giving care to someone else through petting it, sing for it, express care, etc. and not only receive care. Paro is also found to reduce loneliness (Robinson *et al.*, 2013). An ethnographic study describe how the robotic dog AIBO entertained its non-demented owner living alone and bringing her joy and something to tell friends about. She saw AIBO as a companion and showed strong affection, but AIBO was also something she could provide care for (Pols and Moser, 2009), indicating that people actually could develop affections for a technological item.

In terms of safeguarding participants with dementia when interacting with Paro, staff need a high awareness of arising dilemmas and must be prepared to deal with them. This is challenging due to the many implications and considerations, welfare technology break with traditional organization of health care and provide new functions (Hofmann, 2013) in addition to literature being indistinct in recommending the appropriate frameworks for conducting the ethical deliberations. The emphasis on the described ethical issues should rather be on how these robots could contribute and emphasize people's sense of well-being (Borenstein and Pearson, 2010).

Based on the various approaches in the discussion above, a context-dependent approach may seem suitable (Misselhorn *et al.*, 2013). Several philosophers have therefore highlighted the Capability Approach (CA), originally introduced towards issues in developing countries, brought into welfare technology by philosopher Mark Coeckelberg (2010) and regarded as a moderate ethical view in the perspective of people with dementia using emotional robots (Misselhorn *et al.*, 2013; Vallor, 2011).

CA highlight protection of the person's dignity and contains a list of central capabilities which can be used as "signposts" (Coeckelbergh, 2012). The capabilities are (briefly) live a long life, have bodily health and integrity, ability to use your senses, use your emotions, perform practical reason, affiliation (live among/towards others), able to laugh and play, and to control your environment (Coeckelbergh, 2010). These will not solve, but rather determine what old-age should care for, and what minimum threshold could be for each capability, what should be provided. Coeckelberg (2012) claims that this approach moves beyond traditional human rights, meaning that we also must *"analyze and evaluate elderly people's capacities given their specific conditions and in particular contexts and circumstances"*.

The capabilities must be viewed in context of the person having dementia assessing which capabilities being suitable (Misselhorn *et al.*, 2013; Vallor, 2011), which is a context-dependent ethical approach. It also seems to be in line with a PCC approach. Ethical challenges must be viewed in the care context through professional deliberations of what is considered to be appropriate care for each individual determined by the situation, assessments viewed from the inside. The traditional ethical principles will therefore be viewed as a contrast, assessing such situations from the outside and not including the individual care needs, which are unsuitable for the new challenges in care (Thygesen, 2011), such as welfare technology.

To sum up, Paro is not and should not be regarded as replacement for staff, but rather as an additional tool in provided care. When it comes to questions about deception, useful ethical frameworks as guidance through such appearing ethical issues are required. However, a context-dependent ethical approach safeguarding the individual seems to include needs in the person with dementia during Paro-activity.

4.2 Research ethics and considerations in the project

In addition to the ethical issues discussed above, several ethical issues arises when conducting research on persons with dementia. A practical guide describing how to assess performance of informed consent based on recommendations from Regional Committees for Medical and Health Research Ethics was developed, and staff participated in a course regarding considerations in research projects on people with dementia. To include participants without ability to perform informed consent is challenging in several ways even though the local nurses attached to the project gave potential participants, staff and relatives both oral and written information about the project. Project staff were encouraged to inform potential participants more than once for better considerations in the recruitment process. Assessment of participants' ability to perform informed consent, to state voluntary participation and to maintain

confidentiality is challenging. The impaired cognition makes it difficult to be certain of volunteerism in participants, which must be safeguarded by project staff during the whole project period (National Committees for Medical and Health Research Ethics, 2005). Most residents were assessed of not having ability to perform informed consent.

All participants were recruited after the allocation of units was performed. We chose this sequence in order to safeguard the participants from confusion if several options (intervention or control) were presented, although this weakened the design. We anticipated that many potential participants would turn down this offer due to lack of understanding and confusion, which is normal in dementia. Knowing the intervention type, NH staff could ask participants by presenting one option (Paro-activity or control group), being yes or no to participate. Paro was used to recruit participants for testing interest in Paro. If participation was considered to be in the interest of the resident, meaning to be of no harm, next-of-kin gave written informed consent on behalf of the participant.

The study assessments were based on observational psychometric scales describing nurses' thorough evaluations of each participants during the preceding week(s). This means that no questions were asked towards the participants. Use of such observational tools recognize the frailty of and the cognitive impairment in the participants. In advance of turning on the video camera the participants were explained the purpose and asked if anyone had any objections, in which there were none.

The three months wash-out period of visitation dogs before start of intervention could be a possible challenge in recruiting NH. In general, withdrawing a pleasant activity for all residents in a unit could cause displeasure, in particular for residents who were not included in the intervention and for all residents and participants in the control group having treatment as usual, but also displeasure in next-of-kin. However, conducting this kind intervention study must have the most equal possible starting point for the sake of comparison (Shadish *et al.*, 2002; Skovlund and Vatn, 2008). A consequence of not withdrawing dog visitation would be unreliable data, or worse, not conducting research on human-animal or robot-animal interventions. Little knowledge of non-pharmacological treatment on elderly with dementia in NH would result in lack of evidence which could entail continuing harmful medical treatment of NPS.

We consider this intervention to have been conducted in accordance with principles in the Helsinki Declaration (World Medical Association, 2013) in order to reduce risks and safeguard health, well-being and rights of the participants during the research project. However, it could be considered as ethically wrong towards NH participants with dementia to introduce a pleasant activity, such as intervention with

an emotional robot, then withdraw it after a defined time. Ethical rules of not producing harm in participants must be considered first. Some harm in participants might happen in a transitional period, but must be weighed against the benefits of experiencing the pleasant intervention. However, the contrary of not performing perceived pleasant interventions in NH units will have the consequence of not producing new insights and evidence towards health promoting activities in people with dementia. In terms of choosing the best solution for the greater good in a consequentialist view, it would be necessary to perform such interventions in NH when it cannot be performed in a laboratory.

The project was reviewed and approved by the Regional Committees for Medical and Health Research Ethics in Norway. It is registered at ClinicalTrial.gov (study ID number: NCT02008630).

5. Presentation of papers and results

5.1 Paper I:

Group activity with Paro in nursing homes: Systematic investigation of behaviors in participants

Background and aim of the study:
The aim of this study was to systematically investigate the variety of behaviors seen in people with dementia during group activity with the seal robot Paro. We also investigated differences in behaviors related to severity of dementia and explored changes in behaviors during the course of the intervention.

Methods:
30 participants with dementia from five nursing homes formed groups of 5-6 participants at each nursing home. Group sessions with Paro lasted for 30 minutes twice a week during 12 weeks of intervention. Video recordings were conducted in the second and tenth week. The nine most frequent behaviors, mostly positive, were included in the analysis.

Results:
Occurrence of behaviors on group level and divided into dementia severity is shown in figure 6 with the main findings: The behavior “Observing Paro” was the behavior with longest durance in all participants (blue column) in week two with 50 %. We found participants with mild/moderate dementia to observe Paro most with almost 60 % (red column) compared with those having severe dementia of 39.2 % (grey column), resulting in a significant difference ($p = 0.019$). The behavior “Observing other tings” was registered with 14.3 % in all participants (blue column), but mainly performed by participants with

severe dementia with 22.5 % (grey column) compared with those having mild/moderate dementia of 8 % (red column), resulting in a significant difference between the groups (p = 0.042).

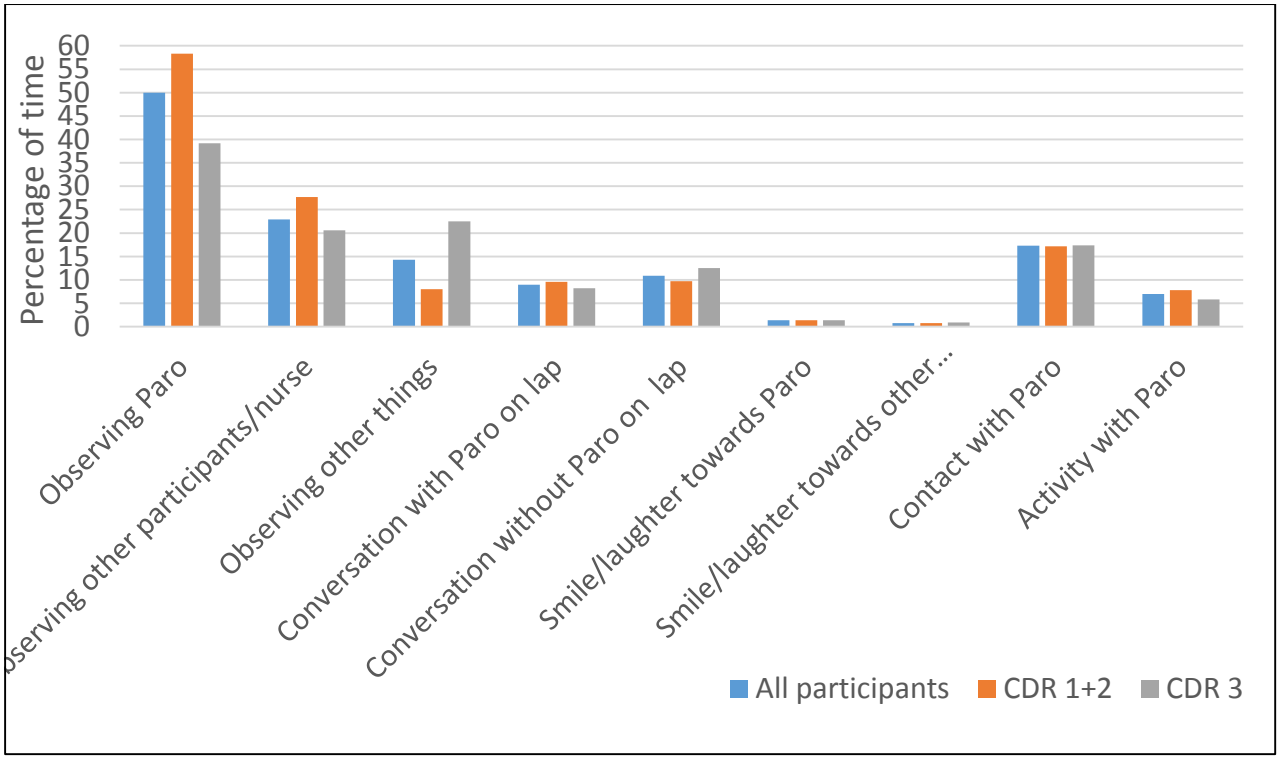

Figure 6: Occurring behaviors in week 2, stratified on mild/moderate dementia (CDR-group 1+2) and on severe dementia (CDR-group 3).
CDR = Clinical Dementia Rating scale.

Further results from occurrence of behaviors in week 2 were: The behavior with the second longest durance was “Observing other participants/nurse” registered in more than 20 % in all participants (blue column) with no differences according to dementia severity. “Contact with Paro” was the behavior with the third longest durance, resulting in 17.3 % in all participants (blue column), which is almost the maximum amount for each participant when distributing Paro among 6 attending participants. There were no differences according to dementia severity. About 20 % of behaviors were on conversation, including with Paro on the lap (9 %) and without having Paro on the lap (10.9 %) on group level and no differences according to dementia severity.

Change in behaviors from week 2 to week 10 in all participants are shown in figure 7, and the main findings were described as: The behavior “Smile/laughter towards other participants” with basically low occurrence, showed a statistical significant increase from 0.8 % (green column) to 1.5 % (brown column) on group level (p = 0.011). The other finding was on “Conversations with Paro on the lap” showing a

significant decrease from 9.0 % (green column) to 6.7 % (brown column) ($p = 0.014$) during the intervention period.

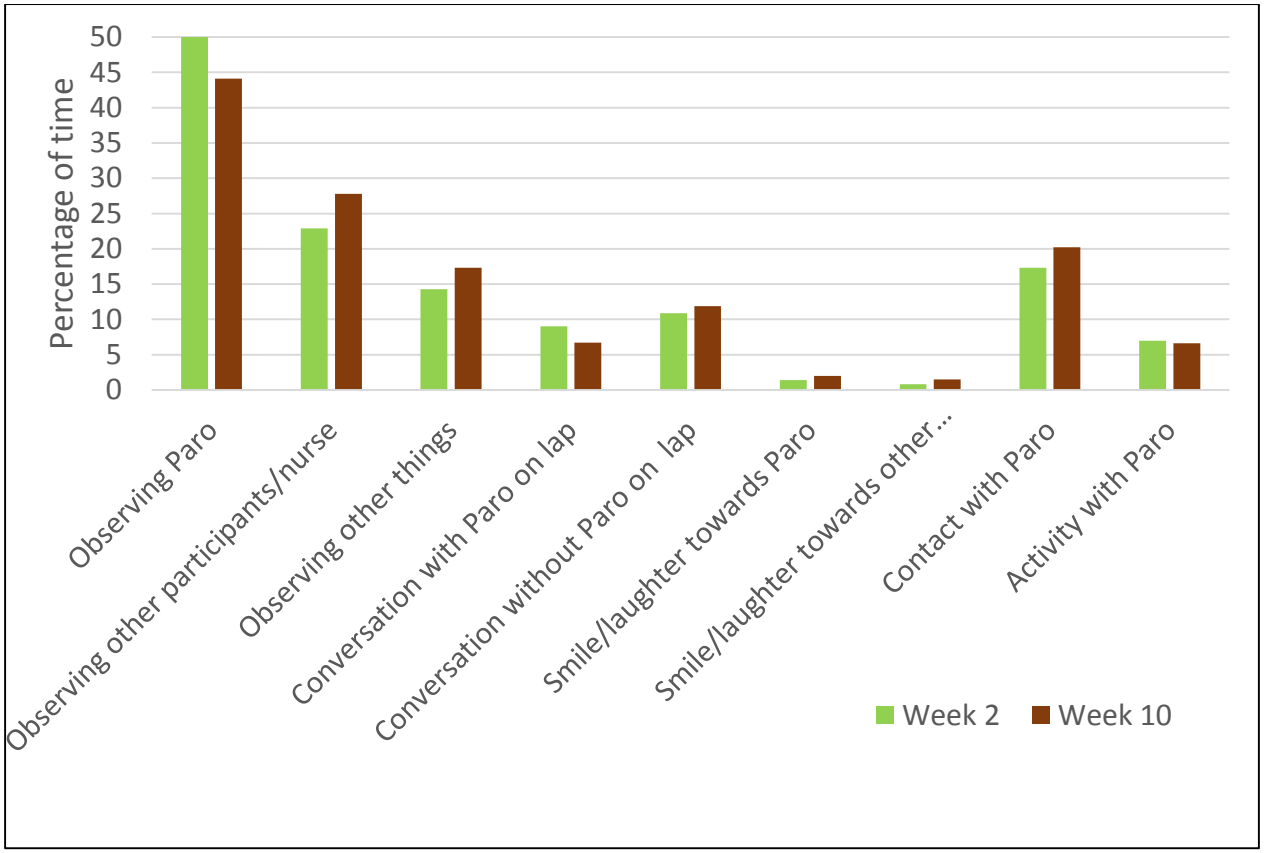

Figure 7: Change in behavior from week 2 to week 10

Other results on change in behaviors were a decreasing trend in "Observing Paro" and an increasing trend in "Observing other participants". There were also increasing trends in "Smile/laughter towards Paro" and "Contact with Paro".

Conclusion:

The overall findings in this paper was Paro to catch attention in all participants from the start, from participants with mild/moderate dementia in particular, while participants with severe dementia showed highest frequency of observing other things. During the course of the intervention, we found an increasing development of social interactions observed as increasing smiles towards other participants and a decrease in conversations while having Paro on the lap.

5.2 Paper II:

Effects on Symptoms of Agitation and Depression in Persons with Dementia Participating in Robot-Assisted Activity: A cluster-Randomized Controlled Trial

Background and aim of the paper:

The aim in this article was to examine effects on symptoms of agitation and depression in nursing home (NH) residents with moderate to severe dementia participating in a robot-assisted group activity with the robot seal Paro.

Methods:

The study was a cluster-randomized controlled trial. Ten NH units were treated as clusters, which were randomized to either Paro-intervention or control group (treatment as usual). A total of 60 residents with dementia were recruited from the ten units. The units recruited up to 6 participants forming a local group for Paro-activity or a control group. The intervention of group sessions with Paro-activity lasted for about 30 minutes and was conducted biweekly in daytime during 12 weeks. Outcome measures were symptoms of agitation (BARS) and depression (CSDD) in addition to regular medication ATC-system subgroup N (nervous system). Data were collected at baseline, after intervention and at follow-up (three months after end of intervention). Low sum score in BARS/CSDD indicates low frequencies of symptoms.

Results:

Seven drop-outs during the course of the intervention, n=53 in the analysis. Effects were found on agitation and depression between groups from baseline (T0) to follow-up (T2)(see figure 8). While the symptoms of the intervention group declined, symptoms in the control group developed in the opposite direction revealing statistical significant differences between the two groups, as shown in figure 8. Symptoms of agitation showed an effect estimate of -5.51, confidence interval (CI) of -0.06 -10.97 ($p = 0.048$). Effect estimate for symptoms of depression showed -3.88, CI of -0.43 -7.33 ($p = 0.028$). There were no significant differences in changes on either agitation or depression between groups from T0 to T1, only trends of development. There were no changes in regular medication between any time point in each of the six subgroups.

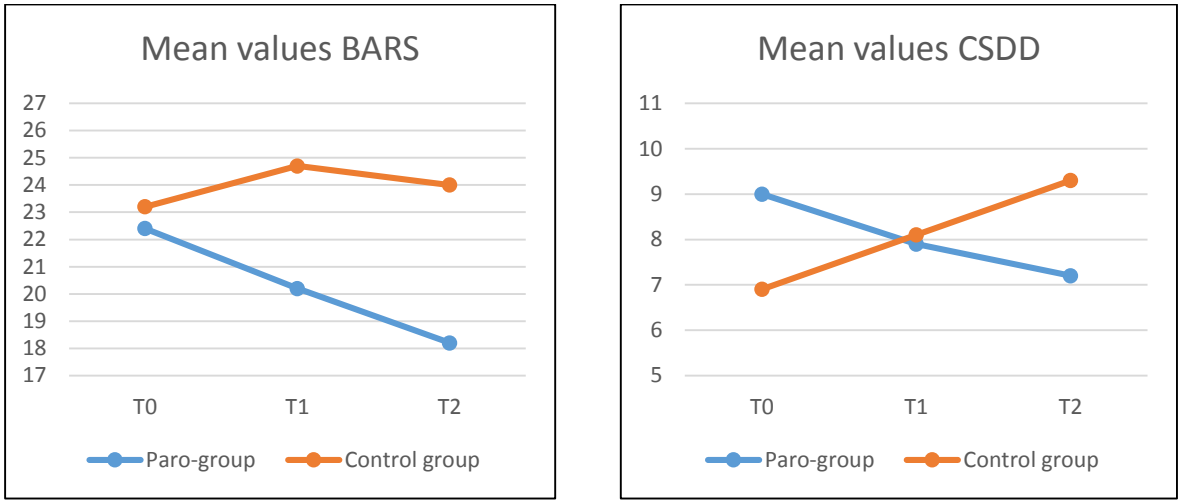

Figure 8: Mean values in BARS and CSDD at baseline (T0), end of intervention (T1) and follow-up (T2).

Additional analysis with stratification on BARS and CSDD

Based on findings of differences between CDR-groups from analysis of video recordings and investigation of QUALID in the cluster-RCT-study (described in 5.3), we tested for possible differences due to dementia severity in BARS and CSDD. This was conducted as additional analysis after paper II was published. Linear mixed models with stratified analysis according to CDR-groups were performed. There were no findings in these analyses.

Conclusion:

The overall findings in this paper were an improvement from T0 to T2 in symptoms of depression and agitation in the Paro group activity compared with the control group. We found no significant statistical differences in these outcome measures between the groups from T0 to T1. Investigation of the six subgroups of medication resulted in no findings.

5.3 Paper III:

Change in quality of life in elderly with dementia participating in Paro-activity: A cluster-randomized controlled trial

Background and aim of the article:

The aim of this article was to investigate change in quality of life (QoL) in persons with dementia participating in robot-assisted group activity with Paro in nursing homes compared with a control group and the correlation of severity of dementia and QoL.

