JAMDA xxx (2017) 1–8

JAMDA

journal homepage: www.jamda.com

Original Study

# A Pilot Randomized Trial of a Companion Robot for People With Dementia Living in the Community

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*Keywords:*
Companion robot
Paro
psychosocial intervention
dementia
home setting

A B S T R A C T

*Objectives:* To investigate the affective, social, behavioral, and physiological effects of the companion robot Paro for people with dementia in both a day care center and a home setting.
*Design:* A pilot block randomized controlled trial over 12 weeks. Participants were randomized to the intervention (Paro) or control condition (standard care).
*Setting:* Two dementia day care centers and participants' homes in Auckland, New Zealand.
*Participants:* Thirty dyads (consisting of a care recipient with dementia and their caregiver) took part in this study. All care recipients attended dementia day care centers at Selwyn Foundation and had a formal diagnosis of dementia.
*Intervention:* Thirty-minute unstructured group sessions with Paro at the day care center were run 2 to 3 times a week for 6 weeks. Participants also had Paro at home for 6 weeks.
*Measurements:* At the day care centers, observations of the care recipients' behavior, affect, and social responses were recorded using a time sampling method. Observations of interactions with Paro for participants in the intervention were also recorded. Blood pressure and salivary cortisol were collected from care recipients before and after sessions at day care. In the home setting, level of cognition, depressive symptoms, neuropsychiatric symptoms, behavioral agitation, and blood pressure were measured at baseline, 6 weeks, and 12 weeks. Hair cortisol measures were collected at baseline and at 6 weeks.
*Results:* Observations showed that Paro significantly improved facial expressions (affect) and communication with staff (social interaction) at the day care centers. Subanalyses showed that care recipients with less cognitive impairment responded significantly better to Paro. There were no significant differences in care recipient dementia symptoms, nor physiological measures between the intervention and control group.
*Conclusion:* Paro shows promise in enhancing affective and social outcomes for certain individuals with dementia in a community context. Larger randomized controlled trials in community settings, with longer time frames, are needed to further specify the contexts and characteristics for which Paro is most beneficial.



Dementia is a complex, neurodegenerative disorder that results in significant cognitive and functional decline.[1] It is estimated that 46.8 million people live with dementia worldwide and this number is expected to triple by 2050.[2] The majority of individuals with dementia are cared for in the home.[3,4] Home care is associated with benefits at both the individual and societal level, and is the preferred option for most caregivers and care recipients.[5,6] Keeping individuals with dementia in the home has been associated with better emotional and physical well-being, compared to moving to a nursing home or care facility.[7,8] Moreover, maintaining the care of individuals with

The authors declare no conflicts of interest.

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http://dx.doi.org/10.1016/j.jamda.2017.05.019
1525-8610/

dementia at home for longer greatly reduces the costs of institutionalization and lessens the burden on the health care system.[5,9]

Dementia is a pervasive illness, with both cognitive and noncognitive symptoms that affect the individual, as well as those close to them. Memory loss and cognitive changes are the defining characteristics of dementia. However, the neurodegenerative nature of dementia affects other areas, resulting in a range of noncognitive symptoms, including changes in behavior, emotion, and social functioning. Many caregivers report the noncognitive symptoms of dementia as the most challenging aspect of dementia care.[1] The most common noncognitive changes observed in individuals with dementia are signs of behavioral agitation, such as fiddling and pacing; affective changes, including depression and anxiety, as well as neuropsychiatric changes, such as delusions.[1] Although the changes in cognition can be hard to ameliorate, the noncognitive symptoms are important and often more modifiable targets. To date, there is no curative treatment available for dementia and existing medication shows modest mitigation of the symptoms, whereas the side effects often do more harm than good.[10] Therefore, psychosocial interventions are increasingly seen as relevant and acceptable options to address the symptoms of dementia. These options need to be suitable in a home setting and viable for family caregivers.

In light of advancements in technology, one relevant psychosocial option is companion robot therapy. Companion robot design stems from the principles of animal-assisted therapy, which has shown physiological and emotional benefits for older individuals in residential care units, as well as reduced agitation in individuals with dementia.[11,12] Companion robots aim to mimic the benefits of caring for a pet, while minimizing the costs and circumventing potential hygiene and safety risks.[13] The most popular companion robot used in older adult therapy is the seal robot Paro (Figure 1). In a randomized controlled trial (RCT), Paro reduced loneliness and served as a salient conversation topic when compared to standard care, for residents at a nursing home.[14] Reductions in agitation and depression were recorded in participants with dementia at a rest home after Paro sessions were run twice a week for 12 weeks in another RCT.[15] A quasi-experimental study showed that Paro not only reduced negative behavior but also promoted relaxation, attention, and sensory stimulation in 91 participants with dementia across multiple rest homes.[16] Furthermore, a cluster RCT showed that participants with severe dementia who interacted with Paro for 12 weeks had lower psychotropic drug use compared with participants who were in the control group.[17] There is also preliminary evidence to suggest that Paro can exert physiological effects. From measurements of hormones (eg, hydroxycorticosteroids, ketosteroid sulfates) in urine, Paro was associated with improved stress levels in mentally healthy participants at a nursing home.[18] After 10 minutes of interaction with Paro, blood pressure appeared lower in rest home residents, indicative of a relaxed and less anxious state.[19]

