JAMDA xxx (2017) 1–4

JAMDA

journal homepage: www.jamda.com

Original Study

The Cost-Effectiveness of Using PARO, a Therapeutic Robotic Seal, to Reduce Agitation and Medication Use in Dementia: Findings from a Cluster–Randomized Controlled Trial

Merehau C. Mervin PhD [a,b,*], Wendy Moyle PhD [b,c], Cindy Jones PhD [b,c], Jenny Murfield BSc [b], Brian Draper MD [d], Elizabeth Beattie PhD [e], David H.K. Shum PhD [b,f,g], Siobhan O'Dwyer PhD [b,h], Lukman Thalib PhD [i]

[a] *Centre for Applied Health Economics, School of Medicine, Nathan Campus, Griffith University, Nathan, Brisbane, Queensland, Australia*
[b] *Menzies Health Institute Queensland, Griffith University, Nathan, Brisbane, Queensland, Australia*
[c] *School of Nursing and Midwifery, Nathan Campus, Griffith University, Nathan, Brisbane, Queensland, Australia*
[d] *School of Psychiatry, University of New South Wales, Sydney, Australia*
[e] *School of Nursing, Queensland University of Technology, Kelvin Grove, Brisbane, Queensland, Australia*
[f] *School of Applied Psychology, Mt Gravatt Campus, Griffith University, Brisbane, Queensland, Australia*
[g] *Neuropsychology and Applied Cognitive Neuroscience Laboratory, Key Laboratory of Mental Health, Institute of Psychology, Chinese Academy of Sciences, Beijing, China*
[h] *Medical School, University of Exeter, Exeter, United Kingdom*
[i] *Department of Public Health, College of Health Sciences, Qatar University, Doha, Qatar*

Keywords:
Economic evaluation
older people
psychosocial intervention
long-term care

A B S T R A C T

Objectives: To examine the within-trial costs and cost-effectiveness of using PARO, compared with a plush toy and usual care, for reducing agitation and medication use in people with dementia in long-term care.
Design: An economic evaluation, nested within a cluster–randomized controlled trial.
Setting: Twenty-eight facilities in South-East Queensland, Australia.
Participants: A total of 415 residents, all aged 60 years or older, with documented diagnoses of dementia.
Intervention: Facilities were randomized to 1 of 3 groups: PARO (individual, nonfacilitated 15-minute sessions, 3 afternoons per week for 10 weeks); plush toy (as per PARO but with artificial intelligence disabled); and usual care.
Measurements: The incremental cost per Cohen-Mansfield Agitation Inventory–Short Form (CMAI-SF) point averted from a provider's perspective. Australian New Zealand Clinical Trials Registry (BLINDED FOR REVIEW).
Results: For the within-trial costs, the PARO group was $50.47 more expensive per resident compared with usual care, whereas the plush toy group was $37.26 more expensive than usual care. There were no statistically significant between-group differences in agitation levels after the 10-week intervention. The point estimates of the incremental cost-effectiveness ratios were $13.01 for PARO and $12.85 for plush toy per CMAI-SF point averted relative to usual care.
Conclusion: The plush toy used in this study offered marginally greater value for money than PARO in improving agitation. However, these costs are much lower than values estimated for psychosocial group activities and sensory interventions, suggesting that both a plush toy and the PARO are cost-effective psychosocial treatment options for agitation.

Conflicts of interest: Dr. Takanori Shibata, the developer of PARO, provided five additional PAROs for the study. He had no role in any aspect of the study design, undertaking, analysis, and interpretation, or in the reporting of findings and manuscript preparation. The authors declare no other financial, personal, or potential conflicts of interest.

Funding: This work was supported by the Australian National Health and Medical Research Council (APP1065320).

