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Does cognitive impairment and agitation in dementia influence intervention effectiveness? Findings from a cluster-RCT with the therapeutic robot, PARO

Running title: COGNITIVE IMPAIRMENT, AGITATION, AND PARO

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Abstract

Objectives: To explore whether severity of cognitive impairment and agitation of older people with dementia predict outcomes in engagement, mood states, and agitation after a 10-week intervention with the robotic seal, PARO.

Design: Data from the PARO intervention-arm of a cluster-randomised controlled trial was used, which involved individual, non-facilitated, 15-min sessions with PARO three afternoons per week for 10-weeks.

Sample and participants: One hundred and thirty-eight residents – aged ≥60 years, with dementia – from nine long-term care facilities.

Measures: A series of stepwise multiple linear regressions were conducted. Dependent variables were participants' levels of engagement, mood states, and agitation at week 10 (assessed by video observation and Cohen Mansfield Agitation Inventory-Short Form [CMAI-SF]). Predictor variables were baseline levels of cognitive impairment (assessed by Rowland Universal Dementia Assessment Scale [RUDAS]) and agitation [CMAI-SF].

Results: Five models were produced. The strongest finding was that participants with more severe agitation at baseline had higher levels of agitation at week 10 (R^2 =.82, p<0.001). Predictors of positive response were less significant. Low levels of agitation at baseline predicted greater positive behavioural engagement with PARO (R^2 =.054, p=0.009) and fewer observed instances of agitation (R^2 =.033, p=0.045) at week 10, whilst greater visual engagement was predicted by both lower levels of agitation and cognitive impairment (R^2 =.082, p=0.006). Less severe cognitive impairment predicted greater pleasure at week 10 (R^2 =.067, p=0.004).

Conclusions/Implications: Participants with severe agitation had poor response to PARO. Lower levels of agitation and higher cognitive functioning were associated with better responses. In clinical practice, we recommend PARO should be restricted to people with low-moderate severity of agitation. Further research is needed to determine the optimal participant characteristics for response to PARO.

Keywords: *Characteristics; Dementia; Long-term care*; *Older people; Psychosocial intervention*.

Introduction

The therapeutic pet-type robot, PARO, was developed by Japanese engineers as an alternative to animal-assisted therapy. Modelled on the features of a baby harp seal and weighing approximately 2.5kg, PARO has five, in-built sensors that enable the robot to respond autonomously to the user and their environment. PARO is diurnally active, and can move its flippers and tail, open and close its eyes, and make sounds similar to a baby harp seal (Figure 1). A number of small-scale trials[1-4] have shown the potential of PARO in the management of behavioural and psychological symptoms of dementia (BPSD) in long-term care (LTC), typically in facilitator-led group sessions. This promise has been substantiated more rigorously in our own research – the largest RCT conducted with PARO to-date – where we found that individual, unfacilitated sessions with PARO encouraged verbal and visual engagement, improved expressions of

pleasure and neutral affect, and had some effect in reducing agitation.[5] Building on this growing body of empirical work, we now need research that explores whom PARO may work best for to aid implementation in practice.

The importance of personal characteristics has been identified as key to maximising non-pharmacological intervention effectiveness,[6] with levels of cognitive impairment and agitation emerging as particularly influential on outcome.[7-10] However, the direction of this relationship remains unclear. Some evidence suggests greater positive effects for those with greater cognitive impairment and more severe BPSD,[7, 10] whilst other evidence indicates the contrary.[8, 9] In the post-hoc analyses of the early PARO studies, similar conflicting findings have also been found regarding cognitive impairment,[1-4] whilst the influence of agitation has yet to be explored.

In light of the described literature, and in response to recommendations to investigate intervention effectiveness in subgroups of older people with dementia,[10] this study aimed to explore whether baseline levels of cognitive impairment and agitation of residents with dementia in LTC predict outcomes in engagement, mood states, and agitation after a 10-week PARO intervention. As this study was secondary analysis of the outcome data, we had no *a priori* hypotheses.

Methods

Design, sample, setting, ethics

We used data from the PARO intervention arm of a larger cluster-RCT, conducted between June 14, 2014, and May 16, 2015, with full details published elsewhere.[5, 11, 12] Briefly, all participants were aged 60 years or older, had a diagnosis of dementia, and were permanent residents of a facility located within a 100km radius of Brisbane's Central Business District (Queensland, Australia). Residents' pharmaceutical treatments continued during the study, and no significant changes were found in medication usage over this time, or between intervention groups.[12] Exclusion criteria extended to participants with a respite care admission, dual diagnosis of a serious/persistent mental illness, terminal illness, and/or unremitting pain/distressing physical symptoms. Baseline characteristics of participants are shown in Table 1. Institutional ethical approval was obtained from Griffith University Human Ethics Committee (NRS/03/14/HREC) and respective care organisations.