Methods:
QoL was measured by the QUALID scale as outcome measure in addition to use of regular psychotropic medication. Measurements were conducted at baseline (T0), after intervention (T1) and at follow-up, 3 months after (T2). Low scores in QUALID indicate high QoL. Development in QoL was further investigated through the three subscales Tension, Well-being and Sadness. Due to low number of participants, the variables sex and age in addition to intervention with Paro/control were in turn used as independent factors to explore their predicting value on QoL.

Results:
We found no effects on QUALID total between the groups, although the control group showed a decrease in QoL (showed as increase in QUALID), while the Paro-group remained almost stable from T0 to T2, as reported in table 7.

Table 7: Mean values (SD) and effects estimates for QUALID total score in Paro group and control group in the total sample and divided into CDR-groups at baseline (T0) and follow-up (T2)

	T0 Mean (SD)	T2 Mean (SD)	Estimate (95% CI) T2 – T0	*p*-value T2 – T0	*Adj. estimate† (95% CI) T2 – T0*	*Adjusted p-value† T2 – T0*
QUALID total						
Control group (n = 26)	22.92 (8.50)	26.48 (10.05)	3.53 (-0.90-7.96)	0.117	*3.78 (-0.52-8.07)*	*0.085*
Paro group (n = 27)	23.46 (6.04)	23.76 (7.22)				
QUALID, CDR 1 + 2						
Control group (n = 14)	20.36 (5.96)	23.00 (6.56)	0.06 (-5.56-5.68)	0.983	*-0.11 (-5.58-5.35)*	*0.967*
Paro group (n = 15)	21.00 (6.19)	23.21 (8.04)				
QUALID, CDR 3						
Control group (n = 12)	25.92 (10.21)	30.91 (12.15)	7.92 (2.16-13.69)	0.008*	*7.22 (1.65-12.79)*	*0.011**
Paro group (n = 12)	26.75 (3.84)	24.45 (6.35)				

SD = standard deviation
CI = confidence interval
**statistical significant at .05-level*
†Adjusted estimates based on pooled results from multiple imputation in mixed model.

Further investigation according to dementia severity required stratified analysis on participants with severe dementia (CDR 3). We found effects on QUALID total from T0 to T2 in participants with severe dementia. While this Paro-group had a decrease in QUALID of -2.18 (yellow line), the control group showed an increase of 5.82 (grey line) reflecting a development of poorer QoL in the control group (p = 0.008) resulting in a difference between these two groups of 8 points, as the graph in figure 9 clearly shows.

We found no differences between the groups of participants with mild/moderate dementia (CDR-group 1+2), also shown with red and blue lines in figure 9.

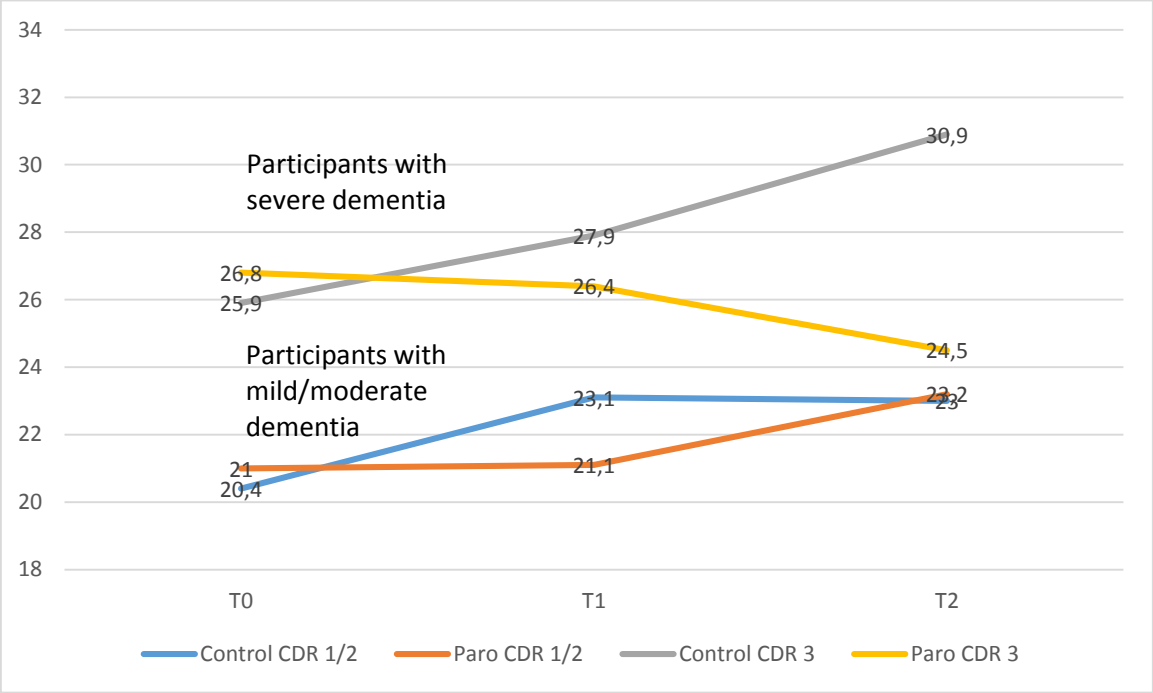

Figure 9: Results on mean in QUALID stratified on participants with mild/moderate dementia (CDR 1/2) and severe dementia (CDR 3).

The Paro-group with severe dementia used significantly less psychotropic medication compared with control group at T1 (p = 0.007).

In the linear regression analysis with change in QUALID total, change in psychotropic medication and intervention type were used as independent factors in one of the models, a combination which showed the highest explanation of variance of 50.5 %. In this regression model, intervention type showed a β of -10.931 (p = 0.002), and change in psychotropic medication showed a β of -5.983 (p = 0.066), as presented in table 8. The other independent variables used in turn with intervention type showed the intervention also in combination with sex or age to explain more than 30 % of the variance.

In the four regression models, we found the Paro-intervention to explain most of the change in QUALID total and in the two subscales Tension and Well-being for the intervention group with severe dementia. These models explained the much of variance, from almost 20 % to more than 30 %, as reported in table 8. We found no statistical significant results in the subscale Sadness.

Table 8: Variables associated with change in QUALID total/subscale scores (T0-T2) for the participants having severe dementia (CDR-group 3).

Dependent variables	Independent variables	β	p-value	R square
Change in QUALID total score	Intervention type	-8.000	.008*	*30.3%*
	Intervention type	-7.983	.011*	*30.3%*
	+ Sex	0.093	.976	
	Intervention type	-8.655	.006*	*35.9%*
	+ Age	-0.077	.674	
	Intervention type	-10.931	.002*	*50.5%*
	+ Change in psychotropic medication	-5.983	.066	
Change in QUALID Tension	Intervention type	-3.909	.045*	*18.5%*
	Intervention type	-3.673	.067	*20.4%*
	+ Sex	1.296	.518	
	Intervention type	-4.167	.040*	*26.3%*
	+ Age	0.119	.337	
Change in QUALID Well-being	Intervention type	-2.636	.005*	*32.8%*
	Intervention type	-2.515	.009*	*34.7%*
	+ Sex	0.667	.470	
	Intervention type	-2.847	.004*	*38.2%*
	+ Age	-0.021	.713	
Change in QUALID Sadness	Intervention type	-1.455	.176	*9.0%*
	Intervention type	-1.795	0.089	*22.0%*
	+ Sex	-1.870	0.088	
	Intervention type	-1.640	.153	*13.4%*
	+ Age	0.063	.384	

**statistical significant of 0.05 level.*

Conclusion:

The overall findings in this paper were QoL in participants with severe dementia to sustain during the course of the intervention whilst the control group worsened. The participants with mild/moderate dementia showed equal and almost stable measures. We found the Paro-intervention and change in psychotropic medication to explain 50 % of the variance in change in QoL in participants with severe dementia. The intervention significantly influenced aspects of QoL, such as tension and well-being, in people with severe dementia.

6. General discussion

Providing meaningful activities for people with moderate and severe dementia in nursing homes is an important task in order to promote health in such a rather frail group. These people with dementia strive with cognitive, behavioral and physical symptoms reducing their physiological, sociological and psychological health. The overall research aim of the thesis was to investigate how implementation of a health promoting activity using Paro in group-setting, affected participants with dementia. Previous research with various research quality describes various findings. To answer the overall research aim we conducted a trial implementing the seal robot Paro in group activity and investigated results by using two complementary methods. The first method was to assess how Paro-activity affected participant's behaviors during the activity sessions by observing and measuring these behaviors. The second method was to assess daily behaviors in participants except during Paro-activity in order to investigate if the intervention had effects on symptoms of agitation, depression, and QoL.

The main findings conclude with the following: Paro was observed to be an engaging activity and the group setting affected the participants towards increased social interactions. The increased social interactions seemed to influence the participant's daily living measured as effects on decreased symptoms of agitation and depression. The intervention, with an additional effect from change in prescribed psychotropic drugs, seemed to influence participants with severe dementia to benefit most according to QoL.

The following discussion will be organized in three subchapters, based on the three research questions in the thesis. 1) How group activity with Paro influenced behaviors during the sessions (findings from paper I), 2) How Paro-activity influenced symptoms of agitation and depression (findings from paper II), 3) How Paro-activity influenced measured QoL (findings from paper III). An additional subchapter discussing long-term effects is included in the end of this discussion. The findings from observed behaviors will be discussed in accordance with the theoretical framework of engagement in dementia. The effects on symptoms of agitation and depression will also be discussed in view of observed engagement. Discussion of findings from paper I and II will further be reflected in the discussion of QoL. Through the whole discussion, all findings will be reflected in light of PCC and the overall focus of the thesis of promoting health in people with dementia.

6.1 How group activity with Paro influenced behaviors during the sessions

The first research question to be discussed is how the participant's behaviors were affected during the group activity with Paro. Observation of behaviors was obtained through video recordings making assessments of behaviors possible. Occurrence of expressed behaviors in the individuals in week two and

potential change over time was assessed. We found participants with mild/moderate dementia to observe Paro significantly more than those with severe dementia, although those with severe dementia observed Paro more than they observed other participants or other things. The most striking finding was that Paro caught interest from the start of the intervention in all participants in 50 % of the time. Paro is therefore considered to be an engaging activity for all participants, and the mechanisms of engagement rising in the participants could be explained through the theoretical framework The Comprehensive Process Model of Engagement (Cohen-Mansfield *et al.*, 2009). The model describes the relationship between tailored activities and creation of engagement through interaction with a perceived interesting stimulus creating engagement, which affect people with dementia (see 2.3.2), and will be used in the following discussion.

Creation of engagement observed in the participants depends on considerations of attributes of three components; the environment, the stimulus and the person (Cohen-Mansfield *et al.*, 2009). In our Paro-implementation, attributes in the NH environment were considered in several ways, such as including maximum 6 participants, conducting the activity in daytime when participants normally are more awake, using a separate room in the NH to avoid unnecessary interruptions, and presenting Paro as a doll to be interacted with and through guidance from the activity leader. An additional staff was also present to handle participants in need of help. These attributes are also in accordance with recommended principles for conducting Paro-activity in group settings (Klein *et al.*, 2013). In the model, attributes in the person will have an impact on engagement in the stimulus. In people with dementia, level of cognitive impairment will influence the ability to attend an activity or influence level of apathy and reduced capacity to concentrate or perhaps to get out from the chair towards an activity, as described in other observational studies (Hasselkus, 1998; Holthe *et al.*, 2007). Such challenges are normal and part of the dementia syndrome, as described in 2.2.1 and 2.2.2. Attributes in the stimulus are assumed to be its degree of social quality or being manipulative. The sophisticated seal robot is designed to attract attention from participants (Shibata *et al.*, 2004). Paro makes authentic sounds and movements in addition to its ability of interacting through advanced sensors capturing movements and touch, and microphones capturing verbal expressions, as described in 2.5.3. It resembles a pet with soft fur inviting participants towards physical interactions for investigation or to play with, in addition to provide both comfort and an opportunity to give Paro care through petting, kissing or hugging, as described in other studies (Klein *et al.*, 2013). Regarding the discussion above, Paro seems to hold both social qualities and to be manipulative during the activity.

The framework also describes interactions between environment and stimulus to create engagement, but in the Paro-interaction, the person-stimulus interactions are of significance, being the degree of previous interests or showing preference for a stimulus. Participants in the Paro-study were recruited based on showing interest in Paro, a procedure based on a PCC approach towards potential and willingly participants. This procedure should also hedge participation in a non-interesting or potentially threatening activity which could increase level of confusion due to severe cognitive impairment. Other attributes in the majority of the participants influencing the person-stimulus interactions might be a premorbid likings for pets, as shown in table 3 in 3.2.2, when considering Paro's resemblance of pets. Such demographic data are considered to influence effects in human-animal-interventions (Perkins *et al.*, 2008), but is also valuable information in a PCC approach regarding identity in people with dementia.

Engagement is assessed through five dimensions, which are created in the participants. The first dimension to consider is whether the participant refused or to which degree accepted the stimulus, another is duration of time for being occupied or involved with the stimulus. The last dimensions are observations of attention to and expressions of various attitudes towards the stimulus, but also how actions towards the stimulus are presented. To assess engagement through these five dimensions from the Paro-activity, findings from paper I are included. As described above, the participants observed Paro 50 % of the time in week two. Although change in this behavior showed a slight decrease, the participants maintained a high level of observing Paro, which is also described in other studies (Marti *et al.*, 2006; Wada and Shibata, 2008). They also showed a high level of activity with Paro in addition to an increasing tendency of having contact with Paro. All participants seemed to accept Paro by having it on the lap for the maximum of time, about 17% due to need for distribution of Paro in the group of up to six participants. They maintained their interactions with Paro, referring to Paro as being a manipulative stimulus. These findings seem to confirm Paro as an engaging activity for the participants.

When assessing Paro as a feasible stimulus, a prominent characteristic is to consider its social qualities (Cohen-Mansfield *et al.*, 2009). As described above, Paro is developed in order to stimulate social interactions, which were found to affect the participants. Change in the behavior of smiling/laughter towards other participants doubled in duration, showing a statistical significant increase. In addition, there was an increase in the behavior of observing other participants in week ten. Change in these variables seem to describe a development of increased social interactions across the group caused by the group setting, as described in other studies (Klein and Cook, 2012; Shibata *et al.*, 2004; Sung *et al.*, 2015; Wada and Shibata, 2008) and recognized as added value of the Paro-intervention (Bemelmans *et al.*, 2016).

Paro is described to work as an ice-breaker (Robinson *et al.*, 2015a; Takayanagi *et al.*, 2014) or to start conversations which otherwise would not take place in a setting due to cognitive impairment in the participants (Klein and Cook, 2012), indicating that Paro works as an impetus towards increased conversations. We did not find increase in conversations, but rather a statistical significant decrease in conversations when the participants had Paro on the lap. Nevertheless, the general and main findings of increased social interactions are considered to be of great importance in Paro-interventions and of significance considering needs for inclusion for people with dementia. Development of increased social interactions are described in several intervention studies with Paro (Chang *et al.*, 2013; Klein and Cook, 2012; Robinson *et al.*, 2015a; Sung *et al.*, 2015; Wada and Shibata, 2008) and confirm this finding.

Taking level of dementia into consideration, participants with severe dementia were found to observe other things significantly more than participants with mild/moderate dementia, a difference which could most likely be explained by severe cognitive impairment and lack of ability to concentrate over time, but also to easily being distracted due to impaired focus ability and divided awareness, as described in 2.1.2. Nevertheless, Paro is also described to produce an increased, but also persistent, affection in participants described as an emotional exchange with the robot (Marti *et al.*, 2006; Robinson *et al.*, 2015a). When considering participants with severe dementia in terms of showing engagement, we anticipate that observing other things (than Paro or people) will indicate more engagement compared with falling asleep, which is to show no engagement. To easily fall asleep is associated with reduced cognitive capacity, apathy (Brodaty and Burns, 2012) and inactivity in this patient group (Kuhn *et al.*, 2005; Perrin, 1997). However, when taking into consideration the fact that these participants observed Paro almost twice as much as they observed other things, the group setting with Paro must be perceived as engaging also towards participants with severe dementia.

An overall consideration of the framework of engagement assessing measured behaviors arising in the participants during the activity sessions is that Paro created engagement in general, as one of the main findings in the thesis. Paro-activity seems to work as a tailored activity for this target group and to meet needs for performing activities in people with dementia. Based on the discussion above, group activity with Paro could also be a means towards meeting psychological needs in people with dementia, such as need for comfort and identity, need for being occupied and for being included, in line with a PCC approach. Based on the cognitive impairment challenging facilitation of activities in moderate and severe dementia, the recognition of increased engagement reveals Paro-activity to be perceived as a meaningful and health promoting activity for people with dementia to stimulate residual functions and improve their relative well-being.

6.2 How Paro-activity influenced symptoms of agitation and depression

Having demonstrated that Paro seemed to create engagement in the participants, the second research question to be discussed is whether the intervention had effects on expressed behaviors and emotions in participants' daily life by assessing effects in the most frequent symptoms of behaviors in people with dementia in NH which are symptoms on agitation and depression (Barca *et al.*, 2012; Bergh *et al.*, 2012; Selbaek *et al.*, 2007). Assessment on symptoms of agitation, measured through the psychometric scale BARS (Finkel *et al.*, 1993), showed a statistical significant difference with clear improvement in agitation in the intervention group compared with the control group found on follow-up measures. Assessment on symptoms of depression also revealed a statistical significant difference found at follow-up showing a clear improvement in the intervention group compared with control group, who worsened symptoms of depression during the course of the intervention. Reflections on development of effects only on follow-up measures will be discussed in 6.4. In this section, effects on symptoms of agitation and depression will be discussed.

To explain development towards these findings, the main findings of creating engagement, as discussed above, must be taken into consideration. Basically, people with dementia often display higher stress levels in their behavior caused by cognitive impairment (Ragneskog *et al.*, 1998). Neuropsychiatric symptoms (NPS), such as agitation and depression, have various causes such as stress-responses in the environment, experience of unmet needs, inactivity leading to boredom, etc. Due to limited medical effects, non-pharmacological interventions are recommended as treatment (Ballard *et al.*, 2009; Gauthier *et al.*, 2010; Salzman *et al.*, 2008), as described in 2.2.3. In this perspective, Paro in group activity was found to create engagement in the participants, and the group setting was found to stimulate and increase social interactions most likely influencing symptoms of agitation and depression in the participants, which will be discussed in the following.

During 12 weeks of biweekly Paro-activity the participants sat physically close in half-circle and in a regular activity setting, and the Paro-group was found to develop the social interactions, as discussed in 6.1. One clinical benefit from studies on Paro-interaction is the calming effect previously described as a physiological response in participants due to an increased level of oxytocin, such as on reduced blood pressure (Robinson *et al.*, 2015b) and long-term effects on reduced levels of cortisol from urine samples (Wada and Shibata, 2008), but also caused by pleasant social interactions (De Dreu and Kret, 2015; Heinrichs *et al.*, 2003; Uvnäs-Moberg, 1998). Such effects are also described in studies on visitation dogs (Bernabei *et al.*, 2013; Perkins *et al.*, 2008; Williams and Jenkins, 2008). This is a beneficial effect towards people with dementia displaying symptoms of agitation reduced most likely as a result of a calming

effect detected through the psychometric scale BARS. In addition, participants also experience a physical interaction with Paro by petting and cuddling Paro and the soft fur producing a tactile stimulation in participant's palms, which also corresponds to effects found on hand massage, measured as reduced agitation (Remington, 2002). Although the calming effect is most likely a physiological response on tactile stimulation and close social setting during the activity, we anticipate the increased engagement from Paro-activity in participants also to influence the participants by affecting their emotions, which most likely resulted in a change of their displayed behaviors. This engagement-mechanism seems to be in accordance with the purpose of tailored activities as non-pharmacological treatment in dementia, as described in The Comprehensive Process Model of Engagement (Cohen-Mansfield *et al.*, 2009) and discussed in 6.1.

The term mood is included in the depression spectrum in the psychometric scale CSDD (Alexopoulos *et al.*, 1988) and our findings on decreased symptoms of depression in the Paro-group were most likely caused by increased mood in the participants. We found Paro-activity to influence laughter and smiles towards others. These are behaviors described as improved mood, which is observed as having higher levels of laughter, smiles and positive expressions during interactions with Paro (Chang *et al.*, 2013; Klein and Cook, 2012; Shibata *et al.*, 2004; Takayanagi *et al.*, 2014). Although we did not find change in communication, the participants showed a statistical significant increase in smiles and laughter towards other participants. We interpret this finding as development of social interactions, as described in 6.1, which indicate an influence towards increased mood which influence symptoms of depression.