* Address correspondence to Merehau C. Mervin, PhD, Centre for Applied Health Economics, School of Medicine, Griffith University, Sir Samuel Griffith Centre, Nathan, Brisbane, Queensland, 4111, Australia.
E-mail address: c.mervin@griffith.edu.au (M.C. Mervin).

https://doi.org/10.1016/j.jamda.2017.10.008
1525-8610/

The prevalence of dementia will increase over the next few decades due to the increased longevity of the population.[1,2] Although some individuals with dementia are able to live independently in the community, most will require informal and/or formal care and support for progressive functional losses.[3] As a result, dementia has a significant impact on health care resources with, for example, the Australian health and aged care system expenditure in 2009–2010 directly attributable to approximate AUD$ 2 billion to dementia care.[4]

Agitation is a common behavioral and psychological symptom of dementia, and its effect can be distressing for individuals with dementia, their families, and their carers.[5] It is a symptom that is difficult to manage,[6,7] and psychosocial interventions are recommended as the first line of treatment.[7,8] Among the psychosocial interventions available, the use of a therapeutic pet-type robot, PARO, has demonstrated initial promise for use with individuals with dementia in long-term care (LTC).[9–13] Building on previous studies, and overcoming their recognized shortcomings,[14] we conducted the largest, most rigorous cluster–randomized controlled trial (RCT) of PARO known to-date, comparing PARO (version 9) with a look-alike plush toy (PARO with artificial intelligence disabled) and usual care. As we reported in detail elsewhere,[15] PARO had modest but significant effects: PARO group participants were more verbally and visually engaged than plush toy participants, whereas both PARO and plush toy were more effective than usual care in improving pleasure and reducing neutral affect. Our findings were less clear, however, regarding changes in levels of agitation. Specifically, when assessed using recorded video observations, PARO was more effective than usual care in improving agitation, yet when assessed using the Cohen-Mansfield Agitation Inventory–Short Form (CMAI-SF),[16] there was no meaningful difference between groups.

In this article, we present the economic evaluation that was carried out alongside the clinical trial that compared the within-trial costs and health outcomes of PARO (version 9) and the look-alike plush toy with usual care, in a cost-effectiveness framework. Very few studies have sought to assess the cost-effectiveness of psychosocial interventions,[1] and, to our knowledge, no analysis of PARO's cost-effectiveness has been undertaken. We have used agitation as the outcome measure within our economic evaluation, given that there is currently no consensus on how to include well-being indices, such as engagement and mood states, within cost-effectiveness analyses.[1] The objective of this study was to determine the value for money of a PARO and a plush toy compared with usual care for reducing agitation and medication use.

Methods

Design, Setting, and Sample

We used data from the described cluster-RCT,[15,17,18] involving 28 LTC facilities and 415 participants. All facilities were located within a 100-km radius of the Brisbane central business district in South-East Queensland, Australia, and provided dementia care. Facility residents were eligible to participate if they had a diagnosis of dementia and were aged 60 years or older.

Written informed consent was obtained from all participants, if capable, or next-of-kin, at enrollment. The trial was approved by the BLINDED FOR REVIEW Human Research Ethics Committee (BLINDED FOR REVIEW) and individual care organizations, and was registered with the Australian New Zealand Clinical Trials Registry (BLINDED FOR REVIEW).

Intervention

Facilities were randomized to 1 of 3 groups by an independent service at BLINDED FOR REVIEW. Stratification occurred by private or not-for-profit status, and allocation was in blocks of 3. The PARO intervention group received individual, nonfacilitated, 15-minute sessions with PARO 3 afternoons per week (between 1:00 and 5:00 PM Monday, Wednesday, and Friday) for 10 weeks in addition to their usual care. The plush toy group received the same intervention schedule, differing in that they were given PARO with all artificial intelligence disabled (ie, no sound or movement) in addition to their usual care. We chose to use PARO with the artificial intelligence disabled for the plush toy condition to control for any potential influences an alternate plush toy may have had on the observed effects. The usual care group received facility care as standard.

Outcome Measures

To assess the value for money of PARO and the plush toy, a cost-effectiveness analysis was undertaken. This cost-effectiveness analysis used the CMAI-SF,[16] with the focus on change in agitation level (relative to cost). The CMAI-SF is a proxy measure of agitation that has established reliability and validity,[19] and has been used in previous cost-effectiveness analyses of psychosocial interventions for managing agitation in dementia.[1] A staff member of each facility completed the 14-item measure at baseline 0, and weeks 10 and 15, rating the frequency of displayed agitated behavior over the preceding 2-week period. Each item is scored between 1 ("never") and 5 ("a few times an hour"), making possible total scores from 14 to 70. Higher scores reflect greater agitation.[16]

Various facility- (cluster) and participant-level information were also collected at baseline (detailed in Reference 15).

