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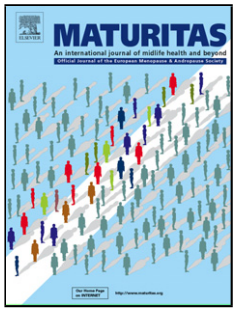

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Effect of a robotic seal on the motor activity and sleep patterns of older people with dementia, as measured by wearable technology: a cluster-randomised controlled trial

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Highlights

- A robotic seal, PARO, has been used as an alternative to animal-assisted therapies with residents with dementia in long-term care.
- A 10-week intervention with PARO had some effect in reducing motor activity.
- There was no evidence that PARO was effective in improving sleep patterns.
- There was inconclusive evidence of short- and long-term effects of PARO.
- There are challenges in using wearable technology with individuals with dementia.

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-minute 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 hours 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).

Keywords: agitation; long-term care; BPSD; accelerometers; wearable technology; PARO.

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 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 (Figure 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].

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 100km 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' pharmaceutical treatments were continued throughout the study, and there were no significant changes in medication usage over the study period nor between study groups [25]. Residents were excluded if they were receiving respite care, had a dual diagnosis of a serious/persistent mental illness, terminal illness, and/or unremitting pain/distressing physical symptoms.

The original sample size calculation was based on our pilot work [26], and on previous studies of an individualised intervention for agitation reduction that used the CMAI-

SF as an outcome measure [24]. We sought to recruit a total sample of 380 participants, calculated on the detection of a 25% reduction in agitation, with a power of 0.90, alpha of 0.05, intraclass correlation design effect adjustment of 0.07, and a 10% rate of attrition.

All participants, if capable, or next-of-kin, provided written informed consent at the time of enrolment, and verbal assent was obtained from participants at the start of every intervention session with PARO or plush toy.

2.4 Study intervention procedures

Facilities were allocated to one of the three study groups, with trained RAs involved in delivering the intervention protocol allocated to work with one group only. Participants allocated to the PARO intervention group received individual, non-facilitated, 15-minute sessions with PARO three afternoons per week (between 13:00-17:00 Monday, Wednesday, and Friday) for 10 weeks. We chose this intervention length, and session frequency and duration based on our pilot work [26], and conducted all sessions during afternoon hours when agitation levels are considered to be usually highest [27]. Each session was conducted wherever the participant was at the time (except when in the bathroom), and began with a trained RA handing the PARO to the participant and repeating a standard introductory script [described in 22]. Participants were left alone with PARO for 15 minutes to interact with it as they liked, after which the RA returned to end the session and collect PARO. All intervention sessions were video recorded.

Participants allocated to the plush toy intervention group received identical sessions to the PARO group described, but were given PARO with all artificial intelligence disabled. Participants allocated to the usual care group received care as standard at each facility (i.e., unchanged and what they would usually receive at the facility, including involvement in activities provided by the facility).

2.5 Outcome measures

Outcomes were changes in participants' levels of daytime and nighttime motor activity, as measured by the number of steps taken and the time spent (hours) in physical activity (Metabolic Equivalent of Task >1.5), and their daytime and nighttime sleep patterns, as measured by time spent (hours) lying down, awake, and asleep, after 10 weeks of the intervention. We were also interested in whether there were any short-term effects of the intervention on motor activity levels and sleep patterns at week 5, as well as any longer-term sustained effects at follow-up (week 15).

Data were collected using the SenseWear® Professional 8.0 activity armband (Temple Healthcare, BodyMedia, Inc). This device was chosen because: it is light-weight; includes multiple sensors, including a triaxial accelerometer that processes data by in-built algorithms; it uses on/off body sensors to record wear-time; and has been used previously with older people with dementia in LTC [28]. All biometric data is predefined by SenseWear® Software based on artificial intelligence (machine learning, neural networks), and is processed by in-built algorithms. Data was set to record in 60-second epochs. Trained RAs placed the armband on participants' upper non-dominant arm over the triceps muscle between Monday to Saturday at baseline (week 0), on a day when the intervention/usual care had been delivered at weeks 5 and 10, and at post-intervention (week 15). Participants were asked to wear the armband continuously for 24-hours, removing only for bathing or discomfort. RAs demonstrated the placement and removal of the armbands to direct care staff and requested armbands be replaced as soon as possible if removed by participants or care staff during the 24-hour period, to encourage as much wear-time as possible.