The PARO intervention

Participants in the PARO intervention group (*n*=138; *n*=9 facilities) received individual, non-facilitated, 15-min sessions with PARO three afternoons per week (between 13:00-17:00 Mon, Wed, and Fri) for 10 weeks. Each session was conducted wherever the participant was at the time within the facility (except when in the bathroom), which was typically the facility communal day room or resident's bedroom. All sessions began with a trained Research Assistant (RA) introducing PARO to the participant using a standard script, detailed elsewhere.[11]

Data collection and analysis

The dependent variables were participants' levels of: engagement (positive behavioural engagement with the object; using the object for social engagement; positive verbal engagement with the object; and visual engagement with the object); mood states (anger; anxiety/fear; neutral; pleasure; sadness); and agitation after 10 weeks of the PARO intervention. Video observations were used to measure all outcomes, with a trained RA recording each participant using a small, handheld GoPro Hero video camera. Each participant was recorded for 30-mins, covering 15-mins immediately before the intervention (serving as each participant's baseline for that observation), and then for the 15-min intervention. All video data were quantitatively coded in Noldus Observer XT® by trained RAs using the Video Coding Protocol - Incorporating Observed Emotion (VC-IOE) Scheme.[13] The 14-item Cohen-Mansfield Agitation Inventory – Short Form (CMAI-SF)[14] was also used as an additional, proxy measure of agitation, with facility care staff using a five-point scale to assess the frequency of each participant's agitated behaviour during the previous two-week period (the total score possible can range from 14 to 70, with higher scores representing greater agitation/behavioural disruption).

The predictor variables were participants' levels of cognitive impairment and agitation at baseline. The Rowland Universal Dementia Assessment Scale (RUDAS)[15] was used to assess cognitive impairment (the total score possible can range from 0 to 30, with lower scores reflecting greater impairment). The CMAI-SF[14] was used to assess agitation levels at baseline.

We conducted a series of stepwise multiple linear regression analyses, with list wise deletion. Diagnostic statistics were produced and examined for each regression analysis to check for univariate and

multivariate outliers and influential cases, and assumptions were tested to ensure generalizability of each regression (i.e., assumption of no collinearity, independence of residuals in the model, etc.). The only model where assumptions were not met was for anger, which was influenced unduly by two cases with values greater than model boundaries for Cook's Distance, Centred Leverage Value, and DFBETA. These cases were removed from the model to meet assumptions, resulting in n=121 cases included in this model. For all other dependent variables, regression analyses using list wise deletion included n=123 cases. Results were comparable in parallel sensitivity analysis using pair wise deletion. All data were analysed using IBM SPSS Statistics for Windows Version 24.0 (Armonk, NY: IBM Corp.).

Results

Five significant regression models were produced (Table 2). The strongest finding was that participants with more severe agitation at baseline had higher levels of agitation at week 10 (R^2 =.82, F(1,121)=559.37, p<0.001). Predictors of positive response were less significant. Low levels of agitation at baseline predicted greater positive behavioural engagement with PARO (R^2 =.054, F(1,121)=6.97, p=0.009) and fewer observed instances of agitation (R^2 =.033, F(1,121)=4.11, p=0.045) at week 10, whilst greater visual engagement was predicted by both lower levels of agitation and cognitive impairment (R^2 =.082, F(2,120)=5.39, p=0.006). Less severe cognitive impairment predicted greater pleasure at week 10 (R^2 =.067, F(1,121)=8.74, p=0.004).

Discussion

Our findings support the suggestion that levels of cognitive impairment and agitation of residents with dementia in LTC predict effectiveness of a 10-week PARO intervention. The most important finding was that participants with more severe agitation at baseline had a poor response to PARO, with the level of baseline agitation being the key factor. From this result we conclude that, in clinical practice, PARO should be restricted to people with low-moderate severity of agitation.

From a statistical perspective, lower levels of agitation, and to a lesser extent, higher levels of cognitive functioning, were associated with significantly better responses to PARO in terms of behavioural and visual engagement, pleasure, and agitation. However, from a clinical perspective, agitation and

cognitive impairment explained only a small proportion of the variance in each of these models (R^2) – between 3 to 8% – indicating that other, unknown factors were also contributing a large part to these outcomes. Given the heterogeneity of dementia as a syndrome, it is likely that our findings are, in part, reflective of this complexity. Further, as we found during the trial, responses to PARO varied considerably between individuals, as well as for the same individual on different occasions,[16] and this may also go some way in understanding why our two predictor variables were unable to explain a large proportion of the variance (a more thorough discussion of response variation can be found elsewhere[16]). Further research is needed to determine if the use of PARO may be optimised for those with mild-to-moderate levels of agitation and cognitive impairment.