Decreased symptoms of depression are almost not described in Paro-studies. Two RCT-studies measured symptoms of depression without fining effects (Moyle *et al.*, 2013; Robinson *et al.*, 2013). The prevalence of depression, in addition to even higher prevalence of agitation, in NH residents with dementia suggest that increased attention of measuring such effects would benefit this target group.

6.3 How Paro-activity influenced quality of life

The findings on reduced symptoms of agitation and depression would most likely also have an influence towards participants' QoL in terms of being found as associated with QoL in some studies (Mjorud *et al.*, 2014b; Roen *et al.*, 2015). A longitudinal study on NH participants with severe dementia found improved or sustained QoL in half of the participants (Lyketsos *et al.*, 2003). However, we found no effects on QoL on group level. Stratified analysis on dementia severity revealed significant differences between the groups with severe dementia at follow-up, and we found the control group to worsen QoL, while the

Paro-group seemed to maintain QoL through the course of the intervention. We also found reduced use of psychotropic drugs to predict development of QoL in severe dementia.

Among participants with mild/moderate dementia we found no difference in QoL between the groups during the course of the intervention or at follow-up. Participants in this group had 5 points higher QoL measures compared with those with severe dementia. Having more intact higher functions enables participants with mild/moderate dementia, in general, to experience a more independent daily living in the SCU. Living a more independent NH life could be characterized by having control over mobility, ability to enjoy meals and conduct personal hygiene, have preserved language ability facilitating social interactions with others, preferably staff and visitors (Hauge, 2004). Such skills are associated with higher cognitive score and thereby higher QoL (Edvardsson *et al.*, 2014). Having social relations, control over daily life and feeling useful are described by NH residents as important factors to influence QoL (Drageset, 2004; Moyle and O'Dwyer, 2012; Moyle *et al.*, 2011). It seems that participants in the control group, having treatment as usual, maintained QoL to the same extent as participants in the Paro-group, indicating that higher cognitive functioning and most likely an ability of more independent living in NH might influence QoL in this patient group.

The finding of effect in the group with severe dementia needs further investigation. Development of QoL in people with dementia is complex, in particular with severe dementia, and analysis of how Paro-activity for people with severe dementia influenced QoL could be illuminated through Lawton's (1994; 1997) four dimensions of QoL in dementia, previously described as to have behavioral competence, experience of physical surroundings, psychological well-being including both positive and negative emotions, and quality of life as perceived by the person with dementia. The overall impression is that the dimensions of QoL seem to underpin the main findings in the thesis regarding participants, as discussed above, although effect on QoL was found only on people with severe dementia. The dimension of behavioral competence seems to be affected through an increase in social behavior in the whole group in general caused by participation in a regular activity during 12 weeks, as discussed above. The dimension of experienced physical surroundings seems to be positive when regarding facilitation of the sessions in a separate room to avoid interruptions during the activity session. Analysis of behaviors from the video analysis found increased social interactions after participation in a positive and meaningful activity to create engagement, which affected the participants positively, as discussed above. The positive affection in participants seems to be explained by behaviors holding the term *relative* well-being, such as relaxation, creativity, evident pleasure, and initiation of social contact, humor, in addition to smiles, laughter and socializing behavior (Hasselkus, 1998; Kitwood and Bredin, 1992). These behaviors are also

described in paper I and discussed in 6.1. Participation in a meaningful occupation, including interaction with others and experience physical wellness, as described above, could promote health and influence well-being (Christiansen and Townsend, 2014). Meaningful activities are assumed to be pleasant activities, which are valued to be of importance in occupational time to influence the quality of time use (Teri and Logsdon, 1991) as part of QoL in terms of positive affect states (Lawton, 1997). Although we used proxy-measures of QoL, we anticipate the positive findings on people with severe dementia to be in accordance with participants' perceived QoL due to the positive observed behaviors displayed in the sessions.

We found change in psychotropic drugs to explain much of the statistical variance on sustaining QoL in participants with severe dementia. This is an important finding and in line with low prevalence of psychotropic drugs to be associated with higher QoL (Mjorud *et al.*, 2014c), and in line with recommendations on reduction of psychotropic drugs as treatment in dementia (Salzman *et al.*, 2008). Our finding on sustaining QoL in participants with severe dementia in addition to reduction in psychotropic drugs should be recognized as an important contribution when assessing Paro-intervention also as a non-pharmacological treatment, in addition to promote health through use of residual functions in people with dementia.

In the further investigation of what the QUALID scale entailed in our study, we found Tension, holding negative behaviors, and Well-being, holding positive behaviors, to describe what influenced QoL in participants with severe dementia. In our study, Tension seems be associated with the increased engagement producing affecting behaviors from Paro-activity, and Well-being, explaining more of the variance than Tension, seems to be associated with improved mood, as discussed in 6.2. These subscales seem to be in accordance with other findings in the thesis confirming the findings on sustaining QoL in severe dementia, in particular Well-being, which holds smiling, touching and enjoying social interactions. The non-finding on Sadness is hard to explain, also when reflected in the significant decrease in symptoms of agitation, although the latter finding was on the whole group. However, the three subscales used in this thesis are derived from one of the component analysis of QUALID, other studies have produced other components (Mjorud *et al.*, 2014a).

Based on the difficulties in reliable proxy-measures on QoL in addition to challenges with self-report in dementia, support from psychometric assessments, such as BARS and CSDD, would be relevant additional information in explaining findings of difference between the groups with severe dementia, although we did not find such differences on BARS and CSDD in our study. While symptoms of

depression, and most likely agitation, are associated with poorer QoL in several studies (Banerjee *et al.*, 2009; Banerjee *et al.*, 2006; Mjorud *et al.*, 2014b; Roen *et al.*, 2015), an improvement in these symptoms would most likely have a positive influence on QoL.

6.4 Reflections on effects found at follow-up on outcome measures

For outcome measures on BARS, CSDD and psychotropic medication we found a clear tendency of development during the intervention period in change from T0 to T1, although the effects from the intervention were found on change from T0 to T2 on group level on BARS and CSDD and sustainment in QoL in participants with severe dementia in QUALID. Such findings could indicate that there has been a further development of the calming effect, improved mood and sustainment in QoL in the intervention group after the activity stopped. Such a continuing development is somewhat hard to explain with certainty due to not having any measures on possible causes to explain this. We did for example not measure staff opinions or observe staff relations with participants from T1 to T2 which could have changed during the intervention.

Having an intervention in a unit will most likely have an influence on staff working in the unit's milieu. A likely explanation would be that this influence has affected a kind of a mechanism appearing in staff during their experience with Paro-intervention, and that this mechanism in turn affected the participants. Our anticipation is based on the following: In all units, two or three nurses, connected to the project, conducted Paro-sessions twice a week through 12 weeks. During these sessions, they observed how participants interacted with Paro, which brought out comments, smiles and laughter, as described in 6.1. The intervention made participants telling stories from their life, showing engagement during activities, some showing affection for Paro and clearly enjoying the activity. These behaviors in participants would most likely affect staff through bringing new insights and reflections on participants' residual functions, making staff more aware of disguised skills in participants during the daily care and routine. Increased focus on resident's need after Paro-activity is also described in one study (Pedersen, 2011). Such tacit influence in staff would then be a mechanism, which most likely has worked as a silent presence in the units from the start of the intervention. Awareness of resident's needs and use of residual functions are core values in PCC, which have effect on agitation (Chenoweth *et al.*, 2009) and on improved QoL (Rokstad *et al.*, 2013) influencing resident's well-being. The anticipated mechanism abovementioned of developing insights, which improved staffs' handling of residents in stimulation of remaining functions, is also in accordance with the aim of promoting health in people with dementia.

6.5 Methodological issues

During the whole process, from recruitment to analysis of the collected data, several threats towards the validity of the results could occur. Findings in thesis are derived from using two methods, cluster-RCT and observation method using an ethogram, and potential threats will be discussed in the following.

In the thesis, the discussion made by Shadish, Cook and Campbell (2002) is chosen as a frame of methodological issues due to the experimental design in the cluster-RCT study and the single-group design in the observation study. Statistical conclusion validity, internal validity, construct validity and external validity will be discussed in the following. Statistical conclusion validity and internal validity are closely related, according to Shadish *et al.* (2002), and reliability, reactivity to experimental situation and novelty effects are included as threats to construct validity.

6.5.1 Statistical conclusion validity

Statistical conclusion validity concerns suitable use of statistical analysis in order to identify the validity of inferences according to the relation between an intervention and scores on outcome measures (Shadish *et al.*, 2002). Relevant threats to statistical conclusion validity according to Shadish *et al.* (2002) in the thesis are low statistical power, violated assumptions of statistical tests and unreliability of treatment implementation.

Analysis with cluster-RCT design

RCT-design was chosen due to several advantages in research to detect effects from an intervention, and is basically considered as the most robust method to test relationship between variables (Shadish *et al.*, 2002; Skovlund and Bretthauer, 2007). The study had groups of participants resulting in a cluster-RCT, which is applied in paper II and III in the thesis. The estimated sample size was met in the overall trial including multiple imputations for missing values. However, in paper III, a sub-analysis according to dementia severity was conducted on the outcome measure QUALID, dividing the two groups into four groups reducing the statistical power, which could produce less precise effect size estimate threatening valid conclusions. Methods to meet low statistical power could be to use almost equal cell sample sizes, use a within-participant design and ensure use of powerful statistical tests (Shadish *et al.*, 2002), which we met through using linear mixed models procedure, as we did in the stratified analysis having almost equal cell sample in the four groups.

Another threat is the cluster design because participants from the same group usually are more related to each other and thereby more equal compared with randomly selected participants, in particular when they are part of a common intervention. Using groups as clusters in the analysis could bias the results and violate assumptions of statistical tests. This threat was met through using linear mixed models

procedure, recommended to treat clusters and repeated measures by random and fixed effects to reduce uncertainty in the model (West, 2009).

Conducting clinical trials in several sites is challenging due to lack of researcher control compared with in a laboratory. Results could be threatened by inconsistent implementation and lack of standardized implementation. In order to minimize unreliability of treatment implementation, the design for the activity was presented for staff conducting the sessions, and staff in the same unit observed each other aiming to conduct almost similar sessions. One project member assessed the first 3-4 sessions and supervised staff after sessions in order to make all group interventions as similar as possible, which was showed in the video recordings. In addition, Paro was distributed twice in each session and the present participants interacted with Paro just as long. We believe such actions to meet these threats towards lack of standardized implementation.

Analysis of the observed behaviors

In paper I, with the observation method, only participants in the intervention group was included in the analysis. This was a limitation due to practical reasons from the design, although resulting in a low number of participants threatening results in the statistical analysis. Several pair-wise correlations were conducted on the nine included variables, but no correction for multiple tests was applied, a threat which could cause an overestimation of statistical significant associations. One strength was that only one person conducted the ten video analyses in the ethogram.

Due to risk of producing false significant results when adding too many variables in the analysis with small samples (type-2 error) (Skovlund and Vatn, 2008), an analysis of examining change in behaviors in the two CDR-groups was not included in the findings.

In general, to collect a variety of observed behaviors through an ethogram, as in paper I, gives a quantitative overview of behaviors according to predefined behaviors to produce evidence of change in behaviors during the intervention. However, a qualitative, descriptive design might produce a more nuanced picture (Polit and Beck, 2004) in addition to also describe content in conversations among participants and with activity leader, which could be analyzed and produce other insights. The most appropriate method would be to combine both these methods when investigating behaviors in people with dementia.

6.5.2 Internal validity

Internal validity in an experiment refers to the certainty of determining that there is in fact the intervention that caused the observed effect (Klepp, 2007). This determination is based on several

considerations from the design of the study in an attempt to reject alternative interpretations of findings. Relevant threats to internal validity according to Shadish *et al.* (2002) in the thesis are selection and history.

Regarding selection, participation in the research study was completely voluntary, indicating that the first ten NH signing up for participation might have a more positive attitude to the project, regardless of intervention type. In addition to being treated as clusters, all participants were recruited after the random allocation of NH to treatment or control. This procedure was due to practical and ethical reasons, although recruitment of participants based on treatment or not threatens the internal validity. In addition, liking of Paro was a criteria in the recruitment session resulting in a convenient sample in the trial, which further could threaten the validity and produce selection bias. However, baseline measures revealed no statistical differences according to background information, level of dementia or on any of the outcome measures. A strength was equal group sizes, also between clusters, in addition to low and equal drop-out rate in the groups (Skovlund and Vatn, 2008).

Regarding history, an obvious challenge in this study was blinding, which was not possible due to practical reasons in the NH. There is a possibility that awareness of study participation in general, in addition to conduct activity sessions, might affect staff's evaluation of the participant's behavior at each time point measure in both groups, which could threaten internal validation. In this kind of trial staff cannot be blinded to whether there is an intervention or not, in contrast to possibilities in medical trials using placebo medication as control. In addition, staff were close on participants during the intervention, which might affect their assessments. This means that we cannot exclude a confounding effect from staff. When assessing participants in a psychosocial intervention with psychometric scales in a RCT, raters should preferably be external and neutral, although that was not possible to conduct in our study. However, in each NH there was only one Paro-group or one control group, and the NH had no contact during the intervention period, strengthening the validity (Klepp, 2007).

"Treatment as usual" was chosen for control groups, being a usual control treatment in medical experiments (Skovlund and Vatn, 2008). Not offering the control group any new activity could increase the risk of novelty effects (as discussed in 6.5.3), and threaten the certainty of Paro being the agent of effect. However, the project was conducted to explore possible effects from activity with Paro, and not to compare the Paro activities with other intervention activities. A control group having another activity, i.e. communication group with staff, would also need a protocol and expertise in order to be conducted and to be compared with the Paro activity as the success of such an activity will be influenced by various

skills in the staff conducting the group activity (Vatne, 2006). This was not possible due to lack of resources and practical reasons. In addition, other functions in the participants are activated during such an activity making comparisons difficult, and communicative skills would be an inclusion criteria.

6.5.3 Construct validity

Construct validity measures degree of how the outcome measures reflect the aims of the thesis which is hard to measure, and several scales are often required in the investigation (Benestad and Laake, 2008). Relevant threats towards construct validity in the thesis are reactivity to the experimental situation, experimenter expectancies, and novelty and disruption effects (Shadish *et al.*, 2002).

We used the three concepts agitation, depression and quality of life, which all have been operationalized in various psychometric scales. Results from other Norwegian NH studies made the chosen scales appropriate for the aims of our investigation. The chosen Norwegian version of the scales BARS, CSDD and QUALID are used in several Norwegian and international studies and are tested for validity and reliability, as described in 3.4.2 and 3.4.3. In our trial, we did not define any minimum level on any scale as inclusion criteria of participants. Staff participated in a mandatory course in advance of the intervention learning how to use psychometric scales properly. Interrater reliability for primary outcome measure among raters in NH before baseline measures showed an intra-class correlation (single measures) of 0.84, regarded as very good (Benestad and Laake, 2008). However, all assessments were proxy-measures. Issues regarding QoL, preferably self-rated by participants, is discussed in 2.2.4. In general, including people with dementia in all stages is challenging, and due to cognitive impairment self-rating or structured interview will be difficult. Although staff who assessed participants had close observations of each participant ahead of each time point, mistakes could appear, such as when assessing emotions in a person with severe dementia who hardly display facial mimics despite actually being in good mood, is challenging.

A clinical trial could possibly influence the participants in an intervention, called the Hawthorne effect. This was originally described from intervention studies in Hawthorne industry during the interwar period to be a placebo effect caused by a reactivity in participants. The effect is seen when participants in a research study/project would modify or improve their behavior caused by knowing they are being observed (McCarney *et al.*, 2007). The participants in our study knew if they had intervention or not, although the dementia most likely blurred daily remembrance of the Paro-activity. Nevertheless, in intervention studies with people with dementia and staff conducting and assessing participants, staff will most likely be affected by the intervention (Braunholtz *et al.*, 2001; Opie *et al.*, 2002). A novelty effect,

such as from implementing a robot in NH or conducting research in NH, could produce enthusiasm contributing to an effect (Shadish *et al.*, 2002).

6.5.4 External validity

External validity concerns the possibility of transferring findings from the sample to other populations, called generalization of findings (Klepp, 2007; Shadish *et al.*, 2002).

Most of the SCU in the study had a group size representing the majority SCU size in Norway, as described in 3.3.1. All NH were run by the municipalities, as most Norwegian NH, and located in both urban and rural areas. Nevertheless, NH willing to participate in research studies are assumed to have a more positive attitude due to willingness of allowing researchers into the units. The participating SCUs, despite being of different shapes and sizes and have various activity levels, were assumed to be representative as SCU.

Efforts were made in order to conduct similar activity, as described in 3.3.2. The sessions seemed to be similar in all groups confirmed through the video recordings.

Participants in our study were assessed by staff as most likely to be able to complete the intervention period of seven months. Otherwise the participants were regular residents in SCU, apart from finding Paro enjoyable, which might make participants in the intervention group somewhat different from those in the control group. However, a worldwide subjective evaluation of cultural opinions regarding Paro in 7 countries showed generally high scores, and the factor “feeling of interacting with real animals” was highest rated in Western countries (Shibata *et al.*, 2009) indicating that Paro is easy to like. When taking findings from other NH studies with Paro and the considerations stated in the above section, we believe our sample from SCUs to represent the population of SCU residents with mild, moderate and severe dementia.

Overall, in terms of generalization of our findings, we consider our results from the intervention to be representative and valid for this patient group. Although a confounding effect from staff is hard to exclude in such an experiment, we anticipate the overall findings to be in accordance with other studies, contributing evidence in the research field on social robotic pets.

The activity setting and use of staff to conduct the sessions made the intervention credible as a feasible NH activity, and the main findings in the thesis should be relevant for most SCUs when considering the purpose of using Paro as an activity.

7. Conclusions and implications

7.1 Summary of findings and conclusion

The main aim of this thesis was to investigate how an intervention with Paro in a group activity could promote health in elderly with dementia in nursing homes. The findings of the thesis can be summarized as follows.

Analysis of group activity described Paro to be perceived as interesting among all participants. The Comprehensive Process Model of Engagement could be used to explain how engagement was created during interactions between participants and Paro and to increase social interactions in all participants (paper I).

The aim of using an emotional robotic seal is to provide social, psychological and physiological benefits (Shibata and Wada, 2011; Shibata *et al.*, 2004) as described in 2.5.3. The main findings in the thesis seem to correspond with the provided benefits for Paro in all participants. *Social* benefits could be seen as increase in social interactions and in mood. Increased mood would also be one of the *psychological* benefits in addition to engagement, which also could be caused by social benefits. The *physiological* benefit would be from the calming effect (paper II). All described benefits seem to influence QoL, in particular in people with severe dementia (paper III). However, the other findings from paper I and II also describe Paro-activity in general to promote health in participants with dementia. Interaction with Paro seem to be in line with a PCC approach in order to stimulate residual functions making abilities in participants to come forward.

Our main findings in the thesis contribute important knowledge of using non-pharmacological activities to reduce symptoms of depression and agitation in people with dementia and to influence QoL in people with severe dementia. A context-dependent ethical approach could be used to assess if Paro seems to be an appropriate activity in each individual. The overall conclusion is that Paro seems to be a health promoting non-pharmacological activity in dementia care for those who are willing to interact with it.

7.2 Theoretical implications

The growing body of knowledge on psychological needs in people with dementia living in NH has produced consensus on non-pharmacological treatment as first choice to treat NPS (American Psychiatric Association, 1997; Gauthier *et al.*, 2010; Salzman *et al.*, 2008). Emotional robots are based on human-animal interactions and described to provide social, psychological and physiological benefits (Shibata and Wada, 2011; Shibata *et al.*, 2004) although these benefits are relatively wide and unclear regarding

theoretical perspectives in research methodology. These mechanisms are still unclear (Kolling *et al.*, 2013) although several published studies during the last few years have contributed with knowledge.

The lack of clear theoretical foundation for emotional robots in dementia care is most likely due to a young research field. Viewing the literature, interventions with Paro seem to have several aims and outcomes, revealing a need for more evident theoretical purposes when these robots are implemented in dementia care. This thesis used a theoretical model to explain development of engagement through interaction with tailored stimulus from the video analysis, which also contributed to explain how observed behaviors in participants most likely affected participants expression of behaviors, found to be effects from outcome measures.