A range of cluster- and participant-level information was recorded by trained RAs at baseline (Table 1).

Masking of RAs involved in data collection and data coding was achieved through assignment to one intervention group only, and also through separate working locations.

2.6 Data analysis

We assessed groups for demographic differences using Pearson's Chi-Square, Fisher's Exact Tests, or ANOVAs, as appropriate. Based on discussions with LTC staff regarding usual bed-times and inspection of data, SenseWear® data were reduced into daytime (8am-7:59pm) and nighttime (8pm-7:59am) summaries, and change scores from baseline to each assessment time-point were computed (e.g., week 10 minus week 0) for analyses.

To explore the effect of the 10-week intervention on our outcomes of interest, we ran a series of repeated measures mixed effects models, using the xtmixed command (adjusted for clustering effects) in Stata (version 13). We calculated intraclass correlation coefficients to establish the effect of clustering, and Cohen's *d* effect sizes for observed between-group differences at the alpha level of 0.05. We ran additional repeated measures mixed effects models, using the xtmixed command (adjusted for clustering effects), to explore the short- (week 5) and long-term (week 15) effects of the intervention for the same outcomes.

Analyses followed an intention-to-treat framework. Using the on/off body-time data provided by SenseWear®, participants were included at baseline if they wore the armbands for ≥10 hours (out of 12 hours) at daytime and nighttime respectively. This wear-time cut-off is standard in accelerometer studies, and considered sufficient to reflect valid activity rates [29]. We observed large variability within the study population on the outcome measures and, thus, it was considered most appropriate to use the method of last observation carried forward (LOCF) for missing data at post-baseline assessment time-points (i.e., weeks 5, 10, 15). As participants are required to have available baseline data to enable imputation of missing data

in subsequent weeks, the total number of participants included in daytime and nighttime analyses differed.

SenseWear® data were extracted using SenseWear® software, with 10% of data extracted at each assessment time-point checked against raw data files for accuracy. Data were analysed using Stata (version 13), with statistical significance set at $p<0.05$.

3. Results

A total of 415 participants from 28 LTC facilities were enrolled in the study between June 14, 2014 and May 16, 2015 (Figure 2). After applying the study's valid wear-time criteria of 10 hours or more, we included $n=175$ participants from 28 facilities in the daytime analyses ($n=67$ PARO; $n=55$ plush toy; $n=53$ usual care), and $n=280$ participants from 28 facilities in the nighttime analyses ($n=98$ PARO; $n=95$ plush toy; $n=87$ usual care). The demographic and clinical profiles of participants at the beginning of the study are described in Table 1. There was similarity between the three groups included in the daytime and nighttime analyses, as well as between those participants included and excluded from analyses.

After the 10-week intervention, there were statistically significant, albeit with clinically small effect sizes, between-group differences observed for daytime and nighttime step count, and for daytime physical activity (Table 2). Specifically, participants in the PARO group showed a greater reduction in the number of steps taken during the daytime compared to those in usual care (-268.81, 95% CI: -37.05 to -500.57, $p=0.023$), and similarly during the nighttime when compared to participants in the plush toy group (-64.88, 95% CI: -7.02 to -122.73, $p=0.028$). There was also a greater reduction in the time spent in physical activity during the daytime in the PARO group than in the plush toy group (-0.61, 95% CI: -0.07 to -1.14, $p=0.026$). We found no significant differences between the groups in the amount of time spent awake, lying down, and asleep during daytime and nighttime periods, and also the

time spent in physical activity during the night (Table 2). Notwithstanding this, however, the PARO group showed the largest improvements in all mean scores after 10-weeks of the intervention – in the directions hypothesised – when compared to plush toy and usual care groups (Table 3).