**Fig. 1.** Paro.

Most studies to date have explored the effects of Paro in improving mood, but few studies have examined physiological variables and none have systematically examined the effects of Paro in a home setting. Addressing this gap in the literature may have important implications for providing nonpharmacologic therapeutic approaches to support the large proportion of individuals with dementia living in the community. This article describes the findings from a pilot RCT conducted to investigate the psychosocial, behavioral, and physiological effects of Paro for people with dementia in both day care and home environments.

## Material and Methods

### *Research Design*

A pilot RCT was conducted with measurements at 3 time points (baseline, postintervention, and follow-up) over the course of 12 weeks. The intervention lasted 6 weeks, and follow-up measures were taken 6 weeks later. Participants (consisting of a dyad of caregiver and care recipient with dementia) were randomly allocated to either the Paro intervention group, or a control group. Cognition, agitation, neuropsychiatric symptoms, and depressive symptoms were the primary outcomes for the care recipients with dementia. Additionally, researchers observed the behavioral, affective, and social responses, as well as measuring physiological indexes (blood pressure, heart rate, salivary, and hair cortisol) of care recipients at 2 dementia day care centers across the 6-week intervention period. The researchers also examined the effects of Paro on caregiver outcomes; the present article focuses on the care recipient outcomes only. Figure 2 provides an overview of the study design and sample size at each stage.

### *Setting*

The study was conducted across 2 Selwyn Foundation dementia day care centers in Auckland, New Zealand. All attendees have a formal diagnosis of dementia, referred by the District Health Board's Needs Assessment and Coordination Services. The day care centers run between 10am-3pm from Monday to Friday. The centers provide meals and run a range of activities, including bingo, quizzes and physical exercises. Participants in the intervention group received Paro at sessions run at the center and at home for 6 weeks. Controls received standard care (see "Control Activities" later). Measurements were also collected in the home setting at baseline, postintervention, and follow-up for participants in both conditions.

### *Participants*

A total of 30 dyads of care recipients with dementia who attended dementia day care (64% female, age range: 67-98 years) and their informal caregivers (96% female, age range: 30-86 years) were recruited. A power analysis showed that 13 patients would be required in each group, based on a power of .80, and the alpha at .05, to detect

