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Original Study

Use of a Robotic Seal as a Therapeutic Tool to Improve Dementia Symptoms: A Cluster-Randomized Controlled Trial

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A B S T R A C T

Objectives: To test the effects of individual, nonfacilitated sessions with PARO (version 9), when compared against a look-alike plush toy and usual care, on the emotional and behavioral symptoms of dementia for people living in long-term care facilities.
Design: Parallel, 3-group, cluster-randomized controlled trial conducted between June 14, 2014, and May 16, 2015.
Setting: Twenty-eight long-term care facilities operated by 20 care organizations located in South-East Queensland, Australia.
Participants: Four hundred fifteen participants aged ≥60 years, with a documented diagnosis of dementia.
Intervention: Stratified by private/not-for-profit status and randomized using a computer-generated sequence, 9 facilities were randomized to the PARO group (individual, nonfacilitated, 15-minute sessions 3 times per week for 10 weeks); 10 to plush toy (same, but given PARO with robotic features disabled); and 9 to usual care. Treatment allocation was masked to assessors.
Measurements: Primary outcomes were changes in levels of engagement, mood states, and agitation after a 10-week intervention, assessed by coded video observations (baseline, weeks 1, 5, 10, and 15) and Cohen-Mansfield Agitation Inventory—Short Form (baseline, weeks 10 and 15). Analyses followed intention-to-treat, using repeated measures mixed effects models. Australian New Zealand Clinical Trials Registry (ACTRN12614000508673).
Results: Video data showed that participants in the PARO group were more verbally [3.61, 95% confidence interval (CI): 6.40−0.81, $P = .011$] and visually engaged (13.06, 95% CI: 17.05−9.06, $P < .0001$) than participants in plush toy. Both PARO (−3.09, 95% CI: −0.45 to −5.72, $P = .022$) and plush toy (−3.58, 95% CI: −1.26 to −5.91, $P = .002$) had significantly greater reduced neutral affect compared with usual care, whilst PARO was more effective than usual care in improving pleasure (1.12, 95% CI: 1.94−0.29, $P = .008$). Videos showed that PARO was more effective than usual care in improving agitation (3.33, 95% CI: 5.79 −0.86, $P = .008$). When measured using the CMAI-SF, there was no difference between groups.
Conclusions: Although more effective than usual care in improving mood states and agitation, PARO was only more effective than a plush toy in encouraging engagement.

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Studies from Australia, the United States, and the United Kingdom indicate that at least 50% of residents living in long-term care (LTC) facilities have dementia.[1–3] Of these, over one-half have behavioral and psychological symptoms of dementia (BPSD).[4] These behaviors are often difficult for care staff to manage,[5] and it is common for psychotropic medication to be prescribed as a first-line approach,[6] despite demonstrated adverse effects and inconclusive efficacy.[7] Nonpharmacologic interventions offer an alternate means of managing BPSD, and animal assisted therapies have been successfully used with older people with dementia to ameliorate such symptoms.[8] However, it is not always appropriate for animals to visit LTC facilities (eg, health and safety concerns, residents with a known dislike/fear of animals, and practical issues of looking after an animal), and researchers have sought to investigate how robotic pets may be used instead.

Developed in Japan and modeled on the features of a baby harp seal (Figure 1), PARO is the most common therapeutic pet-type robot used in studies with people with dementia.[9] The therapeutic version (version 9) is an autonomous robot that is similar in weight to a newborn baby, and has 5 sensors that are processed by artificial intelligence software to enable PARO to respond to the user and the environment. Typically active during the daytime, PARO can move its tail and flippers, open and close its eyes, and make sounds similar to a real baby harp seal.