There was limited evidence to suggest short-term effects of the intervention at week 5, with the only significant between-group difference observed for step count (Tables 3 and 4). Indeed, the PARO group demonstrated greater reductions in the number of steps taken during the daytime when compared to the usual care group (-283.95, 95% CI: -11.85 to -556.06, P=0.041), and during the nighttime when compared to those in the plush toy group (-73.93, 95% CI: -22.77 to -125.09, p=0.005).

We also found little conclusive evidence to suggest sustained effects of the intervention at the week 15 follow-up, with significant differences only observed for step count and physical activity (Tables 3 and 4). Specifically, the PARO group had a greater reduction in step count during the daytime compared to the plush toy group (-187.09, 95% CI: -20.49 to -353.69, p=0.028), and during the nighttime compared to both plush toy (-55.69, 95% CI: -8.97 to -102.41, p=0.019) and usual care groups (-51.60, 95% CI: -0.86 to -102.34, p=0.046). The PARO group also had a greater reduction in the time spent in physical activity at week 15 during the nighttime compared to those in usual care (-0.34, 95% CI: -0.06 to -0.61, p=0.015).

4. Discussion

We found that 10 weeks of individual, non-facilitated sessions with PARO had some effect in reducing motor activity when compared to a plush toy comparison and usual facility care. However, there was no evidence that PARO was effective in improving sleep patterns. These findings, alongside the study's primary outcomes of agitation when measured by video

observation and the CMAI-SF reported elsewhere [23], suggests that PARO has the potential to assist in the management of agitation in older residents with dementia in LTC, perhaps by providing a focus for the person to interact and engage with, or by providing a source of comfort, or the opportunity for quiet-time. These findings are the first of their kind, being the largest and most rigorous of the PARO studies conducted to date and, importantly, the only trial that has assessed the efficacy of PARO in unfacilitated sessions rather than in sessions that use a human to facilitate engagement [15-18].

In our additional analyses of the short- and long-term effects of PARO on motor activity levels and sleep, we found no conclusive evidence to demonstrate effects during the intervention at week 5, and only limited sustainability beyond the intervention period at week 15. More frequent, longer sessions over a greater period of time may have had a more pronounced effect, and further work is needed to confirm this [30].

An important finding arising from this study is the data collection difficulties we experienced with the SenseWear® activity armbands. Participants did not tolerate wearing the armbands well, with only 42% (n=175) meeting the valid wear-time criteria during the daytime, and 67% (n=280) during the nighttime. We also found that devices were often unreliable in their recording, resulting in a large amount of missing data. Another challenge occurred when some residents chose to remove their SenseWear® activity armbands and these often became lost within the environment. Further, we also found that the armbands were particularly challenging to wear for female participants small in stature. Whilst wearable technology has definite advantages in providing an objective measure of motor activity and sleep patterns, our findings serve to highlight some of the current challenges when used in a large sample. More work and modifications are needed in this area, specifically in terms of size, placement, comfort and tolerability of wearable activity-focused technologies. Further, research should also recognise the important role that facility care staff

have in the data collection process using wearable technology, as staff can monitor adherence and remind or help participants to put the armbands back on after daily care activities, such as bathing.

4.1 Limitations

First, we do not know whether the recorded motor activity and sleep data were entirely reflective of agitated-behaviour, as we did not record what the participants were doing across each 24-hour assessment time-point. Second, we acknowledge that increases in motor activity are generally associated with health benefits, and that increases in physical function can also mitigate BPSD. However, research has shown that for people with dementia, it is not always appropriate to increase motor activity, as this can have negative outcomes for the person with dementia [31], and that behavioural interventions may be more effective than physical function programs in managing BPSD [32]. Third, based on the valid wear-time set for this study and the division of hours into daytime and nighttime periods, we excluded a large number of participants from analyses. However, it is standard for the wear-time of ≥10 hours to be employed [29] to ensure data reliability and validity, and our decision to use 20:00 as the nighttime cut-off is supported by the average bedtime for a LTC resident shown to be 20:30 [33]. Fourth, participants wore SenseWear® activity armbands for one 24-hour period only at four time-points, and we recognised that further research would benefit from longer periods of wear-time (i.e., several days of continuous wear). Fifth, SenseWear® activity armbands have been shown to under- and over-estimate step count [34], and this may affect the accuracy of recordings using this technology. Sixth, we captured residents' clinical and demographic profile at baseline only, and did not account for the potential influence of deterioration in mobility or cognitive impairment over the study period. Finally, participants were selected based on a dementia diagnoses, irrespective of their levels of agitation. At

baseline, agitation levels, as measured by the CMAI-SF, were relatively low, indicating low levels of agitation/behavioural disturbance in our sample. These findings, therefore, may not be applicable to LTC residents presenting with higher levels of agitation.