Definition of Costs

The costs of the PARO and plush toy interventions included the cost of equipment used in the trial and the cost of maintaining the equipment (Table 1). As all PARO and plush toy intervention sessions were nonfacilitated, there are no costs related to the supervision of the sessions. A 1-year lifetime was assumed based on the warranty of the PARO. For the 10-week duration of the trial, the costs were $4867.33 and $4383.08 for the PARO and plush toy groups, respectively. During the trial, as indicated earlier, PARO with the artificial intelligence disabled was used as the plush toy. Therefore, the costs of the plush toy arm are comparable to the cost of the PARO arm, apart from the cost of the battery. In clinical practice, the costs of using a plush toy are likely to be significantly lower if a plush toy purchased from high-street outlets is used. As the usual care group received no

Table 1
Within-Trial Costs Delivering a 10-Week Intervention for PARO, Plush Toy, or Usual Care Groups

Resource Item	PARO, n = 138, $	Plush Toy, n = 140, $	Usual Care, n = 137, $
Equipment			
Robotic seal	23,280.00	22,792.00	—
Battery	1810.00	—	—
Accessories	220.12	—	—
Total equipment cost, annual	25,310.12	22,792.00	—
Within-trial equipment cost, 10 wk	4867.33	4383.08	—
Maintenance, within trial			
Maintenance of robotic aspects	1445.00	—	—
Cleaning	442.65	442.65	—
Total maintenance cost, 10 wk	1887.65	442.65	—
Medication, within trial			
Total costs	7071.85	7252.00	6861.60
Total cost	13,826.83	12,077.73	6861.60
Incremental cost vs usual care	6965.23	5216.13	—

—, denotes resource item not used in the intervention group.

intervention, no additional cost of equipment and maintenance were included for them.

The medication used (dementia drugs, such as anticholinesterase, antidepressants, antipsychotics, and opioid medications), dosage, and frequency of use for each participant at weeks 0, 5, 10, and 15 were recorded and extracted from their medical records by trained Research Assistants. Unit drug costs were obtained from the Pharmaceutical Benefits Scheme[20] and were multiplied by the frequency and dose to provide a cost per patient per week. Because brand names were not recorded, it was assumed that all drugs used were generic products when available. The dosage and frequency of medications recorded at each time point were assumed to remain constant until the next time point.

Cost-effectiveness Analysis

The cost-effectiveness analysis was conducted from the perspective of the Australian health care provider. When comparing the intervention groups with usual care, the incremental costs were measured in terms of the costs of the interventions plus medication costs. Effectiveness was measured using the difference-in-differences approach (eg, the before and after change in CMAI-SF scores in the intervention group minus the before and after change in CMAI-SF scores in the usual care group[1]). The incremental cost-effectiveness was measured as the incremental cost per unit improvement in agitation between 2 comparative groups (PARO or plush toy vs usual care). The time horizon was limited to the 10-week intervention time period. All costs are reported in 2017 Australian dollars (AUD$).

Statistical Analysis

An intention-to-treat analysis was conducted. Descriptive statistics were generated for all study group participants. As the medication costs were a mixture of zero and positive values, we considered a Generalized Linear Model (distribution using Gaussian family and identity link) to identify key determinants of total medication costs after controlling for the following baseline covariates: age, cognitive impairment, study group, and sex. Model goodness-of-fit was undertaken using standard diagnostic tests, including the RESET test, the Akaike Information Criterion, and Bayesian Information Criterion metrics. Data were analyzed using STATA/SE (version 12.0) (StataCorp, College Station, TX), and statistical significance was set at $P < .05$.

For the economic assessment, the incremental cost-effectiveness ratio was calculated by dividing the difference in costs by the difference in outcome. Thus, the results of the economic assessment were a cost per CMAI-SF point averted. This is consistent with previous economic evaluations conducted in dementia care.[21–23]

Results

A total of 415 residents from 28 LTC facilities took part in the research. As detailed elsewhere, the profile of facilities and participants in each study group were similar at baseline.[15]

For our cost-effectiveness outcome of agitation, there was no significant difference between study groups (see Appendix 1 and detailed in Reference 15). However, trends in the data showed that at week 10, there was a reduction in agitation in the PARO group (−2.66) and the plush toy group (−1.68), whereas there was an increase in agitation in the usual care group (1.22).

