Original Study

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

Wendy Moyle PhD\textsuperscript{a,b,*}, Cindy J. Jones PhD\textsuperscript{a,b}, Jenny E. Murfield BSc(Hons)\textsuperscript{a,b}, Lukman Thalib PhD\textsuperscript{c}, Elizabeth R.A. Beattie PhD\textsuperscript{d}, David K.H. Shum PhD\textsuperscript{a,e}, Siobhan T. O’Dwyer PhD\textsuperscript{a,f}, M. Cindy Mervin PhD\textsuperscript{a,g}, Brian M. Draper MD\textsuperscript{h}

\textsuperscript{a}Menzies Health Institute Queensland, Griffith University, Nathan, Brisbane, Queensland, Australia
\textsuperscript{b}School of Nursing and Midwifery, Nathan Campus, Griffith University, Nathan, Brisbane, Queensland, Australia
\textsuperscript{c}Department of Public Health, College of Health Sciences, Qatar University, Qatar
\textsuperscript{d}School of Nursing, Queensland University of Technology, Kelvin Grove, Brisbane, Queensland, Australia
\textsuperscript{e}School of Applied Psychology, Mt Gravatt Campus, Griffith University, Brisbane, Queensland, Australia
\textsuperscript{f}Medical School, University of Exeter, Exeter, United Kingdom
\textsuperscript{g}Center for Applied Health Economics, School of Medicine, Nathan Campus, Griffith University, Nathan, Brisbane, Queensland, Australia
\textsuperscript{h}School of Psychiatry, University of New South Wales, Sydney, Australia

\textbf{Keywords:} Agitation, BPSD, engagement, PARO, mood state, older people

\textbf{Abstract}

\textbf{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.

\textbf{Design:} Parallel, 3-group, cluster-randomized controlled trial conducted between June 14, 2014, and May 16, 2015.

\textbf{Setting:} Twenty-eight long-term care facilities operated by 20 care organizations located in South-East Queensland, Australia.

\textbf{Participants:} Four hundred fifteen participants aged ≥60 years, with a documented diagnosis of dementia.

\textbf{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.

\textbf{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).

\textbf{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: −5.72 to −0.45, \(P = .022\)) and plush toy (−3.58, 95% CI: −5.91 to −0.45, \(P = .0001\)) 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.

\textbf{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 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 Non-pharmacologic interventions offer an alternate means of managing BPSD,8 and animal assisted therapies have been successfully used with older people with dementia to ameliorate such symptoms.1 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) including an interactive reading group,10 and a stuffed toy.17 Methods

Randomization and Masking

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 elsewhere20). 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 highest23) 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
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