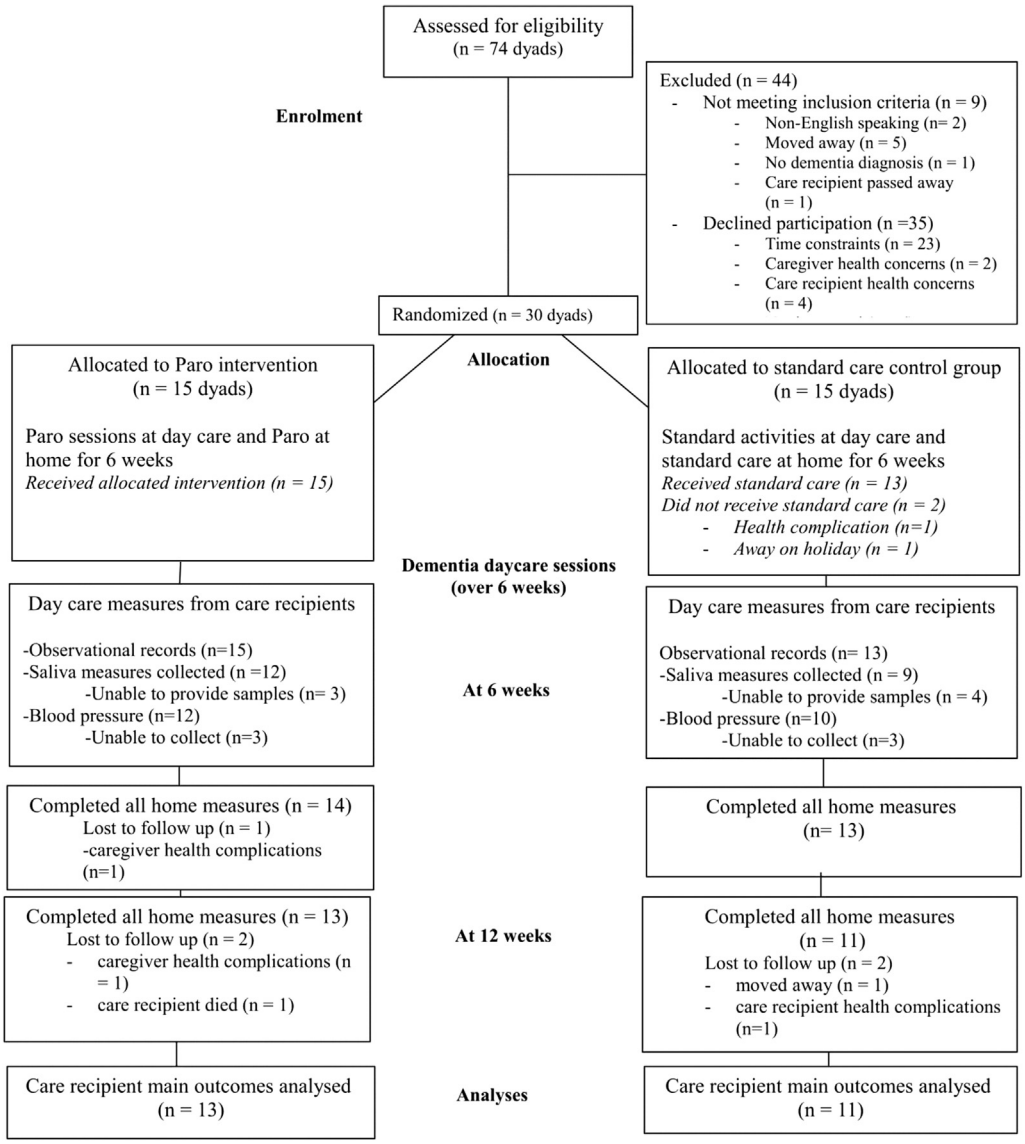


**Fig. 2.** Consort flow diagram.

an effect size d = 1.15, calculated from research showing that Paro enhanced social behavior.[14] Fifteen dyads were allocated to the Paro intervention group and 15 dyads were allocated to the control group using block randomization for the 2 day care centers. A computerized list was generated at randomiser.org by a researcher not involved in recruitment or data collection. There were no significant differences in the demographic or main outcome variables between participants in the control and intervention groups at baseline.

### *Ethical Considerations*

Approval was obtained from the University of Auckland Human Participants Ethics Committee and the trial was registered at the Australian New Zealand Clinical Trials Registry (trial number 368163; http://www.ANZCTR.org.au/). Participant information sheets and consent forms were sent to Selwyn Foundation dementia day care attendees. As the care recipients with dementia were unable to provide informed consent because of cognitive impairments, the caregivers, as their enduring power of attorney, provided written consent on their behalf.

### *Paro*

The intervention group received Paro, a companion robot modeled on a Canadian baby harp seal, developed by Dr Takanori Shibata from the National Institute of Advanced Industrial Science and Technology (AIST) in Japan. Paro has 4 senses—sight, sound, balance, and touch—and is responsive to various stimuli. Paro responds through head, tail, and flipper movement, blinking its eyes and producing various harp seal cries. Paro also relies on its internal states, sensory information, and diurnal rhythm to operate. Paro is battery-operated and is charged by inserting a pacifier-like charger into its mouth. Sixteen Paros were used in this study, one was used for sessions at day care and 15 were given to participants for use at home.

### *Intervention*

#### *Paro sessions at day care*

Paro sessions were scheduled between 1100 and 1200 hours at both day care sites, and 2 to 3 sessions occurred each week for 6 weeks. The sessions lasted for half an hour, plus sufficient time for

collection of measurements. Sessions were run in a separate room with 3 to 6 attendees following an unstructured format to allow flexible interactions. In each session, the researchers introduced Paro and then passed Paro around so each person could interact with it. Paro was given to each participant for up to 5 minutes before they were encouraged to pass it on to the next person. The researchers demonstrated interactions with Paro, such as stroking Paro's flippers, to encourage care recipient interactions.

