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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