Health Care Resource Utilization and Costs

At baseline, the PARO group averaged 1.6 medications, at a total cost of $10.17 per resident per week. This compared to an average of 1.4 medications in both plush toy and usual care groups, at an average medication cost of $10.85 and $9.55, respectively. At week 10, the "per-patient, per-week" values were 1.6 ($11.17), 1.3 ($9.84), and 1.4 ($8.80), respectively, for PARO, plush toy, and usual care. There were no significant differences in the average number of medications between study groups ($P = .31$) and over time ($P = .95$). The results of the Generalized Linear Models showed that none of the covariates were statistically significant (all $P > .05$).

The total within-trial costs of the 10-week interventions were $6754.98 for the PARO group and $4825.73 for the plush toy group (Table 1). The costs of medications for each treatment group (ie, mean cost per patient per week multiplied by the number of patients in the group and the number of weeks of the trial) ranged between $6800 and $7300. Aggregating the intervention and medication costs for each study group resulted in a total cost of $13,826.83 for the PARO group, $12,077.73 for the plush toy group, and $6861.60 for the usual care group. Thus, the incremental cost was $6965.23 for PARO compared with usual care, and $5216.13 for the plush toy compared with usual care. Deriving a within-trial cost per patient (based on the number of patients who participated in each arm), compared with usual care, the PARO group was $50.47 more expensive per resident, whereas the plush toy group was $37.26 more expensive.

The results of the 10-week within-trial cost-effectiveness analysis are reported in Table 2. The point estimate of the incremental cost-effectiveness ratio was $13.01 for PARO and $12.85 for the plush toy group per CMAI-SF point averted relative to usual care. Excluding the cost of medications, the point estimate of the incremental cost-effectiveness ratio was $12.62 for PARO and $11.89 for the plush toy group per CMAI-SF point averted relative to usual care.

Discussion

In this economic evaluation, the 10-week intervention involving PARO was not cost-effective in reducing agitation, as assessed by CMAI-SF, compared with a plush toy comparison and usual care. We also found that medication usage did not significantly change for any of the 3 groups, and neither were there any significant between-group differences. In understanding these findings, the first explanation may be that the PARO intervention was unable to statistically ameliorate agitation. Second, the CMAI-SF is a proxy measure and, thus, it may be that any improvements in agitation were not detected by the staff completing the measure. In addition, we experienced data collection difficulties with the CMAI-SF at week 10, with care staff not completing questionnaires or only partially, which required the use of a conservative missing data strategy (last observation carried forward). Had a complete data set been available, significant group differences may have been detected. Alongside this, the question of whether the intervention dose (15 minutes, 3 times per week for

Table 2
Cost-effectiveness of PARO, Plush Toy, and Usual Care After a 10-Week Intervention

Treatment Group	Costs, $	Mean CMAI-SF Change	Incremental Cost per Patient, $	Incremental CMAI-SF Change	Cost per CMAI-SF Point Averted, $
PARO, n = 67	13,826.83	−2.66	50.47	−3.88	13.01
Plush toy, n = 70					
PARO with artificial intelligence disabled*	12,077.73	−1.68	37.26	−2.90	12.85
$35.00 seal plush toy†	7741.77	−1.68	6.29	−2.90	2.17
Usual care (n=72)	6861.60	1.22	—	—	—

CMAI-SF, The Cohen-Mansfield Agitation Inventory—Short Form.
*Within-trial analysis of the plush toy used in the study.
†Real-world analysis of an inexpensive regularly available seal plush toy.

10 weeks) was strong enough for effects of PARO to be seen, is also important to consider. As for the lack of change in medication use, current prescription practices within LTC facilities, which can see general practitioners (GPs) altering medications at facilities en masse and at prescribed intervals (ie, quarterly reviews), may have prevented any changes being observed. In addition, staff may not have informed GPs of any changes in resident agitation levels. An audit of the baseline data from this cluster-RCT showed that 68% of participants were taking at least 1 potentially inappropriate medication when assessed against Beers criteria,[24] and that there were more than 200 potential medication interactions, of which 38% were classified as severe interactions.[25] Such inappropriate prescribing practices within facilities highlights the challenge of using medication costs within economic evaluations, as well as the potential for inconclusive findings in terms of changes in medication use.