*Paro at home*

Separate Paros were provided for each dyad in the home environment for 6 weeks. The researchers provided verbal instructions and a written instruction manual for caregivers that provided guidelines on when and how to use Paro. The 3-page manual included a brief introduction to Paro, including where it was made, where it was used, and why it was modeled on a Canadian harp seal. The manual stated that Paro was intended to be similar to pet therapy, listed the advantages of Paro over a real animal, and described the demonstrated benefits of Paro based on research. The manual provided ideas for when Paro could be useful, for example, when the care recipient was feeling sad or lonely, distressed, or agitated. It suggested letting the relative hold and stroke Paro, talking with the relative about Paro and talking about previous pets and animals to explore memories. Finally, technical guidance was highlighted, including cleaning and charging, how to interact with Paro through the touch sensors on the body, altering its posture, exposure to light, Paro's sleep function, safety, and troubleshooting. These technical instructions were based on the instruction manual provided with the robot on purchase. Overall, it was emphasized that the caregivers and care recipients should use Paro in a personalized manner. Therefore, the length and nature of interactions with Paro at home was flexible and depended on each dyad's needs and preferences.

*Control Activities*

The control group participated in standard activities run by staff at the day care centers. A range of activities were scheduled each day, including quizzes, exercise, bingo, music, and word activities. In the home setting, care recipients received treatment as usual from their caregivers.

*Measures*

*Measures at day care centers*

Behavioral, affective, and social responses were observed using a time sampling method for care recipients in both conditions at day care. The presence of agitated behavior (eg, repetitive behavior, wandering, fiddling), facial expressions (eg, smiling, sadness, fear), and social interactions (eg, talking to others, co-operation, reciprocity) for care recipients in both conditions were observed and recorded by researchers across three 1-minute intervals. This behavioral record was based on behavioral tracking methods and a rating tool used in research for people with dementia.[14,20] Given that the maximum interaction period was 5 minutes at a time, this was deemed sufficient to capture the range of interactions with Paro. In addition, observations of physical interactions, attention, and communication with Paro were recorded for care recipients in the Paro group. One researcher was assigned to running the sessions while the other researcher completed the observations. Observational scores were then averaged across the sessions and converted into a percentage to provide an index of the frequency of the behavior across the day care sessions. Physiological measures of salivary cortisol and blood pressure were obtained from care recipients before and after the sessions at day care. Saliva samples were selected as a valid and practical way to collect measures of the stress-indicating hormone cortisol from the care recipients with dementia.[21,22] Salivary cortisol concentrations were determined using commercial enzyme-linked immunosorbent assay (IBL, Hamburg, Germany).

*Measures at home*

Demographic information including participants' age, gender, and educational background was collected. Care recipients' cognitive level and blood pressure were measured by researchers across the 3 time points. Hair samples were taken at baseline and at 6 weeks to assess the concentration of hair cortisol by analyzing the 2-cm hair segment most proximal to the scalp. This segment reflects the cumulative cortisol secretion from the prior 2 months, which correspond with the time before and during intervention.[23] Hair cortisol concentrations were used to assess long-term changes in cortisol, which is a relevant biomarker of stress. Measuring cortisol concentrations in the hair is reliable, easily obtainable, and provides a long-term indicator of exposure to the hormone.[24] Hair samples were taken as closely as possible to the scalp from a posterior vertex position of the head. In the lab, the samples were processed and cortisol extracted based on laboratory protocol, using $10.0 \pm 0.5$ mg finely cut hair for cortisol extraction.[25] For hair cortisol concentration, 50 μL was used for analysis with a commercially available luminescence immunoassay (IBL, Hamburg, Germany). Cognition was assessed using the New Zealand version of the Addenbrooke's Cognitive Examination,[26] which is scored out of 100, with scores below 82 indicative of cognitive impairment. It is a reliable, construct-valid, and sensitive assessment tool.[27] The researchers were trained to administer the scale. Blood pressure was measured using 2 Scian automatic blood pressure monitors (Model LD-582).

Care recipients' agitation, neuropsychiatric symptoms, depressive symptoms and medication usage were assessed through caregiver proxy reports at baseline, 6 weeks and 12 weeks follow up. The Cohen-Mansfield Agitation Inventory—Short Form was used to assess the frequency of 14 different signs of agitation observed in the individuals with dementia.[28] The Cohen-Mansfield Agitation Inventory—Short Form is validated and has been used extensively for measuring agitation in people with dementia.[29] The Neuropsychiatric Inventory Brief Questionnaire Form was used to assess the severity of neuropsychiatric symptoms across 12 domains, from sleeping to hallucinations.[30] The Neuropsychiatric Inventory Brief Questionnaire Form shows good psychometric properties and is widely used for research in individuals with dementia.[31] Depressive symptoms were measured using the Cornell Scale for Depression in Dementia, the scale comprises 19 items that assess the presence and severity of depressive symptoms for individuals with dementia.[32] A Cornell Scale for Depression in Dementia score above 10 indicates probable depressive episode, and scores above 18 are indicative of a major depressive episode. The scale shows good internal reliabilities and is seen as the gold standard for assessing depression for individuals with dementia.[27] The use of dementia-related medication was recorded. At 6 weeks, caregivers in the intervention condition were interviewed about how the care recipients interacted with Paro in the home setting.