A PCC approach describe the person's psychological needs through considering residual functions and was used to consider if Paro could be a useful tool to enhance well-being. Use of theory or theoretical models to explain contextual findings could contribute to further explore and explain how Paro, and other robotic pets or socially assistive robots, actually influence people with dementia. This approach is also significant regarding ethical deliberations.

To enhance capabilities and discover concealed functions in each individual aiming towards improved well-being in everyday life is crucial in dementia care. Although reviews describe robotic pets to have a positive impact on QoL measured through various outcome measures, Kachouie *et al.* (2014) request relevant constructs to map physical and physiological well-being in participants in their review paper.

We therefore recommend a theoretical aspect through health promotion, as in this thesis, in future studies to contribute in further improvement and to meet the challenges in dementia care.

7.3 Clinical implications

The thesis seems to add significant knowledge to a relatively young research field of using robotic animals in dementia care. Our findings on reduced agitation and depression in all participants and maintenance of QoL in participants with severe dementia are important and should be recognized. Performance of relevant activities aiming to improve NPS and influence QoL needs further highlighting in dementia care, in particular when performing personal care still is rated as a more important care task among NH staff when compared with performing activities (Kjøs and Havig, 2015). Conducting group sessions with Paro seem to be a feasible and effective activity in NH in addition to being a relevant and practical method to create engagement for those interested in Paro.

Paro is considered to have both social and manipulating attributes, as in 6.1. Although several methods of activities have been developed and implemented in NH settings, Paro is a feasible activity, also in terms of being simple to handle for all, in addition of being self-propelled during activity. Such attributes in a stimulus during an activity could make the activity leader able to observe and include participants during the activity. Activities are regarded more positively among people with dementia when performance requires little verbal instructions in addition to right level of complexity which adds to successful interventions (Lawrence *et al.*, 2012) indicating that the slow pace of Paros movements adapt the impaired cognition in participants.

In addition, Paro could also be used apart from organized activities for those enjoying Paro in periods of time, such as in one-on-one activity when a resident seems to be in urgent need of soft comfort or a diversion from a stress-reaction towards the care environment, or as a means with staff to provide comfort and facilitate care provision, as described in other studies (Bemelmans *et al.*, 2016). Regardless of situation, ethical considerations are context-dependent in each individual. A practical context-dependent ethical framework applied in elderly care practice seems to be a necessary tool to be developed in terms of safeguarding elderly with dementia when using welfare technology.

Paro is developed to mediate communication during interactions, and we found group activity to produce increased social interactions among participants as added value of the interaction (Bemelmans *et al.*, 2016). Although we found participants with severe dementia to benefit from the group activity, not all NH residents are capable of such participation and should be provided with one-on-one interaction as the most suitable treatment.

7.4 Implications for future research

In the thesis we collected data from observing behaviors through video recordings and data from repeated psychometric assessments. These two methods produced data provided from both staff assessments (outcome measures) and researcher assessments (video analysis). To further investigate and contribute with effects in how Paro affect participants during the interactions, future studies should combine methods and use robust research methods. In addition, long-term effects must be highlighted further.

We found indications of Paro-activity to affect level of psychotropic medication and influence QoL. Considering Paro as a non-pharmacological treatment, more studies investigating change in psychotropic medication should be conducted. Change in measured cortisol levels in participants, also long-term measures, might add additional knowledge to the assumed calming effect through observed reduction in

agitation. We also recommend overview of diagnoses or other co-morbid conditions influencing participants and might contribute to explain findings.

Conducting RCT with psychometric scales as assessments often require assessors knowing the participants' behaviors making blinding not possible. Actions should be taken towards reduced influence on staff during assessments, such as use of observational tools (such as Dementia Care Mapping) with external raters rather than or in addition to psychometric scales. Using external/staff outside the included units to conduct the sessions should also be used in future research.

Taking the findings on agitation and depression into account, more RCTs on emotional robots are needed to establish evidence of such interventions. In addition, reviews including RCTs including peer-reviewed studies would soon be possible to conduct due to several published papers the last year.

It would also be interesting to explore if engagement from Paro-activity could affect other frequent behavioral symptoms in dementia, such as apathy. Exploration of Paro's possibilities of creating engagement in residents with severe apathy or severe agitation or depression require different approaches. Severely agitated people with dementia would most likely strive with finding their place in a group setting, making individual Paro-activity a more suitable setting.

Last, but not least, there is a need for a relevant framework for health care staff in practice in order to master ethical issues when using emotional robots towards people with dementia. To raise the psychological needs in people with dementia will be a more fruitful ethical approach than the dichotomous discussion of Paro being right or wrong.

The overall impression is that the research field on studies with Paro and robotic pets is still young and in need of further research to establish more robust design to produce evidence as a non-pharmacological treatment. There is also a need for theoretical development in this field to further establish how and to what extent these robots could promote health in people with dementia.

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9. Papers I – III in full text

9.1 Paper I

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Group activity with Paro in nursing homes: systematic investigation of behaviors in participants

Nina Jøranson,[1] Ingeborg Pedersen,[1] Anne Marie Mork Rokstad,[2,3] Geir Aamodt,[1] Christine Olsen[1] and Camilla Ihlebæk[1,4]

[1] *Department of Landscape Architecture and Spatial Planning, Section for Public Health Science, Norwegian University of Life Sciences, P.O. Box 5003, N-1432 Ås, Norway*
[2] *Norwegian National Advisory Unit on Ageing and Health, Vestfold Hospital Trust, Tønsberg, Norway*
[3] *Faculty of Health Sciences and Social Care, Molde University College, Molde, Norway*
[4] *Faculty of Health and Social studies, Østfold University College, Fredrikstad, Norway*

ABSTRACT

Background: A variety of group activities is promoted for nursing home (NH) residents with dementia with the aim to reduce apathy and to increase engagement and social interaction. Investigating behaviors related to these outcomes could produce insights into how the activities work. The aim of this study was to systematically investigate behaviors seen in people with dementia during group activity with the seal robot Paro, differences in behaviors related to severity of dementia, and to explore changes in behaviors.

Methods: Thirty participants from five NHs formed groups of five to six participants at each NH. Group sessions with Paro lasted for 30 minutes twice a week during 12 weeks of intervention. Video recordings were conducted in the second and tenth week. An ethogram, containing 18 accurately defined and described behaviors, mapped the participants' behaviors. Duration of behaviors, such as "Observing Paro," "Conversation with Paro on the lap," "Smile/laughter toward other participants," were converted to percentage of total session time and analyzed statistically.

Results: "Observing Paro" was observed more often in participants with mild to moderate dementia ($p = 0.019$), while the variable "Observing other things" occurred more in the group of severe dementia ($p = 0.042$). "Smile/laughter toward other participants" showed an increase ($p = 0.011$), and "Conversations with Paro on the lap" showed a decrease ($p = 0.014$) during the intervention period.

Conclusions: Participants with severe dementia seemed to have difficulty in maintaining attention toward Paro during the group session. In the group as a whole, Paro seemed to be a mediator for increased social interactions and created engagement.

Key words: Paro, dementia, ethogram, video analysis, group activity, human–robot interaction

Introduction

Dementia is a clinical syndrome characterized by a progressive decline in cognition and level of functioning (Engedal and Haugen, 2009). People with severe dementia are in need of 24-hour care, most of them living in NHs. Almost 80% of residents in Norwegian NHs have dementia (Strand *et al.*, 2014).

Correspondence should be addressed to: Nina Jøranson, Department of Landscape Architecture and Spatial Planning, Section for Public Health Sciences, Norwegian University of Life Sciences, P.O. Box 5003, N-1432 Ås, Norway. Phone: +47 67 23 12 59; Fax: +47 64 96 50 01. Email: nina.joranson@vid.no.
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NH residents with moderate to severe dementia often have reduced capacity to concentrate and little energy left to participate in any group activity or even to motivate themselves to rise from the chair (Egan *et al.*, 2006). Participating in group activities could provide interaction with others, make residents experience physical wellness, re-create contact with life stories, etc. (Hasselkus, 1998). Various activities are promoted, such as music therapy, reminiscence, aromatherapy, etc. (Kverno *et al.*, 2009; Livingston *et al.*, 2014). Interactions with visitation dogs are also promoted, and reviews describe findings like reduced agitation and apathy, often related to increased levels of oxytocin producing stress reduction, improved degree and quality of social interactions, and

increased mood (Williams and Jenkins, 2008; Bernabei *et al.*, 2013).

A newer form of animal interaction is with animal-looking, socially assistive robots, also called emotional robots, and studies with robotic cat, dog, and baby seal show similar findings as for human–animal interventions (Bernabei *et al.*, 2013; Mordoch *et al.*, 2013). In contrast to live dogs, the slow pace of robotic animals facilitates following for people with dementia, in addition to being more hygienic and not causing allergic reactions. Paro is shaped like a baby seal with a swiveling head and moving legs and tail, and it also has speakers that make the authentic sounds of a real baby harp seal. Paro is adaptive, recognizes voices, and can respond to repeated words (Wada *et al.*, 2004). Its artificial fur contains 12 sensors, creating interactivity between users and the robot as it responds to users' repetitive motions, such as petting.

The aim of using robotic animals is to provide social, psychological, and physiological benefits through an engaging interaction (Shibata *et al.*, 2004; Feil-Seifer and Mataric, 2005). A model of factors influencing engagement describes a mechanism of how perceived interesting stimuli could affect expressed behaviors in people with dementia (Cohen-Mansfield *et al.*, 2009). Attributes of the stimuli, such as Paro, and/or in the person, creates an interaction, which creates engagement with Paro. A change in affect caused by this engagement will influence the presentation of behavior in the person, such as being calmer. In addition, there could be a calming effect caused by sensory stimulation, such as petting, hugging, and kissing Paro, via increased oxytocin levels, as in human–animal interaction.

Studies of video-based analysis of interactions with Paro demonstrate not only increased social interactions between residents and Paro but also increased interaction among individuals in group settings (Giusti and Marti, 2006; Klein and Cook, 2012; Chang *et al.*, 2013; Robinson *et al.*, 2013; Robinson *et al.*, 2015a). One randomized controlled trial (RCT) with video analysis on individual Paro activities demonstrated that Paro created more laughter and positive expressions compared with a stuffed toy (Takayanagi *et al.*, 2014). Other studies have shown high levels of talking to and talking about Paro, also with affective communication toward Paro (Giusti and Marti, 2006) and an increased amount of utterances in general through one year of interaction with Paro (Wada *et al.*, 2005). Paro could also be a trigger to start conversations and interactions that would not otherwise take place (Klein and Cook, 2012). An ethnographic study of one agitated resident describes Paro as a means for open communication in severe dementia (Marti *et al.*, 2006). Better knowledge about a range of behaviors toward Paro is required. Care technology is increasingly a focus of white papers (Ministry of Health and Care Services, 2011), and Paro is implemented in studies worldwide. In addition, we need knowledge about how Paro creates engagement and influence behaviors in people with dementia when using it as a non-pharmacological treatment.

We recently published findings from a cluster-RCT on activity with Paro showing effect on agitation and depression (Joranson *et al.*, 2015). This paper presents analysis of video recordings of Paro groups performed early and late during Paro intervention as additional knowledge of Paro intervention in a group setting. The aim of this study was to investigate in a systematic way the variety of behaviors seen in people with dementia during group activity with Paro. We also wanted to investigate differences in behaviors related to dementia severity and explore changes in behaviors during the course of the intervention.

Method

NH units were recruited to the trial through the Centre for Development in NHs in three counties in Norway. Participants who had been part of an intervention in a cluster RCT that engaged in a 12-week semi-structured group activity with Paro were video recorded early and late during the intervention period to observe change in behaviors. For a detailed description of the cluster RTC, see Jøranson *et al.* (2015).

Participants

Thirty participants from five adapted units in NHs were recruited to participate in the Paro intervention, each unit forming a group. Three participants dropped out during the intervention period, and four participants attended only one of the video-recorded sessions. Inclusion criteria were age over 65 years and having a dementia diagnosis. Showing an interest in Paro was also an important inclusion criterion.

Ethical considerations

Nurses attached to the project recruited participants by oral and written information specially adapted for this patient group and assessed their ability to perform informed consent for participation. Participants gave oral consent and next-of-kin gave informed written consent. The project was reviewed

and approved by the Regional Committees for Medical and Health Research Ethics in Norway.

Paro activity

All sessions were conducted in a quiet, separate room in each NH in accordance with our protocol. Participants were sitting close on chairs in a half circle facing toward the activity leader (AL) conducting the sessions. All participants had regular seats to secure predictability in the setting.

Trained nurses from each unit and connected to the project participated in a three-hour mandatory Paro course ahead of the intervention to become an AL. ALs were supervised by the same project member post-sessions during the first two weeks, aiming to make the sessions as similar as possible for the sake of comparison.

Sessions were semi-structured and facilitated by an AL. All sessions started with the AL presenting Paro as an articulated doll, aiming to reduce misinterpretations. The AL distributed Paro to participants' laps for an equal period of time, preferably during two rounds to reduce waiting time. Sessions involved activities naturally occurring between participants and Paro, and between participants. The AL promoted all participants to interact with Paro. All participants were included in conversations by the AL through themes, such as their perception of Paro, of previous pets, or through other related themes. If participants were engaged or entertained in the activity, no discussion topic was needed. Participants were encouraged to interact with Paro, such as to pet or cuddle it, talk with it, sing to it, or play with it. All sessions were closed by the AL encouraging participants to tell Paro good-bye before turning it off.

Procedures

Recordings of Paro sessions in all groups were conducted during weeks 2 and 10 of the 12-week intervention period (a total of ten recordings). An ethogram was used to define and distinguish different behaviors in participants from the recordings. An ethogram is a catalog of descriptions of relevant behaviors of the subjects of the study (Troisi, 1999). The ethogram in this study was developed by members of the project group. Relevant behaviors were included based on previewing several video recordings, also determined by the first, second, and third author of this paper.

Data collection

NH staff obtained background information, including information about activity level and animal contact, from each participant. Stage of dementia was measured using the Clinical Dementia Rating (CDR) scale, with ratings from 0 (no cognitive impairment) to 3 (severe dementia) (Hughes *et al.*, 1982). To film the group sessions, the video camera was placed to record all participants in the camera's eye simultaneously and for as much time as possible. Data based on video recordings in the ethogram were imported into the data program Solomon Coder beta 14.03.10 (Péter, 2014). One project member conducted the video analysis.

Behaviors were defined both with and without having Paro on the lap to identify nuances in behaviors of direct Paro activity or social activity. Observations of specific behaviors in each participant were registered with duration in seconds during a session (see overview in Table 2). Several variables could be registered in parallel, such as "Observing Paro" and "Smile/laughter toward Paro." Two behaviors in the ethogram had mutually exclusive subcategories; category c) with observation of different objects and category d) with smiles and laughter (Table 2). The subcategory in observation of different objects, c), was changed if the participant changed spot of observed object in more than two seconds.

Analysis

The statistical analyses were conducted using SPSS version 22. The level of statistical significance was set at 0.05.

Sample characteristics at baseline were summarized by descriptive statistics using frequencies.

Registrations in the ethogram were imported to a spreadsheet for calculation of time for each behavior, recorded in seconds. Time out of camera was withdrawn for each participant, leaving the remaining time in each behavior converted to percentage of time for the sake of comparison in the analysis.

The behavior "Conversation with Paro" was only registered when the participant physically had Paro on the lap when communicating. The behavior "Contact with Paro" was registered when the participant physically had Paro on the lap or touched Paro on the next lap. Percentage of time for these variables had to be low as compared to the other variables due to the distribution of Paro among participants' laps. Percentage of time with Paro if distributed among six attending participants in a 30-minute session would result in a maximum 16%–17% occurrence in these variables. The behavior "Active with Paro" was only registered simultaneously as "Contact with Paro" to describe engagement when having contact with Paro. It would therefore always have a lower occurrence than registrations of "Contact with Paro."

Table 1. Variables in ethogram-observed behaviors recorded with time duration in seconds

a)	Conversation with Paro *Take initiative to converse or answer when having Paro on the lap.
b)	Conversation without Paro *Take initiative to converse or answer when not having Paro on the lap.
c)	Observations *Face toward Paro or other participants/activity leader (AL) or other things. Mutually exclusive subcategories: 1. Observing Paro 2. Observing other participants/AL 3. Observing other things in the room
d)	Smile or laughter *Smile or laughter appearing simultaneously when face is toward Paro or other participants/AL. Mutually exclusive subcategories: 1. Smile/laughter toward Paro 2. Smile/laughter toward other participants/AL
e)	Contact (physically) with Paro *Having Paro on the lap, or have physical contact with Paro on the next lap.
f)	Active with Paro *Showing engagement for Paro (by hugging, petting, caring for, playing with, investigating) when having Paro on the lap. Recorded in addition to "Physical contact with Paro."
g)	Singing, whistling, clapping, humming, dancing *Sing a song, declare poems, clap hands, dance, etc.
h)	Napping *Close eyes in more than 10 seconds.
i)	Walking around. *Rise from the chair and move in the room.
j)	Repetitive movement *Movement without a cause, such as shaking legs.
k)	Time out of recording. *No ability to observe participant on video due physical obstacle or blocking of camera.
l)	Physical contact *Take physical contact with participants or activity leader.
m)	Signs of discomfort *Crying, shouting, swearing, yawning, etc.
n)	Leaving the group *Canceling the activity, leaving the group.
o)	No response on contact *Passive behavior during physical contact with Paro, participants or AL, no motoric movements.

*Description of observed behavior in the participant.

Behaviors without registrations, or with registrations on only very few participants, were excluded to avoid biased results regarding the limited sample, resulting in a total of nine variables, all on a scale level. *The variables g) to o) in* Table 1 *did not meet the inclusion criteria.*

We tested occurrence in each behavior in week 2, aiming for overview of the variables early in the intervention by one-way ANOVA. To test for differences in behaviors between dementia severity among the participants, the CDR groups were divided into two subgroups in a dichotomous variable. CDR scores 1 (n = 2) and 2 (n = 11) were merged (n = 13) to represent participants with mild to moderate dementia, while CDR score 3 (n = 10) described participants with severe dementia. The dichotomous variable was set as factor in the one-way ANOVA.

Level of development in the included behaviors from weeks 2 to week 10 on a group level was tested by paired t-test.

Results

A total of 16 women and seven men (n = 23) were included in the statistical analysis, ranging in age from 62 to 92, mean 84.65 ±7.0. The CDR rating showed that 47.8% of the participants had moderate dementia (CDR 2) and 43.5% had severe dementia (CDR 3). Many of the participants preferred physical activities, and many enjoyed animal contact. See Table 2 for baseline descriptions.

Behaviors from a) to f) (Table 1) were the most frequent behaviors observed from the video

Table 2. Personal and medical characteristics at baseline

		n = 23
Mean age (62–92 years)		84.7 ±7.0
Women	%	69.6
Dementia diagnosis	%	100
CDR-rating* 1. Mild	%	8.7
2. Moderate	%	47.8
3. Severe	%	43.5
Prefer cognitive activities	%	17.4
Prefer physical activities	%	34.8
Prefer both types of activities	%	21.7
Do not participate in activities	%	8.7
No information of activities†	%	17.4
Previous animal/pet ownership: Yes	%	46.7
No	%	13.3
No information of pet ownership†	%	40.0
Enjoy animal contact: Yes	%	73.9
No	%	10.5
No information of animal contact†	%	17.4

*CDR = Clinical Dementia Rating scale.
†Missing information in background information form.

recordings and were therefore included in the analysis. The most frequent behaviors registered in week 2 were "Observing Paro," which had the highest occurrence (50% of the time); "Observing other participants/AL," which was registered more than 20% of the time; and "Contact with Paro," which was observed 17% of the time (Table 3). The variable "Observing other things" was registered more than 14% of the time. Conversation, which was divided into the behaviors "Conversation with Paro on the lap" and "Conversations without Paro on the lap," were each registered about 10% of the time, resulting in a total conversation time of 20%. Smile and laughter, divided into "Smile/laughter toward Paro" and "Smile/laughter toward other participants/AL," were registered more than 2% of the time (Table 3).

Next, we compared the different behaviors between participants with different degrees of dementia during week 2 (Table 4). We found a significant higher percent of time for the variable "Observing Paro" among participants with mild to moderate dementia (58.5%) compared to those having severe dementia (39.2%, $p = 0.019$). The variable "Observing other things" also showed a significant difference; participants with mild to moderate dementia had a mean percentage of time of 8.0% compared to 22.5% among participants with severe dementia ($p = 0.042$).