Recommendations for Practice and Policy

Drawing from our wider program of research with PARO,[12, 16-21] we suggest that, while PARO is a feasible psychosocial intervention and has some effect in managing BPSD – particularly in relation to improved engagement and pleasure – it is not suitable for all LTC residents with dementia. In clinical practice, we first recommend PARO should be restricted to people with low-moderate severity of agitation, whilst also recognising that there can be considerable variation in response to PARO between individuals with similar clinical profiles. Considerations after this should include the person's biography, particularly their like or dislike of animals, and the type of agitation displayed (i.e., restlessness and wandering can make it difficult to engage some residents and doing so can actually exacerbate their agitation). When using PARO, staff should uphold a person-centred approach, as just because the resident liked PARO one day, does not mean that they will enjoy it the next. Further, staff need to monitor the levels of attachment residents develop with PARO and ensure they do not become fatigued or over-burdened. Our economic analysis[12] found that, when financial resources are limited, a soft toy animal may be used effectively with a person with dementia to manage BPSD. However, we stress that the use of PARO, or any other psychosocial intervention, should not replace staff time, but rather be used as an additional means of providing comfort and purposeful engagement.

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Table 1. Baseline characteristics

Characteristic	PARO intervention group
Number of facilities	(n=9)
Number of participants	(n=138)
Sex (female)	101 (73%)
Age (years)	84 (8.4)
RUDAS (total score)	6.5 (6.5)
CMAI-SF (total score)	29.0 (10.1)
Type of dementia diagnosed:	
Alzheimer's disease	49 (36%)
Vascular dementia	17 (12%)
Dementia with Lewy bodies	1 (1%)
Fronto temporal lobar degeneration	4 (3%)
Alcohol-related dementia	1 (1%)
Unspecified	66 (48%)
Taking medication (yes)*	118 (86%)
Sensory deficit (yes)†	117/134 (87%)
Facility care-type environment:‡	
Secure dementia unit	81 (59%)
Facility ward/unit	57 (41%)

Notes Data are n (%), mean (SD). RUDAS = The Rowland Universal Dementia Assessment Scale: A Multicultural Cognitive Assessment Scale; lower scores indicate greater cognitive impairment. CMAI – SF = The Cohen-Mansfield Agitation Inventory – Short Form; higher scores indicate more aggressive/disruptive behaviour. *Includes antidepressants; antipsychotics; anxiolytics and hypnotics; anticonvulsants; analgesics; and anticholinesterase medications.
†Includes hearing; vision; olfaction; touch/pain/tingling; and other deficits.
‡Data not available for all randomised participant

Table 2. Significant stepwise multiple linear regressions

Dependent Variable (At Week 10)	**Step**	**Predictor Variable (At baseline week 0)**	***B***	***SE B***	***B***	***p*=**	R^2	Adj. R^2
Behavioural engagement	1	CMAI-SF	-.794	.301	-.233	.009**	.054	.047
Visual engagement	1	CMAI-SF	-.425	.174	-.217	.016*	.047	.039
	2	CMAI-SF	-.382	.172	-.195	.029*	.082	.067
		RUDAS	.627	.292	.189	.034*		
Pleasure	1	RUDAS	.300	.101	.260	.004**	.067	.060
No agitation	1	CMAI-SF	-.323	.160	-.181	.045*	.033	.025
Agitation (CMAI-SF)	1	CMAI-SF	.929	.039	.907	.000***	.822	.821

Notes RUDAS, The Rowland Universal Dementia Assessment Scale: A Multicultural Cognitive Assessment Scale; CMAI-SF, The Cohen-Mansfield Agitation Inventory- Short Form. *$p < .05$; **$p < .01$; ***$p<0.0001$

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Conflicts of interests

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 conflicts of interest.

Author Contributions

WM conceived and designed the larger study, in consultation and review with CJ, BD, EB, DS, and LT. As lead investigator, WM oversaw and managed the study, and coordinated and supervised all study personnel. WM, EB, and CJ trained study personnel. CJ and JM prepared the data for analysis, and CJ and JM analysed the data, in consultation with LT. All authors contributed to the interpretation of the data, assisted in manuscript preparation, and gave final approval for submission.

Sponsor's Role

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.