*Analyses*

Mixed-design, repeated measures analyses of variance were performed to test for significant differences between the Paro and control groups across baseline, 6 weeks postintervention, and follow-up for outcomes measured in the home setting. When significant interactions between condition and time occurred, pairwise comparisons with Bonferroni adjustments were employed. Independent samples *t* tests and Mann-Whitney *U* tests were conducted to compare the mean percentages of agitated behavior, facial expressions, and social interactions between the conditions. Independent samples *t*

tests were run to compare differences in demographic and psychological measures between care recipients who showed positive responses to Paro (eg, touching in an affectionate manner and making positive comments) and those who did not. For salivary cortisol and blood pressure, a mixed-model approach was employed. Change scores were computed by subtracting the presession values from the postsession values. Comparisons of change values between day care sites, across multiple sessions and between conditions, were made. The mixed model procedure was selected to accommodate for the multiple, repeated measures and uneven spacing of sessions across time. For hair cortisol, an analysis of covariance was conducted with corresponding baseline scores entered as covariates. An additional analysis controlling for age and sex was conducted. The data were log-transformed to achieve normal distribution, and there were no demographic covariates that influenced the data. For all analyses, the significance level was set at $P = .05$. Inductive thematic analysis was used to identify the major themes from the caregivers' open responses to how care recipients interacted with Paro in the home setting.[33]

## Results

There were statistically significant differences in affective and social outcomes between care recipients in the Paro and control group at day care (Table 1). Care recipients in the Paro group not only showed significantly more positive facial expressions, they also talked more to staff and researchers compared to those in the control group. No significant differences in negative facial expressions and other social responses were observed between care recipients in either condition. The results are based on 13 participants who attended an average of 6.15 (standard deviation = 2.97) Paro sessions. Two participants did not wish to participate in the Paro sessions at day care, preferring to participate in the control activities, or sit out of all activities completely. The exhibition of agitated behavior in this sample was low, and there were no statistically significant differences in the frequency of agitated behavior between care recipients in the 2 conditions during day care sessions. Twelve participants showed consistently positive responses to Paro across the sessions. These participants touched and communicated with Paro in a positive manner. For example, participants commented that Paro had "pretty eyelashes," was a "good boy," and was "very clever." Paro occasionally elicited negative responses—2 participants commented that Paro was "just a toy" and that they would prefer "real animals." On another occasion, a participant pushed Paro away and expressed irritation at Paro's noises.

Similar results were found from caregiver feedback of using Paro in the home setting (n = 14). Caregivers observed that care recipients responded positively to Paro (n = 7) and that Paro had a positive effect on their mood or behavior (n = 8). Positive responses included smiling, singing, and talking to Paro. For example, caregivers observed that some care recipients had "conversations" with Paro, where they would interpret Paro's noises and respond accordingly. The main reported benefits of Paro at home were in reducing anxiety and enhancing mood. Caregivers reported that touching Paro's soft texture was soothing for some care recipients and that it could serve as a distraction from distressing events. For example, one caregiver reported "I would give Paro to her [the care recipient] in the morning while I was getting ready for work, she is often anxious in the morning but when she had Paro she would not be distressed when I left her alone." Caregivers commented that Paro heightened positive mood in care recipients, who showed amusement and laughter when engaging with Paro. One caregiver said that "Paro gave her [the care recipient] a sense of purpose, something to look after, cuddle and love." Moreover, the companion robot encouraged positive interactions with visitors and other family members. Caregivers highlighted how Paro served as a "good talking point" and care recipients "enjoyed showing Paro off." Many caregivers reported that they felt the need to supervise interactions and to be present to stimulate care recipient interactions with Paro.

Most caregivers (n = 9) reported that there was no particular time period in which Paro was most useful. Nonetheless, 8 care recipients spent at least 10 minutes a day interacting with Paro, and 7 of these spent more than 30 minutes a day with Paro. The mixed responses observed during the interactions with Paro at day care were reflected in the caregiver feedback. The same 2 care recipients who did not participate in the group sessions at day care also did not interact with Paro at home. Some caregivers observed that although some care recipients would interact with Paro, they showed greater engagement with live animals, and another care recipient consistently switched Paro off.

