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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

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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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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

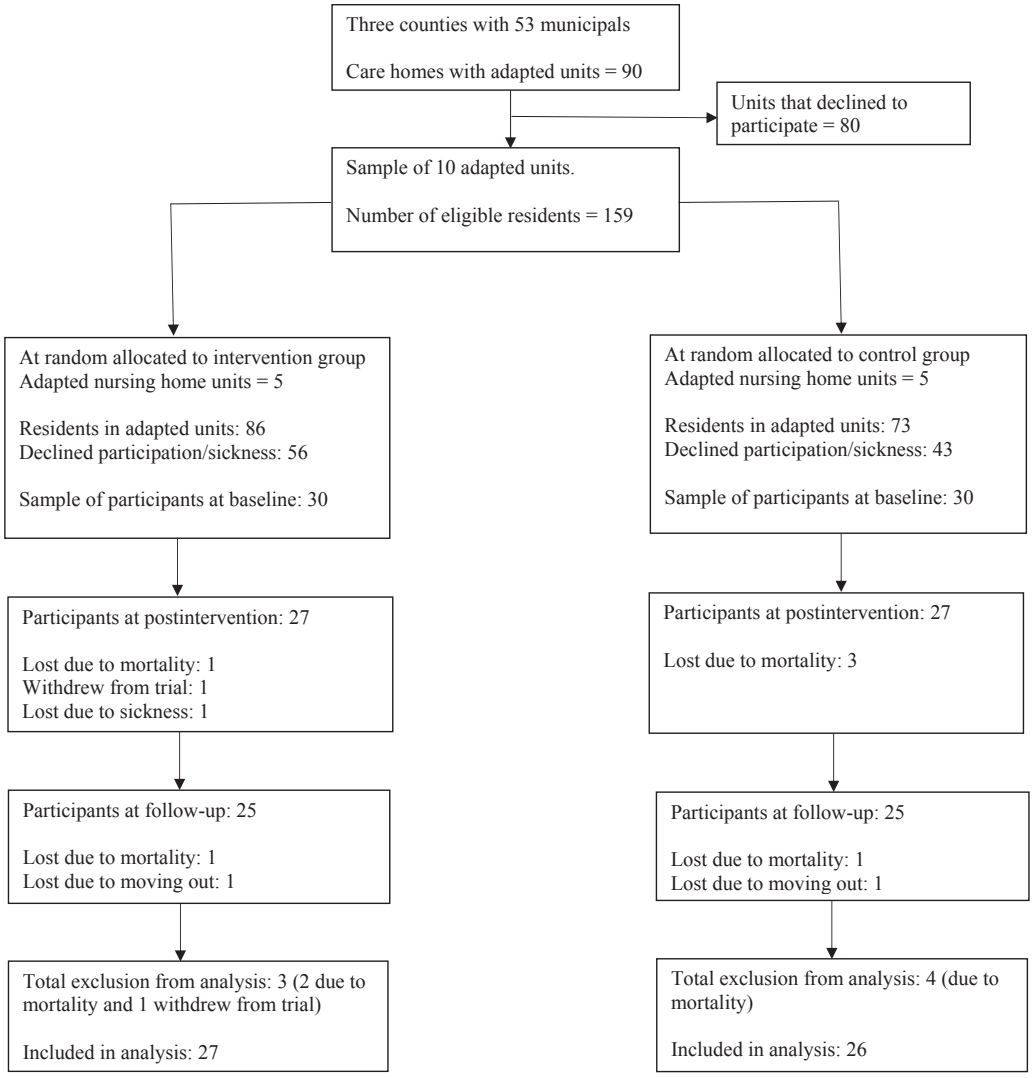

Fig. 1. Consort flow.

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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