In Table 3, we report changes in behavior from week 2 to week 10. We found statistically significant differences of mean percentage in two variables. "Smile/laughter toward other participants/AL" showed a mean change from 0.8% to 1.5%, an increase of −0.7 ($p = 0.011$). The variable "Conversation with Paro on the lap" showed a decrease from 9.0% to 6.7%, a change of 2.3 ($p = 0.014$). There were no significant changes in any of the other variables on group level during the intervention, although the variable "Smile/laughter toward Paro" showed increasing tendency.

Discussion

In this systematic investigation, we describe different behaviors in participants, such as observing objects, conversations, smiles and laughter, and contact with Paro during the video-recorded sessions. Participants with mild to moderate dementia were more likely to observe Paro than participants with severe dementia. Participants with severe dementia showed highest occurrence in observing things other than Paro or people. During the course of the intervention, we found statistically significant increases in smiles and laughter toward others in the group while there was a decrease in conversations when the participants had Paro on the lap. In the following, we will explore and discuss these findings.

Behaviors in Paro group activity

Video recordings from ten sessions with five different Paro groups produced a broad description of behaviors, which we measured in duration. This combination has not been conducted previously in Paro studies. Some studies have measured various interactions among participants and with Paro (Chang *et al.*, 2013; Sabanovic *et al.*, 2013), but our study also describes other behaviors in addition to interactions.

In our study, the behavior "Observing Paro" had the highest observational time from the start of the intervention, indicating that Paro was catching interest from the first sessions. All our participants showed a pre-interest in Paro in the recruitment process in this study. Inclusion of participants' pre-morbid likings for pets and present likings of animal contact (see Table 2) has been described in dog-assisted therapy (Perkins *et al.*, 2008) and could contribute to explain the high attention toward Paro in participants.

We also included a less positive behavior toward Paro activity, such as participants observing objects other than Paro or other participants/ALs. This type of behavior could be interpreted as participants' struggle with concentration over time due to the cognitive impairment. Such information could be important when staff consider participants for group activity or for individual activity with Paro in terms

Table 3. Occurrence of each behavior in means (±S.D.) and results of paired t-test

VARIABLE	OCCURRENCE IN WEEK 2 IN %†	OCCURRENCE IN WEEK 2 IN %	RESULT OF PAIRED t-TEST (95% CI)	*p*-VALUE
c 1) Observing Paro	50.0 ±20.0	44.1 ±18.3	5.9 (−2.4 to14.7)	0.154
c 2) Observing other participants/AL‡	22.9 ±11.3	27.8 ±14.9	−4.9 (−12.4 to 2.6)	0.190
c 3) Observing other things	14.3 ±17.2	17.3 ±12.1	−3.0 (−8.4 to 2.4)	0.261
a) Conversation with Paro	9.0 ±5.5	6.7 ±5.5	2.3 (0.5 to 4.1)	0.014*
b) Conversation without Paro	10.9 ±10.0	11.9 ±14.4	−1.0 (−8.2 to 6.2)	0.772
d 1) Smile/laughter toward Paro	1.4 ±1.3	2.0 ±1.8	−0.6 (0.0 to 2.1)	0.052
d 2) Smile/laughter toward other participants/AL	0.8 ±0.8	1.5 ±1.4	−0.7 (−0.2 to 2.8)	0.011*
e) Contact with Paro	17.3 ±6.5	20.2 ±7.3	−2.9 (−6.6 to 0.9)	0.132
f) Active with Paro	7.0 ±6.1	6.6 ±7.0	0.3 (−2.1 to 2.8)	0.777

*Statistical significant at 0.05-level.
S.D. = Standard deviation.
CI = Confidence interval.
†Values are given as percentage of total session time.
‡AL = Activity leader in the Paro sessions.

Table 4. Results of occurrence in week 2 comparing severity of dementia in means (±S.D.)

VARIABLE	CDR-SCORE†	OCCURRENCE IN WEEK 2 IN %‡	*p*-VALUE
Observing Paro	2	58.3 ±10.8	0.019*
	3	39.2 ±24.3	
Observing other participants/AL**	2	27.7 ±11.2	0.397
	3	20.6 ±11.6	
Observing other things	2	8.0 ±5.8	0.042*
	3	22.5 ±23.5	
Conversation with Paro	2	9.6 ±5.2	0.559
	3	8.2 ±6.1	
Conversation without Paro	2	9.7 ±9.3	0.517
	3	12.5 ±11.1	
Smile/laughter toward Paro	2	1.4 ±1.4	0.959
	3	1.4 ±1.1	
Smile/laughter toward other participants/AL	2	0.8 ±1.0	0.822
	3	0.9 ±0.6	
Contact with Paro	2	17.2 ±5.9	0.944
	3	17.4 ±7.5	
Active with Paro	2	7.8 ±6.7	0.444
	3	5.8 ±5.4	

*Statistical significant at 0.05-level.
†CDR-score 2 = CDR-level 1 (mild dementia) and 2 (moderate dementia), CDR-score 3 = CDR-level 3 (severe dementia).
‡Occurrence in percentage of total session time.
**AL = Activity leader in the Paro sessions.

of how long each individual is able to focus on the activity. This finding will be discussed in the section of differences due to dementia severity.

The two activities of conversations, with or without having Paro on the lap, were found to be almost equal in duration. Conversation is an important part of the social interactions. Only one small (n = 7), unpublished study, which measured duration of behaviors, also showed statistical significant increase in interactions when participants did not have Paro contact (Sabanovic *et al.*, 2013). This means that participants do not need to have Paro on the lap to contribute in conversations, and it might indicate that Paro is suitable for use in a group setting to increase interactions.

Several behaviors from our study are described in other studies with video analysis, but mainly qualitatively and without accurate descriptions of change in behaviors during weeks of interactions (Giusti and Marti, 2006; Klein and Cook, 2012; Robinson *et al.*, 2015a). Our investigation is

important in terms of detecting and measuring various behaviors quantitatively, making statistical analysis of Paro activity possible. In addition, the described behaviors could be seen as expressed engagement during interactions, also knowledge of significance in Paro interventions. Chang *et al.* (2013) published a statistical analysis of video recordings measuring durations of behaviors, describing verbal interactions with Paro or with other participants or with therapist, and physical interactions (petting, holding, etc.). The results showed increased physical and social interactions. The RCT from Takayanagi *et al.* (2014) measured behaviors with frequencies and describes interactions systematically during six minutes of individual interaction. They found that participants talk and laugh more with Paro than with a toy lion and that participants with severe dementia had more neutral expressions toward the toy lion than Paro.

Differences due to severity of dementia

Participants with mild to moderate dementia paid significantly more attention toward Paro ("Observe Paro") compared to participants with severe dementia, which could indicate that Paro is less interesting for participants with severe dementia. To explore this finding, we must consider the severe cognitive impairment in this patient group when performing activities. People with severe dementia often struggle with holding focus due to easily being distracted (Engedal and Haugen, 2009). Comments or laughter from other participants could draw their attention away from Paro. However, participants with severe dementia observed Paro twice as much as they observed other participants/ALs. An ethnographic study describes persistent attention toward Paro as a quality of the intervention understood as an increased affection for Paro (Marti *et al.*, 2006). This indicates that Paro both captures and retains interest in participants with severe dementia. Performing engaging activities in dementia could provide meaning for the person (Hasselkus, 1998). Persistent attention toward Paro among participants with severe dementia could therefore be explained by Paro activity being perceived as a meaningful occupation. Many participants had a pre-morbid liking for pets and present liking for animal contact. Previous interests or past role identities in an individual will influence engagement in people with dementia, and an engaging stimulus, such as Paro, will create affection in the person interacting with it (Cohen-Mansfield *et al.*, 2009). There were no observations of negative behaviors in the recordings, which could underpin our explanations of engagement.

We found a significant higher occurrence in the variable "Observing other things," including attention toward all other things than Paro or people in participants with severe dementia. This behavior during the sessions could be interpreted as an attempt from participants with severe dementia to be engaged in something. Because NH residents struggle with both to participate and engage in activities, engagement in something will be better than no engagement, often resulting in napping or withdrawal, due to the fact that dementia impairs their attention capacity and wakefulness (Engedal and Haugen, 2009). Assessments of potential activities must be based on participants' individual ability to stay engaged during the session.

Changes on group level

We found an increasing amount of smiles and laughter toward other participants or ALs during the course of the intervention. This was expected and in accordance with previous research describing increased laughter and positive expressions (Takayanagi *et al.*, 2014). In the group setting based on our design, participants were sitting close in the half circle in order to facilitate social interactions in the group. Reactions and comments from other participants and staff toward participants in Paro interaction also increase smiles and laughter in the group which are previously described (Marti *et al.*, 2006). In addition, Paro is described to work as an ice-breaker between staff and residents (Robinson *et al.*, 2015a) in terms of working as a medium in communication. Even though the occurrence of smile and laughter was low when compared with other behavior variables, the main issue is the positive development in this behavior during the intervention period. In addition, we saw a tendency of increased smiles and laughter directly toward Paro. Paro is described to be an impetus toward social interactions (Klein and Cook, 2012; Robinson *et al.*, 2015a). Increase in smiles and laughter toward others, not only toward Paro, highlights the purpose of using Paro in the right group setting, also to create additional effects of Paro activity.

The significant decrease in conversation with Paro on lap was unexpected compared with previous research (Wada *et al.*, 2005; Chang *et al.*, 2013). This could most likely be a consequence of the group dynamics working in the Paro groups over time. After attending the sessions several times, the participants would feel more secure in the setting, as shown in other studies through physiological effects, such as lower blood pressure (Robinson *et al.*, 2015b) and reduced cortisol levels (Wada *et al.*, 2004) after interactions with Paro caused

by increased levels of oxytocin from the tactile stimulation in addition to be influenced by social interactions in the group setting (Uvnäs-Moberg, 1998). Positive experiences from Paro activity seem to increase participants' attention toward each other and the general social interactions, as described above. However, on a group level, the participants observed Paro more than twice the time they spent observing other participants in week 2. A decreased observation time toward Paro in week 10 could be explained in the context of Paro being a novelty, and the attention gradually being replaced by increasing social interactions in the group setting, as already described. However, the tendency of increasing conversations without having Paro on the lap could also explain the increasing social interactions caused by the group setting. Such development is described previously in a unit were Paro was found to have a cumulative socially mediating role to increase interactions in general to enable indirect cognitive engagement (Sabanovic *et al.*, 2013).

Strengths and limitations

This study has a relatively large sample, and several behaviors with duration were analyzed systematically through video recordings with an ethogram. To use video recordings above consecutive notes from mapping during the sessions produce possibilities to observe recorded sessions several times, which strengthens the internal validity of the study. Production of quantitative measures of behaviors makes statistical analysis possible; however, lack of statistical analysis from video analysis in other studies prevents comparisons with our study. Nevertheless, more participants could explain the difference between dementia groups.

In this study, we found changes in only two variables on the group level. The lack of significant findings for change in behavior in other variables might partly be due to several of the observed variables already having high occurrence from the beginning and therefore did not change significantly toward week 10, or it might be due to small sample size (type 2 error). However, when considering our explanations and discussion in view of theory of engagement in dementia, Paro seems to create an increasing engagement in the participants, despite few significant changes in the behaviors to quantify this.

Conclusion

In this study, only positive behaviors turned out to be included in the analysis, describing Paro as a positive activity for NH participants. We found Paro to create engagement in participants through high attention from the start. Our study also showed that participants with severe dementia had difficulty in holding focus on the activity, although benefiting from the group setting as described in previous findings (Joranson *et al.*, 2015). Care staff should be aware of the challenges toward maintaining attention for people with severe dementia and consider shorter duration, fewer participants in the group setting, or, if necessary, individual Paro activity.

Interactions changed during the course of the intervention as conversations with Paro on the lap decreased and smiles and laughter toward others in the group increased. Paro could be a medium to increase social interactions, as added value from the group activity for those who are able to participate in activities together with others.

Future studies should include satisfying sample sizes to investigate development of behaviors with stratification on dementia severity. It would also be interesting to investigate topics of conversations to produce clearer pictures of verbalized emotions arising in participants interacting with Paro.

Conflict of interest

None.

Description of authors' roles

Nina Jøranson was the main researcher of this study, formulating the research question, carrying out the study, analyzing the data, and writing the article. Ingeborg Pedersen participated in formulating the research question, designing the study, analyzing the data, and writing the article. Camilla Ihlebæk, Anne Marie Mork Rokstad, and Christine Olsen had a role in formulating the research question, designing the study, and writing the article. Geir Aamodt helped with the statistical analyses of the study and assisted with writing the article.

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9.2 Paper II

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Original Study

Effects on Symptoms of Agitation and Depression in Persons With Dementia Participating in Robot-Assisted Activity: A Cluster-Randomized Controlled Trial

Nina Jøranson MNSc [a,*], Ingeborg Pedersen PhD [a], Anne Marie Mork Rokstad PhD [b,c], Camilla Ihlebæk PhD [a,d]

[a] Section for Public Health Sciences, Norwegian University of Life Sciences, Ås, Norway
[b] Norwegian National Advisory Unit on Ageing and Health, Vestfold Hospital Trust, Tønsberg, Norway
[c] Faculty of Health Sciences and Social Care, Molde University College, Molde, Norway
[d] Faculty of Health and Social studies, Østfold University College, Fredrikstad, Norway

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group activity

A B S T R A C T

Objectives: To examine effects on symptoms of agitation and depression in nursing home residents with moderate to severe dementia participating in a robot-assisted group activity with the robot seal Paro.
Design: A cluster-randomized controlled trial. Ten nursing home units were randomized to either robot-assisted intervention or a control group with treatment as usual during 3 intervention periods from 2013 to 2014.
Setting: Ten adapted units in nursing homes in 3 counties in eastern Norway.
Participants: Sixty residents (67% women, age range 62–95 years) in adapted nursing home units with a dementia diagnosis or cognitive impairment (Mini-Mental State Examination score lower than 25/30).
Intervention: Group sessions with Paro took place in a separate room at nursing homes for 30 minutes twice a week over the course of 12 weeks. Local nurses were trained to conduct the intervention.
Measurements: Participants were scored on baseline measures (T0) assessing cognitive status, regular medication, agitation (BARS), and depression (CSDD). The data collection was repeated at end of intervention (T1) and at follow-up (3 months after end of intervention) (T2). Mixed models were used to test treatment and time effects.
Results: Statistically significant differences in changes were found on agitation and depression between groups from T0 to T2. Although the symptoms of the intervention group declined, the control group's symptoms developed in the opposite direction. Agitation showed an effect estimate of −5.51, CI 0.06 −10.97, $P = .048$, and depression −3.88, CI 0.43–7.33, $P = .028$. There were no significant differences in changes on either agitation or depression between groups from T0 to T1.
Conclusion: This study found a long-term effect on depression and agitation by using Paro in activity groups for elderly with dementia in nursing homes. Paro might be a suitable nonpharmacological treatment for neuropsychiatric symptoms and should be considered as a useful tool in clinical practice.

In Norway, more than 70,000 persons suffer from dementia, and increasing numbers are expected in the future due to the aging population. Almost 80% of Norwegian nursing home (NH) residents suffer from dementia and are in need of diurnal care.[1]

Approximately 80% of the dementia diagnoses include moderate or severe stages of dementia, which means a high level of neuropsychiatric symptoms (NPSs), such as wandering, agitation, anxiety, apathy, or depression.[2] Norwegian NH studies describe at least one NPS in as many as 70% to 80% of the residents.[3–5] More than half of the residents have symptoms of agitation, and symptoms of depression are present in 20% to 40%.[3,5,6] These findings are consistent with international studies on NPSs.[7]

NPSs have different causes, such as various physical ailments, undetected illnesses and pain,[8] discomfort, multiple unmet needs, person-environment conflicts, and stress responses,[9] but also

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* Address correspondence to Nina Jøranson, MNSc, Section for Public Health Sciences, Department of Landscape Architecture and Spatial Planning, Norwegian University of Life Sciences, PO Box 5003, N-1432 Ås, Norway.
E-mail address: nina.joranson@nmbu.no (N. Jøranson).

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boredom as a result of no or few activities in the NH.[10] Staff perceive NPSs as difficult to handle, and they are considered complicated to treat,[11,12] making psychotropic drugs the first choice to alleviate symptoms.[8]

Residents affected by NPSs experience great suffering and require treatment.[13] The efficacy of currently available pharmacological treatment is limited, and the side effects are potentially harmful, including increased mortality rates.[14,15] Hence, nonpharmacological treatments are recommended as first choice NPS treatments for people with dementia.[14]

Recent research shows growing acceptance of psychosocial treatment for alleviating suffering, and several intervention studies have been conducted during the past decades, such as therapy involving music, reminiscence, aromatherapy, light, and validation,[13,16,17] in addition to a variety of staff care interventions.[10,17] Individually tailored activities that are perceived as meaningful and that meet the unmet needs of residents are recommended for treating NPSs in NHs.[10]

One specific psychosocial treatment is animal-assisted intervention. Studies involving animal-assisted therapy conducted in NHs on residents with dementia have shown reduced symptoms of agitation and increased social interaction,[18,19] and reduced symptoms of depression.[20,21] Few studies have investigated the effect of animal-assisted interventions on mood in dementia sufferers,[22] although one study reported that it reduces apathy, but has no effect on depression,[23] whereas another study suggested it reduces sadness and increases pleasure.[21]

Interaction with animal-looking, socially assistive robots, also called SARs, is an alternative to human-animal interaction. SARs are developed to mediate communication and stimulate social exchange so as to provide social, psychological, and physiological benefits.[24] The baby harp seal, Paro, is the most common SAR used in studies.[25] NH studies with Paro interaction without a control group describe reduced symptoms of depression[26,27] and increased positive mood and social interaction.[26–30] One of the few randomized controlled trials (RCTs) conducted on interventions with Paro, compared a group with Paro interaction with interaction with a visitation dog. The authors reported that it reduced loneliness, but not depression.[31] Another cross-over study showed increased pleasure scores and less anxiety in an intervention group with Paro, but there was no effect on depression compared with a reading group as control.[32] The most recent RCT on Paro described effects such as frequent talking, positive expressions, and laughing from individual interaction with Paro compared with interaction with a stuffed toy.[33]

Reviews on intervention studies using SARs emphasize weak methodological quality, small samples, short durations, lack of control group, and follow-up measures. The importance and need for further studies with a more robust research design and larger samples have been emphasized.[24,25,34,35]

The aim of this article was to examine effects on symptoms of agitation and depression in NH residents with moderate to severe dementia participating in Paro group activity compared with a control group.

Method

The research design was a cluster-RCT involving intervention based on group activity with Paro. The control group received treatment as usual. Each NH unit was treated as a cluster and randomly allocated by an external research center to one of the groups (Figure 1). Participants were assessed on several measures at baseline (T0), at end of the intervention period of 12 weeks (T1), and at follow-up 3 months after the intervention ended (T2).

Recruitment of Participants

Ten NHs with adapted units were recruited from 3 counties in eastern Norway during 2012 and 2013 (Figure 1). After randomization of NH units, participation was offered to NH residents older than 65 years with a dementia diagnosis or who met the criteria for cognitive impairment, as per the Norwegian version of the Mini-Mental State Examination (MMSE)[36] with a score lower than 25/30. An important inclusion criterion was that residents showed an interest in Paro when it was demonstrated during recruitment. In NHs, companion animals belonging to the residents are not allowed. As a part of this study, units that received visits from visitation dogs put this activity on hold for 3 months before and after the intervention period in both groups. Other animals, such as cats living in the unit, poultry as a part of the outdoor milieu, or fish tanks were not removed.

A total of 60 participants were recruited (67% women, age range 62–95 years), 30 in each group (Figure 1), in accordance with the power calculation carried out before recruitment. One participant was younger than 65; however, with a Clinical Dementia Rating Scale (CDR) score of 3, was still considered suitable for the trial by staff. The total dropout rate in the Paro group was 10% ($n = 3$) and in the control group was 13% ($n = 4$), which was lower than the estimated dropout rate of 20%.

