Maturitas 110 (2018) 10–17

Contents lists available at ScienceDirect

Maturitas

journal homepage: www.elsevier.com/locate/maturitas

Effect of a robotic seal on the motor activity and sleep patterns of older people with dementia, as measured by wearable technology: A cluster-randomised controlled trial

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

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

ARTICLE INFO

Keywords:
Agitation
Long-term care
BPSD
Accelerometers
Wearable technology
PARO

ABSTRACT

Objectives: The robotic seal, PARO, has been used as an alternative to animal-assisted therapies with residents with dementia in long-term care, yet understanding of its efficacy is limited by a paucity of research. We explored the effects of PARO on motor activity and sleep patterns, as measured by a wearable triaxial accelerometer.

Study design: Cluster-randomised controlled trial, involving 28 facilities in Queensland, Australia. Nine facilities were randomised to the PARO group (individual, non-facilitated, 15-min sessions three afternoons per week for 10 weeks), 10 to a plush toy (PARO with robotic features disabled) and nine to usual care.

Main outcome measures: Changes in day- and nighttime motor activity and sleep after the 10-week intervention, as measured by SenseWear® armbands, worn by participants continuously for 24 h at baseline, during two single intervention days in weeks 5 and 10 respectively, and post-intervention (week 15). Analyses followed intention-to-treat, using repeated-measures mixed-effects models.

Results: After 10 weeks, the PARO group showed a greater reduction in daytime step count than usual care ($p = 0.023$), and in nighttime step count ($p = 0.028$) and daytime physical activity ($p = 0.026$) compared with the plush toy group. At post-intervention, the PARO group showed a greater reduction in daytime step count than the plush toy group ($p = 0.028$), and at nighttime compared with both the plush toy group ($p = 0.019$) and the usual-care group ($p = 0.046$). The PARO group also had a greater reduction in nighttime physical activity than the usual-care group ($p = 0.015$).

Conclusions: PARO may have some effect on motor activity of older people with dementia in long-term care, but not on sleep patterns.

Australian New Zealand Clinical Trials Registry (ACTRN12614000508673).

1. Introduction

Behavioural and psychological symptoms of dementia (BPSD) are common and pervasive, affecting at least half of all residents with dementia living in long-term care (LTC) [1–3]. Defined as symptoms of disturbed perception, thought content, mood or behaviour, frequently occurring in patients with dementia [4], BPSD can present as agitation, apathy, psychosis, and mood and sleep disturbances. One core aspect of

* Corresponding author at: Menzies Health Institute QLD, Griffith University, 2.10 Health Sciences (N48), 170 Kessels Road, Nathan, Brisbane, Queensland, 4111, Australia.
E-mail addresses: w.moyle@griffith.edu.au (W. Moyle), C.Jones@griffith.edu.au (C. Jones), j.murfield@griffith.edu.au (J. Murfield), Lthalib@qu.edu.qa (L. Thalib), elizabeth.beattie@qut.edu.au (E. Beattie), d.shum@griffith.edu.au (D. Shum), S.ODwyer@exeter.ac.uk (S. O'Dwyer), c.mervin@griffith.edu.au (M.C. Mervin), B.Draper@unsw.edu.au (B. Draper).

https://doi.org/10.1016/j.maturitas.2018.01.007
Received 10 December 2017; Received in revised form 11 January 2018; Accepted 12 January 2018

agitation is excessive motor activity [5], which can include wandering, restlessness, rocking and repetitious mannerism. Wandering can have particularly negative consequences for the person with dementia, such as fatigue and injury [6]. Further, due to changes in sleep pattern, residents can experience hypersomnia, asleep-wake reversal, and nighttime wandering [7]. Such behaviours can be a significant source of stress for the person with dementia, as well as their family members, and are associated with an increased use of LTC staff resources [8].

Although the aetiology of BPSD is often unknown, they have been conceptualised as meaningful responses to unmet needs [9]. Therefore, early and ongoing assessment of behaviours is required to foster appropriate management, and psychosocial interventions should be the first approach used for BPSD management [7]. Monitoring and assessment of BPSD can involve any method, such as a simple ABC approach that focuses on the Antecedents, Behaviours and Consequences [10], and standardised tools that allow tracking of behaviours using observation and/or proxy- and self-report measures. Although only the most rigorously tested and psychometrically robust measures are useful in assessing BPSD, these measures require staff training, are often lengthy and time-consuming for staff to complete, and provide only a subjective approximation of symptom assessment.