Regarding the within-trial cost-effectiveness, the findings do not support the study objective that the PARO intervention would be cost-effective compared with usual care. Indeed, the incremental cost per unit improvement in CMAI-SF was $13.01 for the PARO group and $12.85 for the plush toy group. When applying a real-world perspective, an inexpensive plush toy ($35.00) regularly available from high-street outlets, may afford even greater value for money than PARO, with an incremental cost per unit in CMAI-SF of $2.17 (Table 2), if based on comparable levels of effectiveness to the plush toy used in this study. These findings collectively highlight that a plush toy may offer greater value for money than PARO in terms of improving agitation specifically. However, these costs are also much lower than values estimated for psychosocial group activities (from approximately $280 to $6030) and sensory interventions (from approximately $42 to $248),[1] suggesting that both a plush toy and the PARO are cost-effective psychosocial treatment options for agitation. Alongside this, it is also important to recognize that the cost analysis did not take into account the significant effects that PARO had in improving engagement and mood states.[15] LTC facilities should be mindful of the additional effectiveness of PARO, and factor these unaccounted-for benefits into their own “weighing-up” of costs when considering purchasing a PARO.

Our study is limited for the following reasons. First, although the costs of medications prescribed to all residents enrolled in the trial were included, other costs incurred from managing agitation were not included (eg, increased staff time). Second, our incremental effectiveness was measured in terms of unit improvement in agitation rather than quality of life or the well-being indices of engagement and mood states where we observed significant group effects.[15] Third, interpretation is limited, as there is no cost-effectiveness threshold for the CMAI-SF.

Conclusion

Our findings show that the plush toy used in the study (PARO with artificial intelligence disabled) offered marginally greater value for money than PARO in terms of improving agitation. However, these costs are also much lower than values estimated for psychosocial group activities (from approximately $280 to $6030) and sensory interventions (from approximately $42 to $248),[1] suggesting that both a plush toy and the PARO are cost-effective psychosocial treatment options for agitation.

Acknowledgments

The authors thank Professor Paul Scuffham, Health Economist, Menzies Health Institute Queensland, Griffith University, for his review and comment on a draft of the paper.

The sponsor had no role in any aspect of the study design, undertaking, analysis, and interpretation, or in the reporting of findings and preparation of the manuscript.