All but one had diagnosed dementia (MMSE score of 7/30). The stage of dementia was measured by the CDR, rating from 0 (no dementia) up to 3 (severe dementia),[37] showing primarily moderate to severe dementia (see Table 1), a normal prevalence in NHs.[2]

Ethical Considerations

Local nurses attached to the project gave potential participants, staff, and relatives oral and written information about the project, stating that participation was voluntary and that confidentiality would be maintained. They recruited participants and assessed their ability to perform informed consent for participation. Participants gave oral consent and next-of-kin gave informed written consent. The project was reviewed and approved by the Regional Committees for Medical and Health Research Ethics in Norway. It is registered at ClinicalTrial.gov (study ID number: NCT02008630).

Paro

Paro has the size of a baby harp seal with a swiveling head, moving legs and tail, and microphones that make the authentic sounds of a real baby harp seal. Paro is a highly advanced, adaptive robot with artificial intelligence software.[27] It recognizes voices and can respond to repeated words. Its artificial fur contains 12 sensors, creating interactivity between users and the robot as it responds to the user's repetitive motions, such as stroking. It is recommended that Paro is used during periods of time when staff are present, particularly when being used by people suffering from dementia.[38]

The Intervention

The trial was organized in 3 intervention periods during 2013 and 2014. Three months in advance, external researchers randomly assigned NH units to intervention or control. A maximum of 6 participants from each unit formed a Paro group. Sessions lasted for approximately 30 minutes and were conducted twice a week during the day on weekdays over the course of 12 weeks. The project group developed a protocol for the Paro program. The protocol states that sessions are to take place in a separate, quiet room, that all participants sit close together in a half circle without a table in front of

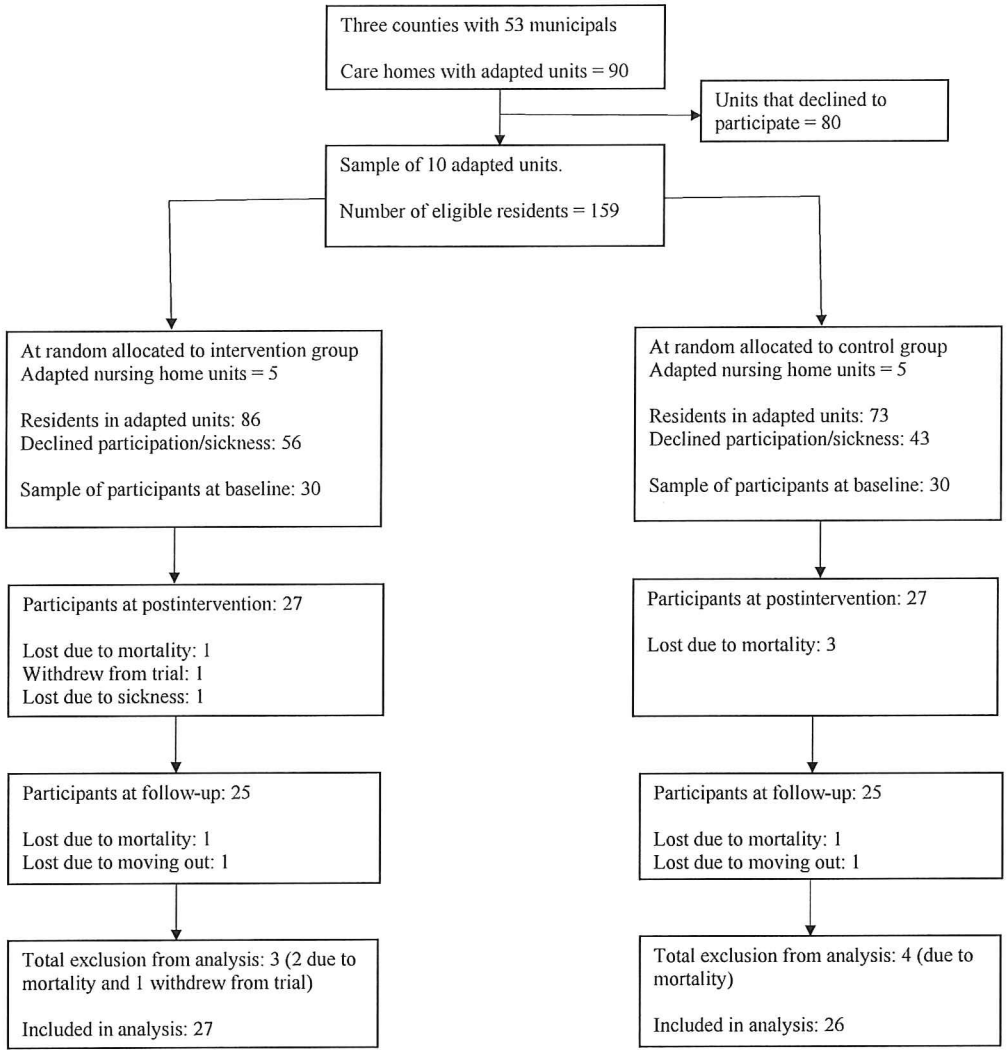

Fig. 1. Consort flow.

them, and that they all sit in their usual seats. During sessions, the activity leader should sit in front of the group. Each session started with a presentation of Paro as an articulated toy to reduce misinterpretations. The activity leader promoted interaction with Paro and distributed it to participants' laps for equal periods of time, preferably during 2 rounds to reduce waiting time. Sessions involved activities naturally occurring between the participants themselves, between the participants and the activity leader, and between each participant and Paro, such as petting, talking to and about, smiling to, and singing for. An additional staff member was always present in the background if participants needed assistance during the session or wanted to leave the room.

Staff members from each unit participated in a mandatory Paro training course before the intervention period. Activity sessions were led by one of the trained NH staff, who was supervised post sessions during the first 2 weeks by one member of the project group, aiming to make sessions in all intervention units as similar as possible for the sake of comparison.

Assessments

Staff obtained background information, including information about activity level and animal contact, from each participant in a form. An overview of regular medication also was obtained. All project staff participated in a 3-hour mandatory course on how to assess participants using the assessment scales. The Brief Agitation Rating Scale (BARS) was chosen as the trial's primary outcome measure. It is the brief version of the Cohen-Mansfield Agitation Inventory.[39] The validated Norwegian version of BARS consists of 9 frequent behaviors in dementia to be assessed on a 7-point Likert scale according to occurrence frequency during the preceding 2 weeks (score range of 9–63).[40] BARS has been used in several studies on people with dementia.[40] Symptoms of depression in dementia were measured by the validated Norwegian version of the Cornell Scale for Symptoms of Depression in Dementia (CSDD).[41] This assessment scale includes 19 questions on a 3-point scale assessing symptoms during the preceding week (score range 0–38).[42] The recommended cutoff score for the level of depression when assessing NH residents with dementia is 8/9 when using the CSDD.[41] The CSDD has been used in some studies on frail elderly.[43] In both assessment scales, high values mean more observed symptoms. Assessment scales were used at baseline, at postintervention, and at follow-up (3 months after postintervention).

Overviews of regular medication in accordance with the Anatomical Therapeutic Chemical (ATC) Classification System[44] on the second level N (nervous system) in the 6 subgroups (strong

Table 1
Personal and Medical Characteristics at Baseline

	Intervention Group n = 27	Control Group n = 26	*P* value
Mean age (SD)*	83.9 (7.2)	84.1 (6.7)	.922
Age no information, n = 1, %		1.9	
Women,† %	70.0	63.3	.584
Dementia diagnosis	27	25	
Cognitive impairment	0	1	
CDR-rating‡ %:			.716
1 Mild, %	7.4	7.6	
2 Moderate, %	48.1	46.2	
3 Severe, %	44.4	46.2	
Participation in activities,† :			.449
Prefer cognitive activities	20.0	30.0	
Prefer physical activities	40.0	40.0	
Prefer both types of activities	13.3	13.3	
Do not participate in activities	10.0	6.7	
No information	16.7	10.0	
Previous animal/pet ownership,† %:			1.000
Yes	46.7	46.7	
No	13.3	13.3	
No information	40.0	40.0	
Enjoy animal contact,† %:			.493
Yes	73.3	93.3	
No	10.0	6.7	
No information	16.7	0	
Mean agitation, BARS (SD)*	22.4 (7.7)	23.2 (11.4)	.759
Mean depression, CSDD (SD)*	9.0 (4.9)	6.9 (4.7)	.116
Regular medication prescribed,† %			
Analgesics	26.9	23.1	.749
Antipsychotics	7.7	23.1	.124
Anxiolytics	23.1	26.9	.749
Hypnotics/sedatives	34.6	30.8	.768
Antidepressants	38.5	42.3	.777
Cognitive enhancers	30.8	30.8	1.000
No information (n = 1)	1.9	0	

*Continous variables tested with 1-way analysis of variance.
†Dichotomous variables tested with χ^2 tests.

analgesics, antipsychotics, antidepressants, anxiolytics, sedatives, and cognitive enhancers [antidementia drugs]) were collected. Registrations of extra medication according to ATC level N in the 4 subgroups of strong analgesics, antipsychotics, anxiolytics, and sedatives were also collected. A drug was recorded if present in a subgroup. Medicine overviews were collected at baseline, at postintervention, and at follow-up for both groups.

Analysis

Sample characteristics at baseline were explored by descriptive and comparative statistics using 1-way analysis of variance for continuous variables and χ^2 test for categorical variables between the intervention group and control group. Continuous variables were examined for normal distribution by inspecting histograms.

Missing items were handled in the following manner: If an assessment scale lacked 1, 2, or 3 items, the mean score of the remaining items in the scale was imputed. If an assessment was missing (the whole scale) at any time point, it was imputed using a multiple imputation procedure (in SPSS [IBM SPSS Statistics, IBM Corporation, Chicago, IL]) including all outcome measures for all participants. The only exceptions were for mortality (n = 6) or withdrawal from trial (n = 1).

A mixed-model analysis was used to estimate effects in outcome measures between allocation groups, setting NH as a random factor nested within intervention type. Intervention type, time point of measurements, and the interaction between these 2 factors were used as fixed effects. Outcome measures were BARS and CSDD with 3 measurement times: Baseline (hereafter called T0), postintervention (called T1), and follow-up (called T2). Results from the multiple imputation are reported as pooled values. Both original and pooled results are shown in Table 2.

A subanalysis of amount of participation included a dichotomous variable to control for participation level in the intervention group (high = participation in at least 22 of 24 sessions) set as fixed effect. Changes in regular or extra medication between groups during intervention and follow-up was carried out with χ^2 tests. All analyses were done using SPSS version 22. The level of statistical significance was set at .05.

Results

No statistical differences were found in outcome measures or regular medication between groups at baseline (Table 1). The 2 groups were quite similar with respect to background information and medication, except for a lower prevalence of prescribed antipsychotics in the intervention group (Table 1).

Interrater reliability for primary outcome measure (BARS) ahead of baseline measures was conducted in 5 units (n = 28) with an intraclass correlation (single measures) of 0.84.

Mean values for BARS as an outcome measure for agitation decreased in the intervention group from T0 (mean 22.4, SD 7.7) to T2 (mean 18.2, SD 7.0), whereas mean values slightly increased in the control group (Table 2). BARS showed significant differences in effect estimates (95% confidence interval [CI]) of −5.5 (0.1–11.0), $P = .048$, when comparing the change in the intervention group with the control group from T0 to T2 (Table 2). The same pattern was found for depression measured by CSDD with a clear decrease for the intervention group from T0 (mean 9.0, SD 4.9) to T2 (mean 7.2, SD 6.4) and an increase in the control group (Table 2). CSDD also showed a significant difference in effect estimates (95% CI) of −3.9 (0.4–7.3), $P = .028$, when comparing the change in the intervention group with the control group from T0 to T2 (Table 2). There were no significant differences from T0 to T1, although the intervention group showed a clear decrease in both outcome measures at the end of intervention,

Table 2
Effects of Intervention in Intervention Group and Control Group at Baseline, Postintervention, and Follow-up

Measurement Time	Baseline, n = 53	Postintervention, n = 51	Follow-up, n = 50	Estimate (95% CI) T1–T0	Estimate (95% CI) T2–T0	*P* Value T1–T0	*P* Value T2–T0	Adj. estimate* (95% CI) T2–T0	Adjusted* *P* Value T2–T0
Outcome Measures	T0 Mean (SD)	T1 Mean (SD)	T2 Mean (SD)						
BARS:									
Control	23.2 (11.4)	24.7 (14.0)	24.0 (13.2)	−3.6 (−0.7–7.8)	−5.51 (0.1–11.0)	.098	.048	−5.4 (0.1–10.7)	.044
Intervention	22.4 (7.7)	20.2 (10.1)	18.2 (7.0)						
CSDD:									
Control	6.9 (4.7)	8.1 (5.6)	9.3 (6.6)	−2.3 (−0.4–5.0)	−3.9 (0.4–7.3)	.098	.028	−3.99 (0.7–7.3)	.019
Intervention	9.0 (4.9)	7.9 (6.7)	7.2 (6.4)						

*Adjusted estimates based on pooled results from multiple imputation in mixed model.

and the development was the opposite in the control group. The level of participation in the Paro group showed no statistically significant results.

Changes in both regular and extra medication showed no statistically significant differences between the groups at any time point.

Discussion

Our study demonstrated significant improvements from T0 to T2 in symptoms of depression and agitation when comparing participants in the Paro group activity with the control group. We found no significant statistical differences in these outcome measures between the groups from T0 to T1.

Despite the relatively high prevalence of agitation among NH residents,[7] few studies based on Paro interventions describe symptoms of agitation as an outcome measure. One pilot study on Paro assessed wandering, which showed an increased level in the intervention group.[32] The preliminary results of an ethnographic study assessed one severely agitated patient interacting with Paro over the course of 6 months, and found that Paro stimulated emotions and facilitated open communication.[29] Our study measured agitation and found a significant decrease at follow-up according to BARS in the intervention group compared with a slight increase in the control group. Even with a low level of measured agitation, as seen in our study, a difference of 5.5 points between the groups could be perceived as clinically beneficial to people with symptoms of agitation. This finding can have several explanations, which are discussed in the following paragraphs.

Paro is described as having a calming effect[24,34] by affecting the human stress response. In positive social settings, an increase in the hormone oxytocin will reduce cortisol levels and lower blood pressure, resulting in a reduced stress response. This also is seen as a response to positive social interaction occurring in therapeutic settings.[45] In our group activity, the positive social setting could be a possible contributing factor to the positive effect of the intervention. A Paro study, without a control group, reported improved oxytocin levels and a continued increase in oxytocin levels measured 4 weeks after the end of the intervention.[46] In our study, hormone levels were not measured; however, a similar response might offer a plausible explanation for the trend of decreasing levels of agitation during the intervention and the long-term effect found at T2.

Although the intervention was in a group setting, a central part of the activity program was the 1-to-1 interaction with Paro. Physical responses to Paro included stroking, cuddling, and petting, seen as common and more lasting behaviors when Paro is resting on the lap.[33,46–48] Animal-assisted interventions are found to reduce stress and aggression, and to lower blood pressure,[49,50] in addition to providing tactile comfort.[51] Because Paro is designed to imitate a living animal, findings from animal-assisted interventions can contribute to explaining our results. Petting the soft fur of Paro could stimulate participants' palms, corresponding to results from studies on hand massage, which also release stress-reducing hormones that alter the stress response and produce effects such as reduced agitation.[52] Given that people with dementia often display higher stress levels in their behavior,[9] such beneficial health reactions will most likely occur and affect participants during interaction with Paro.

Participants in our intervention group showed values indicating mild depression at baseline, in contrast to the control group. Mild depression has a cutoff of 8/9 when measuring symptoms with CSDD in NHs.[41] Even in a case of mild depression, a reduction of 3.9 points is perceived as a substantial reduction, resulting in beneficial health effects in the intervention group compared with the control group.

There are few studies on Paro that measure symptoms of depression[24,34] despite a prevalence of 20% to 40% in NHs.[7] One study without a control group found a nonsignificant decrease in symptoms of depression after long-term intervention with Paro.[26,53] A recent RCT with Paro intervention showed a slight, but statistically nonsignificant decrease in symptoms of depression at postintervention.[31] A pilot RCT demonstrated reduced symptoms of depression that were not clinically significant.[32] Neither of these RCTs had follow-up measurements and thereby no measurement of any further possible reduction in symptoms of depression. However, both of these studies had a different group design than our study, which makes comparisons difficult. The pilot study by Moyle et al[32] used 2 seal robots in an intervention group of 9 residents, and the study by Robinson et al[31] had a visitation dog in addition to Paro. The control groups in both studies had alternative social activity, not treatment as usual, as in our study. The different settings and the use of an alternative social activity in the control group might, to some extent, explain the limited differences between the groups compared in these previous studies with respect to depressive symptoms, and might explain the different findings compared with our study.

Mood is included in the depression spectrum in CSDD.[42] Mood is also used as a single outcome measure in several studies. In Paro studies, mood is often found to improve, based on observations from activity sessions where elderly with dementia are described as having higher levels of laughter, smiles, and positive expressions during interaction.[27,33,54] When Paro interaction creates an improved mood, the activity enables each participant to project their emotional state into the interaction. Persistent attention on Paro is seen as a quality of the interaction and could increase the way Paro affects participants, described as an emotional exchange with Paro.[29] Studies describe the way in which some residents demonstrate their affection for Paro by hugging and kissing or patting and soothing it as if the seal robot was a baby.[46,47] This could be seen as similar to the bonding between a mother and child, which also is found to increase oxytocin levels in the mother.[45] If Paro creates emotions that are similar to caring for a baby or pet, this could contribute to explaining the increased oxytocin levels measured in the Paro study by Wada and Shibata (2007).[46] We expect our participants in the intervention group also to be affected as described in the previously mentioned studies, which contributes to explaining our findings.

Willingness to participate in the Paro activity, as in our study, could be seen as a tailored activity aiming to maximize engagement in dementia,[55] an appropriate approach to unmet needs observed as NPSs in NHs. This is in accordance with person-centered care,[56] with a care philosophy suited to reducing symptoms of agitation in dementia.[57,58] Increased attention on basic individual needs and the wishes of each participant during the 12-week intervention could contribute to a positive change in our participants. This interaction creates activities such as petting, stroking, playing with, singing for, and talking to and about Paro. Creating activity is in accordance with residents' wishes to take on a more active role during activities, as described in a Norwegian NH study.[59] Such beneficial nonpharmacological treatment, creating engagement in NH residents, is assessed as being an effective means of treating NPS.[10,14]

To summarize, some of the key causes of the reduced symptoms of agitation in the intervention group from T0 to T1 include the calming effect and reduced stress responses caused by social and physical interaction, tactile effects, and bonding with Paro through emotional exchange. When interaction in the group setting with Paro is perceived as a meaningful activity by participants, elevated mood and increased social interaction could reduce symptoms of depression. We believe these factors explain most of the development during the 12 weeks of intervention. An increase in depression and a slight

increase in agitation, as seen in the control group with treatment as usual, was anticipated due to the progressive nature of dementia[60] and the described prevalence of NPSs.[7]

Reduced frequencies of observed NPSs in the intervention group must be seen as indicators of good-quality dementia care,[10] and a decline in NPSs at T2, as seen in our study, is rather rare[18] and deserves attention. Some of the lasting decrease in agitation and depressive symptoms measured at T2 might therefore be explained by mechanisms occurring in the NH units' psychosocial milieu, which has been a silent presence throughout the whole intervention period, from T0 to T2. Introducing Paro in these units is a novelty, and hence creates curiosity and increases interaction among residents and with staff.[28] Staff reactions to Paro are diverse, but one study found increased attention on and staff awareness of residents' needs after experiences with Paro activity.[61] Paro intervention in a unit could therefore influence the psychosocial milieu by increasing attention on residents' needs. Bearing in mind residents' need for an activity that meets their behavioral needs, the lasting impact 3 months after the end of the intervention is likely to be caused by lasting changes in the care provided by staff at the unit.[10] Although this was an unexpected finding in our study, a lasting effect such as this is seen in interventions with staff on implementing person-centered care with follow-up measurement of agitation.[57] Increased staff attention on participants is therefore a probable explanation for the continued decrease in symptoms of agitation and depression among participants until follow-up measurement.

Strengths and Limitations

This study has a number of strengths compared with previous studies using SARs. The RCT design used to demonstrate effects is important, as only a few comparable RCTs have been published. The study also included a larger sample conducted in 10 different NH units. It is strengthened by the fact that central NPSs in dementia are assessed both postintervention and at follow-up, using validated scales in the assessments. It was also a strength that there were few dropouts.