Modern, wearable devices, such as actigraphs and accelerometers, may offer an alternate way of assessing the presence and severity of excessive motor activity and sleep disturbance through recording biometric data directly from the person with dementia. By extension, this technology may also enable the efficacy of an intervention to be objectively evaluated by permitting the comparison of participants' 'usual' physiological data with that collected on a day when the participant has received an intervention aimed at reducing the behaviour. Research with people with delirium supports the use of accelerometry as an objective means of continuously and unobtrusively monitoring people with heightened agitated states [11]. Further, recent studies with dementia populations have shown that the biometric data collected by devices are reflective of agitation-related behaviour, with motor activity significantly related to agitation and apathy [12], and both motor activity and sleep disturbance related to the severity of dementia [13,14]. This suggests that, for older people with dementia, the motor activity and sleep data collected through wearable devices may represent, in-part, agitation-related behaviour, and can be used within intervention-research as a means to explore efficacy.

1.1. PARO

The therapeutic pet-type robotic seal, PARO (Fig. 1), has been used as a promising alternative to animal-assisted therapies for residents with dementia in long-term care. Initial small RCTs showed positive effects on measures of anxiety and stress [15], usage of psychotropic and pain medication [15,16], agitation, depression, quality of life, social interaction and engagement [17], and loneliness [18].

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

1.2. Primary outcomes from this study

Building on this work, and in response to calls for more rigorous RCTs in the area [19,20], we undertook a large cluster-RCT to explore the effects of PARO (version 9) compared to a plush toy (PARO with robotic features disabled), and usual facility care, on emotional and behavioural symptoms of dementia [21–23]. On the primary outcomes measured by direct video observation data and the proxy-rated Cohen-Mansfield Agitation Inventory- Short Form (CMAI-SF) [24], we found that, after 10 weeks, PARO group participants were more verbally and visually engaged with the intervention object than those in plush toy, and that both PARO and plush toy were more effective than usual care in improving pleasure and reducing neutral affect. The effect of the intervention on agitation levels, however, was inconclusive: video data showed that PARO was more effective than usual care in improving agitation levels, but was no different to plush toy. However, when measured using the CMAI-SF, there were no differences between any of the three groups after 10 weeks [23].

In this paper, we present findings from the study's secondary outcomes, motor activity and sleep patterns, which were collected using the wearable triaxial accelerometer, SenseWear® Professional 8.0 activity armband (Temple Healthcare, BodyMedia, Inc). The biometric data recorded at baseline were considered representative of each participant's usual pattern of motor activity and sleep, and was compared with the data collected during an intervention day to determine the effects of the intervention. Given the high rate of BPSD within the LTC population, and the demonstrated relationship between motor activity and agitation/apathy [12], we assumed that the recorded motor activity and sleep represented aspects of agitation-related behaviour. We hypothesised that, after the 10-week intervention, participants in the PARO group would show greater reductions in motor activity and improved sleep patterns than participants in the plush toy and usual care groups.

2. Methods

2.1. Design

The study adopted a parallel, three-group, single-blind, cluster-RCT design [22]. Ethical approval was obtained from Griffith University Human Ethics Committee (NRS/03/14/HREC) and respective care organisations, as necessary. The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000508673).

2.2. Setting

LTC facilities that provided care to residents with dementia and were located within a 100 km radius of the Brisbane central business district in South-East Queensland, Australia, were eligible to participate. Thirty-seven LTC facilities were approached for inclusion, with 28 formally enrolled into the study following verbal consent from each facility manager.

Randomisation of facilities was performed by an independent web-based, centralised, service at Griffith University. Using a computer-generated sequence, LTC facilities were stratified by private/not-for-profit status, and randomised in blocks of three to PARO, plush toy, or usual care conditions (1:1:1). The allocation of facilities to study groups was concealed from facility staff, participants, and families until the commencement of intervention activities.

2.3. Sample

LTC facility managers identified potential participants. Trained Research Assistants (RAs) screened and recruited eligible residents if they were aged ≥60 years and had a dementia diagnoses, as documented in resident's medical and care records. Residents'