Further analyses were run to specify the characteristics of care recipients in the Paro group who responded most positively to the robot. Seven care recipients were identified as those who showed consistent positive responses to Paro based on observations by researchers at day care. There were no significant differences of gender, agitation, neuropsychiatric symptoms, and depressive symptoms between care recipients who showed positive responses and those who did not. However, there was a significant difference in cognitive scores, where care recipients who responded positively to Paro had significantly higher cognitive scores compared to the care recipients who showed neutral/negative/mixed responses to Paro (Table 2). This suggests that Paro may be most beneficial for care recipients who show mild cognitive impairment rather than those with severe

**Table 1**
Observations of Care Recipients During Day Care Sessions

| Observations of Care Recipients | Paro Group (n = 13) | Control Group (n = 11) | *t*/*z* | *P* Value | *r* |
|---|---|---|---|---|---|
| Observations of agitated behavior | | | | | |
| Repetitive behavior,* eg, fiddling | 4.36 (11.4) | 14.3 (21.6) | −1.41 | .160 | 0.29 |
| Wandering/pacing* | 4.41 (13.3) | 1.11 (3.15) | −0.85 | .397 | 0.17 |
| Negative verbal expression* | 0.60 (2.23) | 1.11 (3.51) | −0.55 | .579 | 0.11 |
| Observations of facial expressions | | | | | |
| Happy/smiling | 81.9 (17.5) | 56.7 (33.8) | −2.22 | .043 | 0.49 |
| Sad* | 0.30 (1.11) | 3.47 (7.67) | −0.86 | .392 | 0.17 |
| Fear* | 0.42 (1.57) | 1.25 (3.95) | −0.18 | .856 | 0.04 |
| Anger/irritation* | 1.02 (2.63) | 0 | −1.33 | .184 | 0.27 |
| Observations of social interactions | | | | | |
| Talk to others* | 26.0 (29.2) | 17.1 (25.1) | −0.56 | .579 | 0.11 |
| Talk to staff or activity coordinator* | 46.9 (26.5) | 25.5 (24.3) | −2.30 | .042 | 0.47 |
| Reciprocate, eg, respond to others' comments | 61.8 (26.7) | 41.3 (33.4) | −1.64 | .116 | 0.32 |
| Cooperate, eg, sharing, following instructions | 62.4 (28.6) | 54.7 (35.2) | −0.58 | .565 | 0.15 |

Values are mean % (standard deviation), unless otherwise indicated.
*Indicates data are nonparametric and *z* values are given instead of *t* values.

**Table 2**
Differences Between Care Recipients Who Responded Well and Not So Well to Paro

| Care Recipient Characteristics | Positive Response to Paro (n = 7) | Neutral/Negative/ Mixed Responses to Paro (n = 7) | *T* | *P* Value | *r* |
|---|---|---|---|---|---|
| Care recipient gender,* n (%) | | | | | |
| Male | 3 (60.0) | 2 (40.0) | | .500 | 0.15 |
| Female | 4 (44.4) | 5 (55.6) | | | |
| Care recipient age, mean (SD) | 84.6 (9.09) | 82.9 (6.72) | −0.40 | .695 | 0.11 |
| Addenbrookes' Cognitive Score, mean (SD) | 42.6 (23.0) | 13.0 (16.4) | −2.78 | .017 | 0.59 |
| Cohen-Mansfield Agitation score, mean (SD) | 26.0 (8.45) | 27.6 (9.93) | 0.32 | .755 | 0.08 |
| Neuropsychiatric symptom severity, mean (SD) | 9.14 (6.87) | 9.29 (7.14) | 0.40 | .970 | 0.01 |
| Depressive symptoms, mean (SD) | 8.00 (5.48) | 5.57 (6.02) | −0.79 | .445 | 0.21 |

SD, standard deviation.
*Indicates that data were categorical and Fisher exact test was performed. A Cramer *V* value is reported instead of *r* as an indication of effect size.

cognitive impairments. Likewise, some caregivers suggested that Paro may be more helpful for individuals with "higher functioning capabilities" and for those at "earlier stages of dementia who would be more responsive to Paro."

There were no significant interactions across time, or between conditions in blood pressure [systolic: $F(1, 19) = 0.0001$, $P = .982$; diastolic: $F(1, 19) = 0.56$, $P = .464$] or heart rate [$F(1, 19) = 0.06$, $P = .812$] measurements for care recipients. Salivary cortisol samples were obtained before and after sessions from 21 care recipients across 11 day care sessions. No significant differences were detected in salivary cortisol change values between participants in the control and intervention group during day care sessions [$F(1, 18) = 1.51$, $P = .235$].