To our knowledge, this is the first published RCT based on Paro intervention compared with a treatment-as-usual control group, making the implementation of Paro more realistic when comparing the groups. On the other hand, we are aware that having an activity as the only treatment in the intervention group may mean that the new activity itself could probably affect participants in the intervention group to some extent. Not knowing the activity level in control group units in our study also is a weakness.

Blinding the assessors or participants is not possible in this kind of trial. This is a challenge and must be regarded as a limitation in using the RCT design in effect studies on psychosocial interventions for patients with dementia. In research on elderly NH residents with dementia, the inclusion of participants is complicated due to poor health, additional diseases, behavioral problems, and side effects of medication, as previously described.

Because of the practical limitations, the cluster design was chosen, making each NH unit a cluster. Ten NH units indicate 10 different NH environments, cultures, and staff-competence, with a possible influence on the participants during and after intervention, but this was not investigated in this study. The positive effect of conducting research in clinical practice (ie, enhancing staff members' attention and knowledge) is well known and could contribute to the positive findings. It is not possible to distinguish this effect from the effect of the intervention per se. Recruitment of participants interested in and willing to join the Paro activity does affect the external validity of results for elderly with dementia with a clear interest in this kind of activity.

Ethical issues arise when using Paro with people with dementia, but are not in the scope of this article.

Conclusions

We found reduced symptoms of agitation and depression at the end of the intervention, probably caused by effects such as stress-reducing responses in participants from interaction with Paro, but also as the result of Paro increasing social interaction within the group setting. In addition, 1-to-1 interaction with Paro (ie, letting each participant interact freely with Paro and thus create his or her own activity) influenced our results. The significant results measured at follow-up have uncertain causes, but could be caused by changes in the psychosocial milieu. This includes increased staff attention on residents' needs based on their experiences with participants' behavior and abilities through Paro activity. Our study identifies long-term effects on depression and agitation among elderly with dementia. Paro might be a suitable nonpharmacological treatment for neuropsychiatric symptoms for people interested in and willing to participate in group activity with Paro. Hence, it should be considered as a useful tool in clinical practice.

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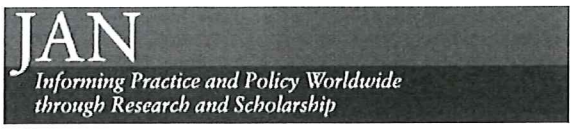
9.3 Paper III

Journal of Advanced Nursing



Change in quality of life in elderly with dementia participating in Paro-activity: A cluster-randomized controlled trial

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Manuscript ID	JAN-2015-1096
Manuscript Type:	Original Research: Clinical Trial
Keywords:	Dementia, Nursing Home Care, Quality of Life, Randomised controlled trials
Category:	Nursing

Abstract:

Aim

To investigate effects of robot-assisted group activity with Paro on quality of life (QoL) in persons with dementia.

Background

Nursing home (NH) residents with severe dementia often experience social withdrawal and lower QoL. Non-pharmacological interventions are suggested to enhance QoL.

Design

A cluster-randomized trial. Ten NH units were randomized to robot-assisted intervention or control group (treatment as usual).

Methods

27 participants participated in group activity for 30 minutes twice a week in 12 weeks, 26 participated in the control group. Change in QoL measured by the QUALID scale at baseline (T0), after intervention (T1) and at 3 months follow-up (T2). QUALID and regular psychotropic medication were analyzed stratified on dementia level. Subanalysis of QUALID subscales "Tension", "Well-being" and "Sadness" were performed. Mixed models, one-way ANOVA and linear regression models were used.

Results

Among participants with severe dementia an effect was found on QUALID total from T0 to T2 (effect estimate of 7·92, CI 2·16-13·69, p = 0·008), with an increase in QoL in the intervention group and a decrease in the control group. The intervention group used significantly less psychotropic medication compared with control group at T1 (p = 0·007). For participants with severe dementia, the intervention explained most of the variance in change in QUALID total and in change in the subscales Tension and Well-being.

Conclusion

Pleasant and engaging activities, such as group activity with Paro, could improve aspects of QoL, such as tension and well-being, in people with severe dementia.

Key words: Dementia care, Paro, nursing, severe dementia, quality of life, nursing home, group activity

Change in quality of life in elderly with dementia participating in Paro-activity: A cluster-randomized controlled trial

INTRODUCTION

Development of dementia leads to a progressive decline in cognition, increased apathy and level of functioning, and people having severe dementia are normally in need of diurnal care (Engedal *et al.*, 2009). About 80% of residents in Norwegian nursing homes (NH) are suffering from dementia. Of these, the prevalence of moderate dementia is less than 30% and severe dementia 33-63% (Selbaek *et al.*, 2007, Testad *et al.*, 2007, Bergh *et al.*, 2012). More than half of NH residents have symptoms of agitation and symptoms of depression are present in 20-40% (Selbaek *et al.*, 2007, Bergh *et al.*, 2012, Barca *et al.*, 2012). The prevalence found in Norway is in accordance with international studies of neuropsychiatric symptoms (NPS) in NH residents with dementia (Selbaek *et al.*, 2013).

A strong association is stated between both symptoms of depression and behavioral disorder in dementia with poorer quality of life (QoL) (Banerjee *et al.*, 2009). This association is confirmed in Norwegian NH studies by Mjorud et al. (2014b) reporting associations between severe dementia, increasing prevalence of NPS, amount of prescribed daily psychotropic drugs and QoL, and Barca et al. (2011) reporting association between QoL, major depression, severe dementia and impaired daily function.

Observational studies in NH describe people with severe dementia to be doing almost nothing in more than half of awaken time. Such inactivity will lead to social withdrawal and lower QoL (Ballard *et al.*, 2001, Kuhn *et al.*, 2005, Brooker and Duce, 2000, Perrin, 1997). An internal state of lack of interest and inactivity, as apathy (Brodaty and Burns, 2012), are common symptoms in people with moderate to severe dementia (Engedal *et al.*, 2009) and challenge participation in meaningful activities (Holthe *et al.*, 2007). Hence, engaging activities is recommended to enhance QoL in NH residents suffering from dementia, although measures on QoL with assessment scales to detect effects on people with severe dementia rarely are used in intervention studies (Moyle and Murfield, 2013).

Background

Participation in pleasant activities is beneficial for people with dementia (Teri and Logsdon, 1991). The significance of conducting positive activities in dementia is stated in reviews of intervention studies (Kverno *et al.*, 2009, Livingston *et al.*, 2014, Cohen-Mansfield, 2001, Cabrera *et al.*, 2015, Cooper *et al.*, 2012). Experiences of positive events and engagement can elevate positive affect and thereby increase QoL in severe dementia (Lawton, 1994).

QoL can broadly be defined as the subjective and objective judgement of the person's behavioural and environmental situation, as described by Lawton (1994). Lawton's domains of QoL in dementia

include competent cognitive functioning, ability to engage in positive pastime and in social activities, in addition to experience positive emotions and not being negatively affected, a definition used by most researchers (Roen *et al.*, 2015, Moyle and Murfield, 2013, Logsdon *et al.*, 2002). Rather than measuring QoL by assessment scales, several intervention studies measure NPS, such as agitation and depression, to explore effects on QoL in severe dementia because NPS is presumed to have a negative influence on QoL (Ballard and Margallo-Lana, 2004, Beerens *et al.*, 2013). However, some intervention studies use assessment scales to measure QoL. Spector et al. (2003) report effect on QoL in a randomized controlled trial (RCT) using cognitive stimulation therapy. Rokstad et al (2013) found effect on formal QoL in a RCT implementing person-centred care in NH. Studies with music (Cooke *et al.*, 2010), activity therapy (Politis *et al.*, 2004) or high intensity physical training program (Telenius *et al.*, 2015) as RCT interventions report no effect on QoL.

One specific non-pharmacological intervention in NH includes animals, and some studies report effect on QoL after dog visitation (Nordgren and Engström, 2014, Moretti *et al.*, 2011). Intervention studies with robotic emotional animals are based on the experience of interactions with animals. There is still scarce knowledge about how emotional robots affect QoL (Broekens *et al.*, 2009, Mordoch *et al.*, 2013). However, studies measuring increased mood and decreased loneliness consider these robots as possible tools to enhance QoL (Bemelmans *et al.*, 2012, Huschilt and Clune, 2012).A study using the robot dog AIBO found improved health-related QoL in patients with dementia (Kanamori *et al.*, 2003). The pilot study of Moyle et al. (2013) using the seal robot Paro revealed a moderate to large clinical influence on QoL, while Robinson et al. (2013) report a non-significant improvement of Paro. Additionally, a recent RCT of group-activity with Paro found no improvement on QoL (Valentí Soler *et al.*, 2015). Although several non-pharmacological interventions have been conducted aimed to enhance QoL in dementia, more knowledge and further research in general is needed (Cooper *et al.*, 2012).

Recently published findings from a cluster-RCT using Paro in group-activity revealed positive effect on agitation and depression in NH residents with dementia (Joranson *et al.*, 2015). This paper presents additional analyses of effect on QoL from group activity with the seal robot Paro in NH residents and explores potential differences related to severity of dementia.

THE STUDY

Aims

The aim of this study was to investigate the effect on QoL of a robot-assisted group activity in NH for people with dementia. We also wanted to explore the effect on different dimensions of QoL, and how dementia severity was associated with possible effects.

Design

The study was a cluster-randomized controlled trial containing intervention with group activity with Paro. The control group received treatment as usual. Each NH unit was treated as a cluster and allocated to one of the groups (fig. 1) by external researchers. Participants were assessed on several measures at baseline (T0), at the end of intervention period 12 weeks after (T1), and at follow-up (three months after end of intervention)(T2). The trial was organized in three intervention periods of 7 months during 2013 and 2014.

Participants

Ten NH with adapted units were recruited by Centre for Development of Institutional and Home Care Services from three counties in Eastern Norway during 2012 and 2013. After randomization of NH units, participation was offered by units' nurses to five-six residents over the age of 65 years with a dementia diagnosis or who met the criteria for cognitive impairment, as per the Norwegian version of the Mini-Mental State Examination (MMSE) (Folstein *et al.*, 1975) with a score lower than 25/30.

A total of 60 participants were recruited (67% women, age range 62-95 years), 30 in each group (fig. 1), in accordance with the power calculation on the primary outcome measure The Brief Agitation Rating Scale (BARS) (Finkel *et al.*, 1993), which included the following values: Standard deviation: 8.4 (Sommer and Engedal, 2011), least significant difference between groups: 7·0, significance level: $\alpha = 0{\cdot}05$, carried out before the recruitment. The total drop-out rate in the Paro group was 10% (n = 3) and in the control group 13% (n = 4), which was lower than the estimated drop-out rate of 20%.

All but one had diagnosed dementia (MMSE-score of 7/30). Stage of dementia was measured by Clinical Dementia Rating Scale (CDR), rating from zero (no dementia) up to three (severe dementia) (Hughes *et al.*, 1982), showing primarily moderate to severe dementia (table 1). One of the participants was under 65 years, however with a CDR-score of three, was still considered suitable for the trial by nurses.

Insert figure 1 here.

Ethical considerations

Nurses attached to the project recruited participants by giving oral and written information specially adapted for this patient group. They also assessed residents' ability to perform informed consent for participation. Participants gave nurses oral consent and next-of-kin gave written informed consent. The project was reviewed and approved by the Regional Committees for Medical and Health Research Ethics in Norway. The trial is registered at ClinicalTrial.gov (study ID number: NCT02008630).

Paro

The baby seal Paro is developed for people with dementia. It has a swiveling moving head, legs and tail, and speakers making the authentic sounds of a real baby harp seal. It is a highly advanced,

adaptive robot with artificial intelligence software (Wada *et al.*, 2004a). Paro can recognize voices and respond to repeated words. Sensors in the artificial fur create interactivity between users and the robot as it responds to the user's repetitive motions, such as stroking.

The Paro-intervention

The intervention was group activity conducted in a quiet, separate room in each NH in accordance with our protocol. All participants had regular seats during the setting to secure predictability. Participants sat close on chairs in a half circle towards the nurse, conducting the sessions. Paro was distributed to participants' laps for an equal period of time, preferably during two rounds to reduce waiting time. Sessions involved activities naturally occurring between participants and Paro and between participants.

Trained nurses from each unit connected to the project participated in a three hour mandatory Paro-course ahead of the intervention to lead the sessions. They were supervised by the same project member post sessions during the first two weeks, aiming to make the sessions as similar as possible for the sake of comparison. For further detailed descriptions, see our published article (Joranson *et al.*, 2015)

Data collection

All project staff participated in a three-hour mandatory course on how to assess participants by using the scales. No inter-rater-reliability test were conducted for QUALID, however, inter-rater-reliability for the study's chosen primary outcome measure, The Brief Agitation Rating Scale (BARS) (Finkel *et al.*, 1993), showed an high intra-class correlation (single measures) of 0·84.

Stage of dementia was measured at T0 by Clinical Dementia Rating Scale (CDR) (Hughes *et al.*, 1982), assessing cognitive impairment based on observation of care personnel during the last 4 weeks. The scale has 6 items to be rated on 5 levels from 0 (no impairment), via 0·5 (questionable impairment), 1 (mild impairment), 2 (moderate impairment) up to 3 (severe impairment). The rater should relate the person's function to their cognitive ability and last performance (Hughes *et al.*, 1982).

Self-reported assessment is challenging in severe dementia (Lawton, 1997), but proxy measures can provide meaningful and valid insights (Logsdon *et al.*, 2002). The Quality of Life in Late-Stage Dementia scale (QUALID) (Weiner *et al.*, 2000) was therefore chosen as outcome measure for assessing the participants' QoL by the Norwegian version. QUALID consists of 11 items regarding different aspects of proxy-rated assessments of QoL in people with severe dementia, reflecting observations during the preceding week. Each item is assessed related to an observed behavior between the score 1 and 5. The minimum scale score is 11, indicating good QoL, and maximum score

is 55, reflecting a poor QoL. The Norwegian version is a reliable and validated tool in studies of elderly with dementia (Roen *et al.*, 2015). Assessment of QoL was performed at T0, T1 and at T2.

An attempt to provide better insight in outcome measures from QUALID when assessing QoL in this patient group is to divide QUALID total scale into subscales based on component analysis, although several studies report different numbers of factors (Mjorud *et al.*, 2014a). A component analysis from a large (n = 661) Norwegian NH study investigated factors holding the Norwegian version of QUALID, resulting in three factors explaining most of the variance (53,5%) which could be handled as subscales. The first, "Tension", includes items as facial expression of discomfort, appears physically uncomfortable, verbalizes expression of discomfort, being irritable and aggressive, and appears calm. The second, "Well-being", includes items as smiles, enjoys eating, enjoys touching/being touched, and enjoys social interaction. The third, "Sadness", includes items as appears sad, cries and shows facial expression of discomfort (Mjorud *et al.*, 2014a). These subscales were chosen to be included in subanalysis after being considered as to reflect previous psychometric outcomes in our study (Joranson *et al.*, 2015).

The side effects of psychotropic drugs are considered potentially harmful for elderly with dementia (Salzman *et al.*, 2008, Selbaek *et al.*, 2007), often associated with poorer QoL (Ballard and Margallo-Lana, 2004). Overviews of regular medication in accordance with the Anatomical Therapeutic Chemical (ATC) Classification System (WHO, 2014) on the second level N (nervous system) were collected at T0, T1 and T2. Drugs were divided into four subgroups (antipsychotics, antidepressants, anxiolytics and sedatives), and a drug was recorded if present in subgroup(s). Due to low number of participants causing low number of values in the subgroups, they were merged into one variable called psychotropic medication, making a score from 0-4.

Demographic information including age and sex was collected from each participant by staff.

Insert table 1 here.

Data analysis

Sample characteristics at baseline were explored by descriptive and comparative statistics using one-way ANOVA for continuous variables and χ^2-test for categorical variables between the intervention group and control group. Continuous variables were examined for normal distribution by inspecting histograms.

If the QUALID scale lacked one or two items at a time point, the mean score of the remaining items in the scale was imputed. In addition, for the mixed-model analysis, if an assessment was missing (the whole scale) at any time point, it was imputed using a multiple imputation procedure (in SPSS) including all outcome measures for all participants. The only exceptions were for mortality (n = 6) and withdrawal from trial (n = 1).

A mixed-model analysis was used to estimate effects in the outcome measure between the allocation groups. Time was modelled as a repeated variable, an autoregressive covariance structure (AR1) was used to accommodate dependencies between the three points of time. Nursing home was set as a random factor nested within intervention type, intervention type was used as fixed factor. To accommodate different time trends between the groups, we also included an interaction term between intervention group and control group and points of time, which was the effect of interest in this study.

Outcome measure was QUALID with the three measurement times T0, T1 and T2. To explore differences in change of QoL due to level of dementia, a sub-analysis with data stratified in CDR-group 1 + 2 (mild and moderate dementia), n = 29, and CDR-group 3 (severe dementia), n = 24, was performed. Results from the multiple imputation are reported as adjusted estimates based on pooled values. Both original and adjusted results are shown in table 2.

A one-way ANOVA with mean in psychotropic medication as dependent variable and "Intervention type" as fixed effect was also conducted, see table 3.

Multiple linear regression analysis was performed for CDR-group 3, with change in total QUALID (T0 - T2), as well as in the three subscales Tension, Well-being and Sadness as dependent factor. Due to the low number of participants, sex and age in addition to intervention/control were in turn used as independent factors to explore their predictive value on QoL. On QUALID total also medication was used as independent factor.

All analyses were done using SPSS version 23. The level of statistical significance was set at 0·05.

RESULTS

At baseline, 53 participants were included in the study. There were no significant differences in personal and medical characteristics between the participants in the intervention group and control group at baseline (table 1).

As illustrated in table 2, QoL as measured by QUALID during the course of the intervention revealed an increase in mean score (SD) in the control group from T0 of 22·92 (8·50) to T2 of 26·48 (10·05), meaning a decrease in QoL. The mean QUALID score in the intervention group remained almost unchanged from T0 of 23·46 (6·04) to T2 of 23·76 (7·22). The difference between the groups in effect estimate from T0-T2 was 3·53 (CI -0·90-7·96), a non-significant result, p = 0·117.

Insert table 2 here.

The sub-analysis on QUALID including stratification on dementia severity showed a statistical significant difference in effect estimate between the groups with severe dementia from T0 to T2 of 7·92 CI (2·16-13·69), p = 0·008, indicating this control group to have an exacerbation of QoL,

compared with the intervention group remaining almost stable during the course of the intervention. We found no statistical differences between the groups with mild/moderate dementia (table 2).

One-way ANOVA for psychotropic drugs showed statistical significant difference in mean (SD) of 0·75 (0·46) for participants with severe dementia in Paro-group compared with control group with 1·67 (0·71) at T1 ($p = 0·007$). At T2, the difference between Paro-group and control group was slightly smaller and non-significant ($p = 0·088$). There were no differences between the groups for participants with mild/moderate dementia.

Insert table 3 here.

Results from the linear regression models for testing effect from the intervention on participants with severe dementia are presented in table 4. Change in QUALID total scores and in the two subscales Tension and Well-being were significantly explained by intervention. All models explained more than 30% of the variance. Intervention and change in psychotropic medication explained 50·5% of the variance in change in QUALID total. We found no association of sex or age for any dependent variable. We detected no statistical significant results in the subscale Sadness.

Insert table 4 here.

DISCUSSION

We found a significant effect of the Paro intervention on QoL for participants with severe dementia. An effect of the intervention was also found for the subscales Tension and Well-being, reflecting a positive development in QoL. We also found a difference on prescribed psychotropic drugs between the groups with severe dementia at T1. Intervention and change in medication explained 50% of the variance in change in QoL in the group with severe dementia. These findings will be discussed in the following.

Effect on QoL in mild/moderate stage of dementia

We found no statistical significant differences in QUALID scores when comparing participants with mild to moderate dementia in the intervention group to control. This means that participants in the control group did worsen QoL equally with those receiving Paro-activity. Due to normal progression of cognitive impairment in NH residents, we expect a decrease in QoL during the course of the intervention (Barca *et al.*, 2011, Valentí Soler *et al.*, 2015). Our finding of steady and parallel development in QoL might be related to higher remaining psychological and physical functions in people with mild/moderate dementia (Engedal *et al.*, 2009) in general, enabling them to have a more independent daily living. Independent living in NH is observed as having control of mobility to move freely, ability to enjoy meals and participate in perceived meaningful activities, and ability to communicate and keep social contact with other residents, staff and family visitors (Hauge, 2004). To

keep relations with others and have control over life are aspects influencing QoL in dementia (Moyle *et al.*, 2011). In our study the additional activity may not affect QoL to the same extent in this patient group due to the possibility of interacting freely with others without assistance from staff, being active without the need of organized activities. To perform activities in daily living in NH is seen as valuable skills in a person (Edvardsson *et al.*, 2014, Drageset *et al.*, 2009). Such abilities seems to be in line with Lawton's (1994) domains of higher QoL in dementia, as described earlier, and could confirm the finding of no difference between participants with mild and moderate dementia.