The few randomized controlled trials (RCTs) undertaken to date demonstrate the potential efficacy of using PARO with older people with dementia on measures of anxiety,[10] stress,[10] usage of psychotropic[10–13] and pain medication,[10] depression,[11–13] agitation,[11–13] loneliness,[14] quality of life,[11–13] social interaction,[11–13] and engagement.[11–13] Similarly promising findings on a range of outcomes have also been demonstrated comparing PARO with various control group activities including an interactive reading group,[15] a humanoid robot,[16] a live dog,[16–18] and a stuffed toy.[17–19] Methodological shortcomings limit the reliability and generalizability of these findings, however, and recent editorials and reviews have highlighted the need for more rigorously designed RCTs to further current understanding.[9,20,21]

The aim of this study was to test the effects of individual, nonfacilitated sessions with PARO (version 9), when compared against a look-alike plush toy and usual care, on the emotional and behavioral symptoms of dementia for people living in LTC facilities. We hypothesized that participants in the PARO group would demonstrate improvements in engagement, mood states, and agitation more so than participants in the plush toy and usual care groups.

Methods

Study Design, Setting, and Sample

This parallel, 3-group, single-blind cluster-RCT was conducted in 28 LTC facilities in South-East Queensland, Australia. A cluster-RCT design was chosen to reduce between-group contamination likely in LTC facilities (ie, inadvertent exposure to activities from different intervention arms because of the nature and layout of facilities); 3 groups enabled PARO to be comparatively assessed against an identical, nonrobotic plush toy and usual care; and the delivery of the interventions in individual, nonfacilitated sessions allowed the unique effect to be evaluated, independent of any extraneous effects of group or facilitator-led sessions. Institutional ethical approval was obtained from Griffith University Human Ethics Committee (NRS/03/14/HREC) and respective care organizations, and approval was obtained from individual facility managers. The study protocol can be read in detail elsewhere.[22]

Fig. 1. PARO (version 9) (permission for image given by Dr. Takanori Shibata, National Institute of Advanced Industrial Science and Technology, Japan).

LTC facilities were eligible for inclusion if they were Australian government approved and accredited, provided care to residents with dementia, and were located within a 100-km radius of the Brisbane central business district. Residents were recruited if they were aged ≥60 years and had a documented diagnosis of dementia. Exclusion criteria were respite care admission; dual diagnosis of a serious/persistent mental illness; terminal illness; and unremitting pain/distressing physical symptoms. Potential participants were identified by facility managers, and formally screened against the described criteria by trained research assistants (RAs). Written informed consent was obtained from all participants (if capable) or next-of-kin at the time of enrollment, and participant verbal assent was obtained at each intervention session with PARO or plush toy.

Randomization and Masking

Participating facilities were stratified by private/nonprofit status and randomized in blocks of 3 to PARO, plush toy, or usual care groups. An independent service at Griffith University performed the randomization process, using a computer-generated sequence. Allocation to treatment groups was concealed from facility staff, participants, and families until it was operationally required to begin intervention activities (ie, postbaseline data collection). RAs involved in data collection and data coding were masked to the other intervention groups through assignment of work to 1 group only, and by separate working locations. Intervention RAs were allocated to specific facilities, working with only one of the groups, and were masked to all outcome measurements, as were participants and their families.

Procedures

Participants from facilities allocated to the PARO intervention group received an individual, nonfacilitated, 15-minute session with PARO 3 times per week (Monday, Wednesday, and Friday) for 10 weeks. This duration and frequency of sessions was chosen based on findings from our pilot work.[15] A trained RA gave the PARO to the participant at the start of each session, repeating the same introductory script each time (described elsewhere[22]). RAs left the participant with the PARO to interact with it as they liked, returning after 15 minutes to collect PARO. All sessions were conducted during the afternoon hours of 1:00 PM-5:00 PM (when agitation levels are commonly highest[23]) and wherever the participant was at the time of the allocated session.

Participants in facilities allocated to the plush toy intervention group received the same sessions as described above, but were given a plush toy (PARO with robotic features disabled). Participants in facilities allocated to usual care received care as standard.

Outcome Measures

The 3 primary outcomes of interest were changes in participants' levels of engagement, mood states, and agitation after 10 weeks of the