References

1. Livingston G, Kelly L, Lewis-Holmes E, et al. A systematic review of the clinical effectiveness and cost-effectiveness of sensory, psychological and behavioural interventions for managing agitation in older adults with dementia. Health Technol Assess 2014;18:488–494.
2. Rice D, Fillit H, Max W, et al. Prevalence, costs, and treatment of Alzheimer's disease and related dementia: A managed care perspective. Am J Manag Care 2001;7:809–818.
3. Kaplan DB, Berkman B. Dementia care: A global concern and social work challenge. International Social Work 2011;54:361–373.
4. Australian Institute of Health and Welfare. Dementia in Australia. Cat. no. AGE 70. Canberra: AIHW; 2012.
5. Kong EH, Evans LK, Guevara JP. Nonpharmacological intervention for agitation in dementia: A systematic review and meta-analysis. Aging Ment Health 2009;13:512–520.
6. Spenceley S, Witcher CS, Hagen B, et al. Sources of moral distress for nursing staff providing care to residents with dementia. Dementia (London) 2017;16:815–834.
7. Kales HC, Gitlin LN, Lyketsos CG. Assessment and management of behavioral and psychological symptoms of dementia. BMJ 2015;350:h369.
8. National Institute for Health and Care Excellence. Dementia: Supporting people with dementia and their carers in health and social care. Available at: https://www.nice.org.uk/guidance/cg42. Accessed March 15, 2016.
9. Joranson N, Pedersen I, Rokstad AM, et al. Effects on symptoms of agitation and depression in persons with dementia participating in robot-assisted activity: A cluster-randomized controlled trial. J Am Med Dir Assoc 2015;16:867–873.
10. Moyle W, Cooke M, Beattie E, et al. Exploring the effect of companion robots on emotional expression in older adults with dementia: a pilot randomized controlled trial. J Gerontol Nurs 2013;39:46–53.
11. Petersen S, Houston S, Qin H, et al. The utilization of robotic pets in dementia care. J Alzheimers Dis 2017;55:569–574.
12. Takayanagi K, Kirita T, Shibata T. Comparison of verbal and emotional responses of elderly people with mild/moderate dementia and those with severe dementia in responses to seal robot, PARO. Front Aging Neurosci 2014;6:257.
13. Thodberg K, Sørensen LU, Videbech PB, et al. Behavioral responses of nursing home residents to visits from a person with a dog, a robot seal or a toy cat. Anthrozoös 2016;29:107–121.
14. Bemelmans R, Gelderblom GJ, Jonker P, et al. Socially assistive robots in elderly care: A systematic review into effects and effectiveness. J Am Med Dir Assoc 2012;13:114–120.
15. Moyle W, Jones C, Murfield J, et al. Use of a robotic seal as a therapeutic tool to improve dementia symptoms: a cluster-randomised controlled trial. J Am Med Direct Assoc 2017;18:766–773.
16. Werner P, Cohen-Mansfield J, Koroknay V, et al. The impact of a restraint-reduction program on nursing home residents. Geriatr Nurs 1994;15:142–146.
17. Moyle W, Beattie E, Draper B, et al. Effect of an interactive therapeutic robotic animal on engagement, mood states, agitation and psychotrophic drug use in people with dementia. a cluster randomised controlled trial protocol. BMJ Open 2015;5:e009097.
18. Moyle W, Bramble M, Jones C, Murfield J. Care staff perceptions of a social robot called paro and a look-alike plush toy: a descriptive qualitative approach. Aging Ment Health; 2016:1–6.
19. Sansoni J, Marosszeky N, Jeon Y-H, et al. Final report: Dementia outcomes measurement suite project. Wollongong, NSW, Australia: Centre for Health Service Development, University of Wollongong; 2007.
20. Department of Health. Pharmaceutical Benefits Scheme (PBS). Available at: http://www.pbs.gov.au/pbs/home. Accessed February 23, 2016.
21. Chenoweth L, King MT, Jeon YH, et al. Caring for Aged Dementia Care Resident Study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: A cluster-randomised trial. Lancet Neurol 2009;8:317–325. Accessed February 23, 2016.
22. Mintzer JE, Colenda C, Waid LR, et al. Effectiveness of a continuum of care using brief and partial hospitalization for agitated dementia patients. Psychiatr Serv 1997;48:1435–1439.
23. Norman R, Haas M, Chenoweth L, et al. Dementia care mapping and patient-centred care in australian residential homes: An economic evaluation of the care study. Sydney, NSW, Australia: Centre for Health Economics Research and Evaluation, University of Technology, Sydney; 2008.
24. American Geriatrics Society. 2015 Beers Criteria Update Expert Panel. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc 2015;63:2227–2246.
25. Moyle W, El Saifi N, Draper B, et al. Pharmacotherapy of persons with dementia in long-term care in australia: a descriptive audit of central nervous system medications. Curr Drug Saf; 2017 Feb 9 [Epub ahead of print].

Appendix 1

Effect of PARO, Plush Toy, and Usual Care on Agitation, as Measured by the CMAI-SF, at Weeks 10 and 15

Treatment Group	Frequency, n	Change at wk 10	Change at wk 15
		Mean (SD)	Mean (SD)
PARO	67	−2.66 (6.15)	−4.18 (7.67)
Plush toy	70	−1.68 (9.90)	−2.56 (10.44)
Usual care	72	1.22 (9.24)	−0.25 (9.10)

CMAI-SF, The Cohen-Mansfield Agitation Inventory—Short Form.
At week 10, the main effect of the intervention, pG = 0.6353; for the main effect of time pT = 0.2926; and the interaction between group and time, pGT = 0.1925.
At week 15, the main effect of the intervention, pG = 0.0668; for the main effect of time pT = 0.1667; and the interaction between group and time, pGT = 0.9148.