No statistical differences were found between care recipients in the Paro intervention and control group for measures completed in the home setting (Table 3), including levels of agitation, neuropsychiatric symptoms, and medication usage. Depressive symptoms showed improvements from baseline to 6 weeks for participants in both conditions. However, there was a significant interaction effect, where depressive symptoms significantly increased during follow-up from 6 weeks to 12 weeks for care recipients in the Paro group only. There were no statistical differences in blood pressure, heart rate, and hair cortisol measures taken in the home setting. After the exclusion of

**Table 3**
Care Recipient Outcomes in the Home Setting

| | Paro Group (n = 13) | Control Group (n = 11) | *F* Test for Group × Time Interaction Effect | | | |
|---|---|---|---|---|---|---|
| | Mean (SD) | Mean (SD) | *F* | df | *P* Value | Partial $\eta^2$ |
| Cognitive score† | | | 0.43 | 2, 28 | .655 | 0.030 |
| Baseline | 38.5 (19.2) | 34.9 (13.8) | | | | |
| 6 wk | 38.8 (17.6) | 37.1 (14.8) | | | | |
| 12 wk | 37.9 (19.2) | 37.6 (20.9) | | | | |
| CMAI-SF score | | | 0.61 | 2, 44 | .549 | 0.027 |
| Baseline | 26.5 (9.21) | 25.6 (9.25) | | | | |
| 6 wk | 25.8 (9.44) | 22.6 (4.57) | | | | |
| 12 wk | 26.4 (10.4) | 24.7 (7.16) | | | | |
| NPI-Q score | | | 1.17 | 2, 44 | .321 | 0.050 |
| Baseline | 9.15 (7.00) | 8.45 (5.89) | | | | |
| 6 wk | 7.23 (5.97) | 6.27 (3.10) | | | | |
| 12 wk | 8.23 (6.83) | 5.09 (2.43) | | | | |
| Depressive symptoms | | | 4.41 | 2, 44 | .018 | 0.17 |
| Baseline | 6.38 (5.69) | 8.27 (6.42) | | | | |
| 6 wk | 4.77 (4.29) | 4.91 (2.74) | | | | |
| 12 wk | 7.77 (6.72) | 5.18 (3.06) | | | | |
| Medication usage* | | | | | | |
| Baseline | | | | | | |
| Yes | 3 (23.1) | 4 (36.4) | | | | |
| No | 10 (76.9) | 7 (63.6) | | | | |
| 6 wk | | | | | | |
| Yes | 3 (23.1) | 4 (36.4) | | | | |
| No | 10 (76.9) | 7 (63.6) | | | | |
| 12 wk | | | | | | |
| Yes | 3 (23.1) | 4 (36.4) | | | | |
| No | 10 (76.9) | 7 (63.6) | | | | |
| Systolic blood pressure† | | | 1.32 | 2, 16 | .296 | 0.14 |
| Baseline | 142 (32.4) | 129 (15.6) | | | | |
| 6 wk | 134 (22.0) | 119 (32.4) | | | | |
| 12 wk | 144 (28.5) | 146 (19.1) | | | | |
| Diastolic blood pressure† | | | 1.60 | 2, 16 | .233 | 0.17 |
| Baseline | 82.8 (13.7) | 90.5 (19.4) | | | | |
| 6 wk | 81.5 (10.9) | 68.8 (7.23) | | | | |
| 12 wk | 78.3 (1.97) | 91.3 (35.9) | | | | |
| Heart rate† | | | 0.34 | 2, 16 | .715 | 0.041 |
| Baseline | 73.2 (10.2) | 81.8 (24.9) | | | | |
| 6 wk | 84.0 (22.3) | 89.0 (27.4) | | | | |
| 12 wk | 70.2 (15.1) | 83.5 (27.9) | | | | |
| Hair cortisol† | | | 0.10 | 1, 15 | .753 | 0.007 |
| Baseline | 15.0 (22.0) | 9.13 (4.83) | | | | |
| 6 wk | 22.2 (30.8) | 11.9 (13.4) | | | | |

CMAI-SF, Cohen-Mansfield Agitation Inventory—Short Form; NPI-Q, Neuropsychiatric Inventory Brief Questionnaire Form; SD, standard deviation.
*Indicates data were categorical; total counts and percentages are provided.
†Not all participants were capable of providing measures; df reflects the different sample size.

outliers (n = 6), 17 hair cortisol measures were analyzed (8 participants in the control group and 9 participants in the Paro group). There were no significant differences in hair cortisol concentrations between care recipients in the control and Paro group across the 2 time points.

## Discussion

From the observational accounts, care recipients in the Paro group smiled and talked more to staff and researchers in comparison to participants in the control group at day care centers. These findings support previous studies of Paro with individuals with dementia, where improvements in mood, greater frequency of laughter, and more positive facial expressions are the main findings.[34–36] Likewise, in the home setting, caregivers reported that Paro was helpful in improving mood and reducing anxiety, and that Paro acted as a social stimulus. Prior evidence also suggests that Paro can enhance communication and cooperation with therapists and staff.[37,38] In this study, most participants preferred one-on-one interactions with Paro compared to shared group interactions. It is therefore unsurprising to find that Paro did not improve other social metrics of cooperation, reciprocity, and talking to others. This suggests that meaningful, one-on-one engagement with the robot is important in dementia day care.