Effect on QoL in severe stage of dementia

We found change in QUALID scores at follow up after intervention with Paro for participants with severe dementia, showing a slight improvement in QoL compared with a clear decrease in QoL for the control group. Effects from assessment scales on QoL have not been described in studies on emotional robots, as reported previously. In addition, these studies lack long term measures at follow up (Kolling *et al.*, 2013) in addition to stratified analysis on dementia severity, making comparison of our findings difficult.

When we consider our findings viewing Lawton's (1994) theoretical domains for improved QoL in dementia, participants in this group are considered to have severe reduced cognitive functioning and therefore reduced ability to perform daily activities, interpreted to reduce QoL according to the domains. When further considering Lawton's domains, such as the ability to engage in positive pastime and social activities, we describe our participants to have experienced socially stimulating activity with Paro, perceived as being beneficial in people with dementia (Bemelmans *et al.*, 2012). Using robotic animals, such as Paro, are described to be a valuable non-pharmacologic tool also to reduce NPS, especially to meet a need for protection against loneliness through tailored activities with stimulation of social interactions (Cohen-Mansfield, 2013). Participation in meaningful activities is valued to influence QoL in NH residents with severe dementia (Moyle *et al.*, 2011). We therefore consider our participants' experiences with Paro to have produced positive emotions and thereby preserving QoL despite being in a state of having severe dementia.

As described in the above section, residents with moderate dementia could have remaining cognitive capacity which could protect against decline in QoL. This is not the case for people with severe dementia relaying on the ward milieu to activate them, aiming to persist decline in QoL. For these participants, meaningful activities, such as group activity with Paro, would be both valuable, but also a necessity for QoL in terms of be given possibilities into social interactions, achieve tactile stimulation through petting, stimulate communication with Paro and other participants, and show affections for Paro (Klein *et al.*, 2013). We suppose participation in Paro-activity to have influenced and prevented poorer QoL despite the expected progression of cognitive impairment. Regarding the described positive development in intervention group, it is important to pay attention towards the significant

opposite developments in change in QUALID total of almost 8 points between these groups during the course of the intervention. This development must also be viewed in our previous findings showing the same trends with opposite development between the intervention group and the control group on symptoms of agitation and depression, although not stratified on dementia severity (Joranson *et al.*, 2015). The opposing trends on agitation and depression could underpin our findings of the opposing development of QoL in participants with severe dementia in this paper.

Our study seems to be the first to describe effects on improved QoL, also by investigating content of the measurement scale QUALID, such as on tension and well-being. Test of effects on change in QUALID subscales Tension and Well-being showed significant explanations of variance from the intervention, which are positive and interesting findings needing explanations.

The subscale Tension has items such as physically uncomfortable, verbalization, irritability and aggression, items seen as neuropsychiatric symptoms (NPS) and viewed as negative behaviors in an agitated person. A preliminary case-study exploring how Paro could calm an agitated male with moderate dementia reported Paro to evoke affections and act as a social mediator (Marti *et al.*, 2006). Marti et al. (2006) describe Paro to reduce tension, as part of NPS, in people with severe dementia through engagement which stimulate emotions. Participating in pleasant activities is appropriate for the individual's functioning and could improve mood and reduce agitation (Teri and Logsdon, 1991). Reduced prevalence of NPS is associated with higher QoL (van de Ven-Vakhteeva *et al.*, 2013, Ballard *et al.*, 2001) and could explain the finding in the subscale Tension.

The subscale Well-being has items such as smiling, enjoy touching/being touched and enjoy social interaction, all associated with positive behaviors. These behaviors are also described in several studies implementing Paro. Smiling, as a part of the mood aspect, and increased social interactions with both Paro and other participants, are frequent findings from Paro-interventions (Wada *et al.*, 2004b, Wada *et al.*, 2004a, Klein and Cook, 2012, Marti *et al.*, 2006). In addition, touching, petting and kissing the soft fur of Paro are significant in terms of tactile stimulation, a hand-massage activity soothing people with dementia (Remington, 2002). In a more general perspective, assessment of increased well-being in dementia was found after Paro-activity in the study of Inoue et al (2012) through an observational mapping tool, although it was a small study. Based on findings from other Paro-studies, well-being viewed as increased mood and engagement seems to influence QoL for people with severe dementia and explains our finding.

Use of psychotropic drugs and QoL in severe dementia.

The intervention group with severe dementia had different mean values on prescribed psychotropic drugs during the course of the intervention. We found a significant opposite mean value with lower prescription for intervention group versus higher in control group at T1 and a non-significant difference between groups at T2. Reduced prescription of psychotropic medication could possibly be

seen as a consequence from the Paro-intervention, which has not, to our knowledge been described previously. However, a study of van de Ven-Vakhteeva et al (2013) did not find antipsychotics to change QoL in Dutch NH, only reduction in NPS was found to increase QoL.

Symptoms of agitation and depression are diagnosis commonly treated with medication in NH residents with dementia, as earlier described. We fond reduced prescription of psychotropic medication after end of intervention. A scenario of reducing pharmacological treatment because of a non-pharmacological treatment is a positive development and reflect the goal of an updated and appropriate treatment of NPS in dementia (Salzman *et al.*, 2008).

Continuing development after end of intervention

There was about 7 months between measured QoL at baseline and follow-up in our study. The poorer QoL measured in the control group at follow-up might be caused by expected progress of cognitive impairment in NH residents with severe dementia, also described in Valentí Soler et al (2015) intervention study with Paro. During the course of the intervention and to follow-up, we found a continuing positive development in QoL in the intervention group and continuing decrease in the control group for participants with severe dementia. This development is difficult to explain considering the activity to end three months earlier. In addition, there are almost no studies with follow up measures making comparisons from our study difficult. Intervention studies with follow up measures report long-term effects to be rare, hence, tailored and engaging activities are continuing tasks in NH for staff (Selbaek, 2005).

However, local nurses connected to our study spent time with the unit's participants during many Paro-sessions, probably also experiencing unknown abilities, life-stories and engagement in the participants. Reflection on new insights could possibly make nurses more aware of remaining skills and disguised needs in the daily care. Such mechanism in staff has been described previously after use of Paro in NH (Pedersen, 2011). If so, such a mechanism might have been a "silent presence" almost from the intervention started.

Strengths and limitations

This RCT included a larger sample in a Paro-intervention and from 10 clusters, considered as a robust design. In addition, the association between change in outcome measure and time points was analyzed with statistical models for hierarchical data due to possible cluster effect. Few drop outs in this study is also a strength. Measurement on QoL with assessment scale has been used in addition to other factors associated with QoL in dementia, such as symptoms of agitation and depression and use of psychotropic drugs, to explain change in QoL. We also collected measures at follow up.

There are several limitations in this study. Although a power calculation was carried out before the intervention, we did not have a large sample to run the linear regression analysis. Including all

independent variables in step-wise analysis was therefore impossible. We chose to stratify our further analysis on level of dementia, making the groups even smaller in the analysis. Even so, the findings in this paper is clearer compared with other studies in terms of analyzing and suggesting which residents in NH that Paro could be more suitable for. Further research with stratification is needed to confirm this, including larger studies to prove generalizability of the findings.

Blinding the assessors or participants is not possible in this kind of trial. This is a challenge and must be regarded as a limitation using the RCT design in effect studies on psychosocial interventions for people with dementia. Another challenge is use of proxy-ratings in QoL giving observations rather than subjective assessments, but not possible otherwise when including participants with severe dementia.

Another challenge in research on elderly nursing home residents with dementia is the inclusion of participants being complicated due to poor health, additional diseases, behavioral problems, and side-effects of medication.

The intervention did not show any predictive power on the subscale Sadness, which include the items sadness and signs of discomfort. Although these items are reflected in both CSDD and in BARS, we found no relation to change between the groups. We find this hard to explain, but might be random due to use of three subscales in our analysis instead of using two factors, as Barca et al (2011) found in their study. This result could be due to a different, but also smaller, sample in our study.

We compare some of our findings in this paper with our published findings (Joranson *et al.*, 2015), which lack of stratifying on CDR-level on results. This made our comparisons of findings on QoL, based on severity of dementia in this paper, challenging and therefore more general.

Despite stratifying on severity of dementia, our participants had slightly higher baseline mean in QUALID total compared with other recent Norwegian NH studies (Roen *et al.*, 2015, Mjorud *et al.*, 2014b). This could be random, but might be caused by only nurses performing all assessments without having present supervision from research assistants in our study.

CONCLUSIONS

We found an increase in QoL in the intervention group with severe dementia after Paro-activity and a decrease in QoL in the control group at follow up. Pleasant and engaging activities, such as group activity with Paro, could improve aspects of QoL, such as tension and well-being, in these participants. The lack of findings in the groups with mild/moderate dementia we relate to better cognitive function. Higher level of remaining skills is associated with higher QoL, and we assume better cognition enabled these participants into other activities in their daily living influencing higher QoL in general.

We believe interaction with Paro in group-sessions to be an accessible non-pharmacological activity in nursing homes. Activity with Paro seems to be especially suitable for NH residents with severe dementia to improve quality of life.

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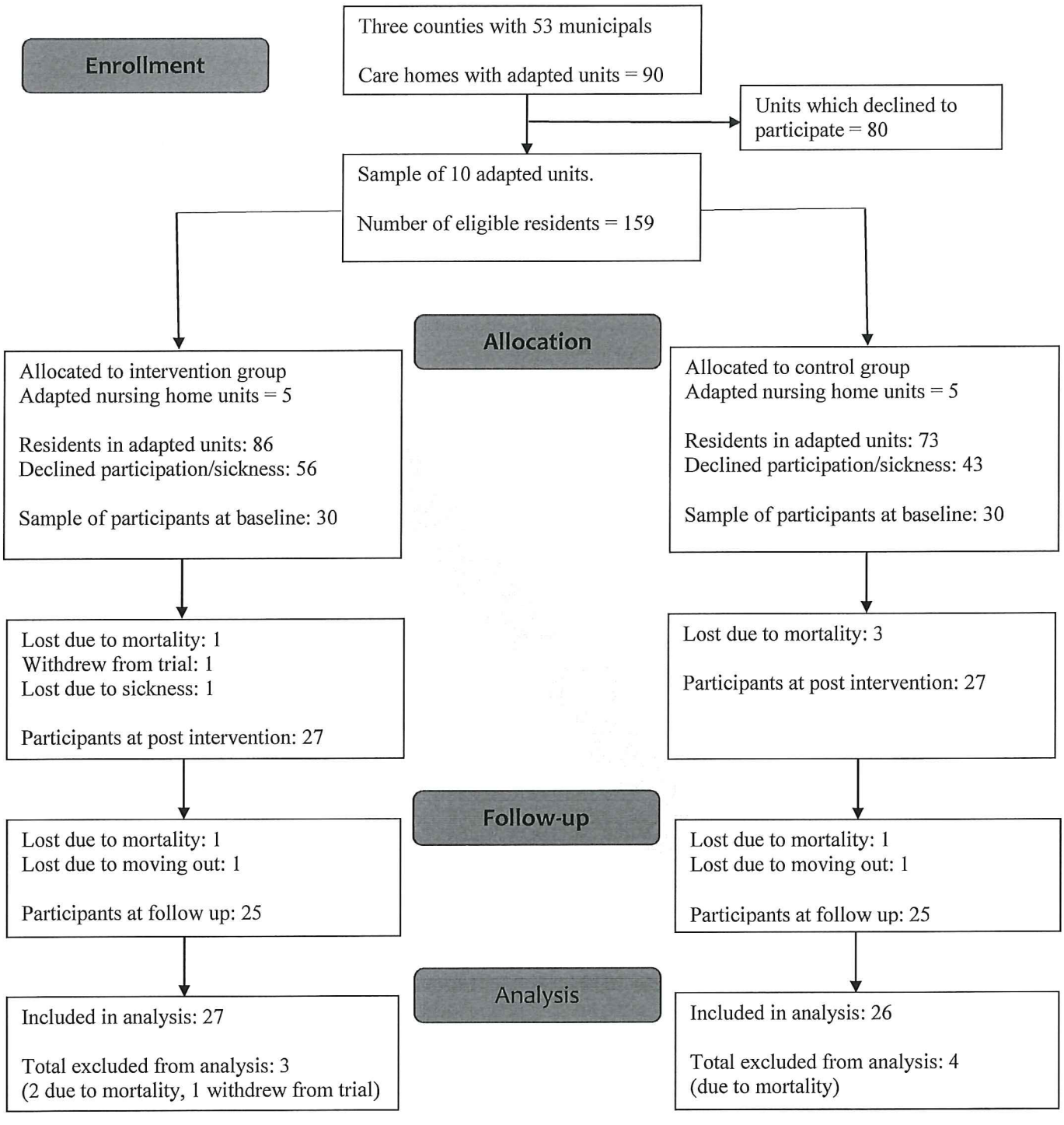
Enrollment
Three counties with 53 municipals
Care homes with adapted units = 90
Units which declined to participate = 80
Sample of 10 adapted units.
Number of eligible residents = 159
Allocation
Allocated to intervention group
Adapted nursing home units = 5
Residents in adapted units: 86
Declined participation/sickness: 56
Sample of participants at baseline: 30
Allocated to control group
Adapted nursing home units = 5
Residents in adapted units: 73
Declined participation/sickness: 43
Sample of participants at baseline: 30
Lost due to mortality: 1
Withdrew from trial: 1
Lost due to sickness: 1
Participants at post intervention: 27
Lost due to mortality: 3
Participants at post intervention: 27
Follow-up
Lost due to mortality: 1
Lost due to moving out: 1
Participants at follow up: 25
Lost due to mortality: 1
Lost due to moving out: 1
Participants at follow up: 25
Analysis
Included in analysis: 27
Total excluded from analysis: 3
(2 due to mortality, 1 withdrew from trial)
Included in analysis: 26
Total excluded from analysis: 4
(due to mortality)

Table 1. Demographical and medical characteristics at baseline

		Intervention group n = 27	Control group n = 26	*p* value
Mean age (SD)		83·9 (7.2)	84·1 (6.7)	0·922[a]
Age no information (n=1)	%		1.9	
Women	%	70·0	63·3	0·584[b]
Dementia diagnosis		27	25	
Cognitive impairment	n	0	1	
CDR-rating: 1 Mild	%	7·4	7·6	
2 Moderate	%	48·1	46·2	0.716[b]
3 Severe	%	44·4	46·2	
Mean QUALID (SD)		23·6 (5·9)	22·9 (8·5)	0·754[a]
Mean QUALID – CDR-group 1 + 2		21·0 (6·2)	20·4 (6·0)	0·778[a]
Mean QUALID – CDR-group 3		26·8 (3·8)	25·9 (10·2)	0·794[a]
Regular psychotropic medication				
- Antipsychotics	%	7·7	23·1	0·124[b]
- Anxiolytics	%	23·1	26·9	0·749[b]
- Hypnotics/sedatives	%	34·6	30·8	0·768[b]
- Antidepressants	%	38·5	42·3	0·777[b]
No information (n=1)	%	1·9	0	
Mean (SD) psychotropic medication		1·04 (1·1)	1·23 (0·9)	0·506[a]

SD = standard deviation
CDR = Clinical Dementia Rating Scale
QUALID = The Quality of Life in Late-Stage Dementia Scale
[a]Continous variables tested with one-way ANOVA
[b]Dichotome variables tested with χ^2-tests

Table 2:
Mean values (SD) and effects estimates for QUALID total score in Paro group and control group in the total sample and divided into CDR-groups at baseline (T0), post intervention (T1) and follow-up (T2)

	T0 Mean (SD)	T1 Mean (SD)	T2 Mean (SD)	Estimate (95% CI) T1 – T0	Estimate (95% CI) T2 – T0	*p*-value T1 – T0	*p*-value T2 – T0	*Adj. estimate† (95% CI) T2 – T0*	*Adjusted p-value† T2 – T0*
QUALID total									
Control group (n = 26)	22·92 (8·50)	25·31 (10·26)	26·48 (10·05)	2·66 (-0·72-6·03)	3·53 (-0·90-7·96)	0·121	0·117	*3·78 (-0·52-8·07)*	*0·085*
Paro group (n = 27)	23·46 (6·04)	23·35 (7·65)	23·76 (7·22)						
QUALID, CDR 1 + 2									
Control group (n = 14)	20·36 (5·96)	23·07 (9·50)	23·00 (6·56)	2·58 (-2·28-7·44)	0·06 (-5·56-5·68)	0·292	0·983	*-0·11 (-5·58-5·35)*	*0·967*
Paro group (n = 15)	21·00 (6·19)	21·13 (7·75)	23·21 (8·04)						
QUALID, CDR 3									
Control group (n = 12)	25·92 (10·21)	27·92 (10·90)	30·91 (12·15)	2·25 (-2·05-6·56)	7·92 (2·16-13·69)	0·298	0·008*	*7·22 (1·65-12·79)*	*0·011**
Paro group (n = 12)	26·75 (3·84)	26·36 (6·68)	24·45 (6·35)						

SD = standard deviation
CI = confidence interval
**statistical significant at .05-level.*
†Adjusted estimates based on pooled results from multiple imputation in mixed model.
QUALID = The Quality of Life in Late-Stage Dementia Scale
CDR = Cognitive Dementia Rating Scale
CDR 1 + 2 = mild and moderate dementia
CDR 3 = severe dementia

Table 3 Mean (SD) of the psychotropic medication score (0-4) at T0, T1, and T2 for stratified by severity of dementia

Outcome measure	Inter-vention type	T0 – mean (SD)	*p-value*	T1 – mean (SD)	*p-value*	T2 – mean (SD)	*p-value*
Psychotropic medication – CDR 1+2	Paro	0·93 (0·88)	*0·989*	0·92 (0·95)	*0·670*	0·67 (0·89)	*0·468*
	Control	0·93 (0·92)		1·08 (0·90)		0·93 (0·92)	
Psychotropic medication – CDR 3	Paro	1·00 (0·63)	*0·442*	0·75 (0·46)	*0·007**	0·63 (0·91)	*0·088*
	Control	1·25 (0·87)		1·67 (0·71)		1·27 (0·52)	

All analysis conducted by one-way ANOVA, split file.
**statistical significant at 0·05-level.*
SD = standard deviation
CDR-group 1: mild dementia, CDR-group 2: moderate dementia
CDR-group 3: severe dementia
Psychotropic medication = ATC index, subgroup N, including antipsychotics, antidepressants, anxiolytics and sedatives.

Table 4 Variables associated with change in QUALID scores (T0-T2, total and subscales) for the CDR 3 group with severe dementia

Dependent variables	Independent variables	β	p-value	R^2
Change in QUALID total score	Intervention	-8·000	0·008*	*30·3%*
	Intervention	-7·983	0·011*	*30·3%*
	+ Sex	0·093	0·976	
	Intervention	-8·655	0·006*	*35·9%*
	+ Age	-0·077	0·674	
	Intervention	-10·931	0·002*	*50·5%*
	+ Change in psycho-tropic medication	-5·983	0·066	
Change in QUALID Tension	Intervention	-3·909	0·045*	*18·5%*
	Intervention	-3·673	0·067	*20·4%*
	+ Sex	1·296	0·518	
	Intervention	-4·167	0·040	*26·3%*
	+ Age	0·119	0·337	
Change in QUALID Well-being	Intervention	-2·636	0·005*	*32·8%*
	Intervention	-2·515	0·009*	*34·7%*
	+ Sex	0·667	0·470	
	Intervention	-2·847	0·004*	*38·2%*
	+ Age	-0·021	0·713	
Change in QUALID Sadness	Intervention	-1·455	0·176	*9·0%*
	Intervention	-1·795	0·089	*22·0%*
	+ Sex	-1·870	0·088	
	Intervention	-1·640	0·153	*13·4%*
	+ Age	0·063	0·384	

All analysis performed by multiple linear regression analysis.
Control group = 1, Paro-intervention = 2
**Statistical significant at 0·05-level.*
QUALID = The Quality of Life in Late-Stage Dementia Scale