Paro elicited heterogeneous responses in care recipients with dementia. Notably, people with greater cognitive capacity seemed to respond more positively to Paro compared to individuals who were more cognitively impaired. Prior research suggests that people with greater cognitive capabilities may have more meaningful interactions because they are better able to draw on mental resources and prior experiences than those with lower capabilities.[16,34] A small number of care recipients directed negative verbal comments toward Paro, showed negative physical interactions, or chose not to interact with Paro at all in both the day care and home settings. Many caregivers commented on how the heterogeneity of dementia profiles and different contexts may contribute to differing responses to Paro. Indeed, prior research highlights how different individual and contextual factors may influence how people respond and interact with robots.[39–42] It is therefore important to understand that Paro's therapeutic benefit depends on individual users' needs and desires.[43,44]

Depressive symptoms showed improvements at 6 weeks compared to baseline for care recipients in both the Paro and control group, which could be seen as a positive by-product of participating in research.[45] A prior study also found improvements in depressive symptoms for participants with dementia in both the Paro intervention and control group.[46] There was an increase in depressive symptoms at the 12-week follow-up for participants in the Paro group, but not for participants in the control group, which implies that Paro may have positively impacted the care recipients' mood, and the subsequent removal of Paro reversed this effect.

The null findings regarding Paro's effects on physiological outcomes, agitation, and other problematic symptoms for individuals with dementia are inconsistent with some existing studies.[15,16,34] Our findings are also inconsistent with a prior study which showed that interactions with Paro reduced the need for dementia-related medication.[15,17,47] One explanation for differences in the findings of this study compared to others could be the small sample size, or differences in sample characteristics. Our sample of participants had lower rates of dementia-related medication use and exhibited fewer behavioral symptoms compared to previous studies. Another reason could be that existing research is largely dominated by exploratory and observational studies, in which there can be biases and confounds. Recent research employing randomized controlled methods have yielded mixed findings, with modest effects, if any, when examining the effects of Paro on symptoms of agitation and other problematic behavior in people with dementia.[36,46,48] Paro elicited differential effects in outcomes for people with dementia in an RCT, showing no clear advantage over a humanoid robot and live dog.[48] Both the humanoid robot and Paro seemed to reduce apathy in a nursing home setting, but Paro seemed to enhance irritation and neuropsychiatric symptoms. Another trial found increased wandering behavior for participants in the Paro intervention, no effect on affective outcomes, but improved quality of life in comparison to a reading activity control group.[36] These mixed findings warrant future research to distinguish the specific therapeutic effects of Paro and identify the settings and individuals for whom Paro is most beneficial.

## Strengths and Limitations

A strength of this study was the examination of individual characteristics to investigate who benefited the most from Paro. This is of practical importance as dementia is a highly heterogeneous condition and it is important to provide targeted support. Second, the study examined a range of self-report, observational, and physiological variables to provide a comprehensive assessment. It employed novel approaches to explore the physiological effects of Paro using salivary and hair cortisol measures. Third, this is the first study to provide insight into the feasibility of Paro in a home context. Conducting research in populations with dementia is challenging, and there were a number of limitations. First, recruiting and maintaining participants was difficult. Many people declined because of busy schedules or health complications, and 4 dyads dropped out as a result of health deterioration. Lack of comprehension and inability to provide physiological samples because of cognitive impairment resulted in fewer assessments than expected. Participants often had thinning, or very fine, hair, which sometimes resulted fewer hairs being collected than is recommended. The small sample size limited the power to detect statistically significant differences. The study was open to all day care attendees but not all people consented, and characteristics of our sample may not generalize to the wider population of people with dementia living in the community.

## Conclusion

Paro had beneficial effects on emotional and social functioning in people with dementia in a day care setting. Individuals with greater cognitive functioning were more responsive to Paro. There were no significant differences in the behavioral and physiological measures between the intervention and control condition; however, the small sample size and sample characteristics may have limited the power and further work is needed. Of practical significance, this research highlights the importance in specifying the characteristics of individuals who may benefit the most from interactions with Paro. This may enhance development of personalized and effective ways to improve the well-being of people with dementia. The results highlight the importance of employing RCTs for evaluating the benefits of companion robots, and suggest the need for larger-scale trials with selective inclusion criteria.

## Acknowledgments

This work was supported by the University of Auckland Faculty Research Development Fund to E.B. (grant 360813), and A.L. received funding from the Sasakawa Young Leaders Fellowship Fund (SYLFF).

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