4.2 Conclusion

Our findings show some support for the potential of using PARO to affect motor activity levels of older people with dementia in long-term care, as measured by SenseWear® Professional activity armbands. However, there were challenges in using these devices with individuals with dementia, especially over a long RCT intervention period.

Contributors

Wendy Moyle conceived and designed the larger study, in consultation and review with Cindy Jones, Brian Draper, Elizabeth Beattie, David Shum, Lukman Thalib, Siobhan O'Dwyer, and M. Cindy Mervin.

Wendy Moyle and Cindy Jones oversaw the data collection.

Jenny Murfield and Cindy Jones led the analysis and interpretation of data.

Wendy Moyle, Cindy Jones, and Jenny Murfield prepared the draft manuscript.

All authors provided comment/revision and approval of the final version.

Conflict of interest

Dr Takanori Shibata, the developer of PARO, provided five additional PAROs to Wendy Moyle 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 preparation of the manuscript. The authors declare no other conflicts of interest.

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Ethical approval

Ethical approval was obtained from Griffith University Human Ethics Committee (NRS/03/14/HREC) and respective care organisations, as necessary. All participants, if capable, or next of kin, provided written informed consent at the time of enrolment, and verbal assent was obtained from participants at the start of every intervention session with PARO or plush toy. The trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12614000508673).

Provenance and peer review

This article has undergone peer review.

Research data (data sharing and collaboration)

There are no linked research data sets for this submission. The authors do not have permission to share data.

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Table 1. Baseline characteristics of participants

	Daytime (8am – 7:59pm)		
	PARO	**Plush toy**	**Usual care**
Number of facilities *n*	9	10	9
Number of participants *n*	67	55	53
Sex (female) *n* (%)	53 (79)	42 (76)	35 (66)
Age (years) mean (SD)	84 (8·8)	86 (7·6)	85 (6·9)
Type of dementia: *n* (%)			
Alzheimer's disease	23 (34)	16 (29)	15 (28)
Vascular dementia	12 (18)	12 (22)	6 (11)
Fronto temporal lobar degeneration	1 (1)	0 (0)	0 (0)
Alcohol related dementia	1 (1)	0 (0)	1 (2)
Dementia with Lewy Bodies	0 (0)	1 (2)	1 (2)
Unspecified	30 (45)	26 (47)	30 (57)
RUDAS (total score) mean (SD)	7·6 (6·8)	7·5 (6·2)	9·7 (7·5)
CMAI-SF (total score) mean (SD)	29·9 (9·5)	29·1 (10·9)	29·3 (10·8)
Taking medication (yes)[a] *n* (%)	62 (93)	38 (69)	40 (75)
Sensory deficit (yes)[b,c] *n* (%)	55/65 (85)	51/52 (98)	37 (70)

Mobile (yes)[c] *n* (%)	20/60 (33)	15 (27)	28 (53)
Facility care-type environment:[c] *n* (%)			
Secure dementia unit	41 (61)	33/54 (61)	28 (53)
Facility ward/unit	26 (39)	21/54 (39)	25 (47)
	Nighttime (8pm – 7:59am)		
	PARO	**Plush toy**	**Usual care**
Number of facilities *n*	9	10	9
Number of participants *n*	98	95	87
Sex (female) *n* (%)	76 (78)	76 (80)	58 (67)
Age (years) mean (SD)	85 (8·3)	87 (7·0)	85 (7·1)
Type of dementia: *n* (%)			
Alzheimer's Disease	37 (38)	31 (33)	27 (31)
Vascular dementia	13 (13)	20 (21)	10 (11)
Fronto temporal lobar degeneration	2 (2)	1 (1)	0 (0)
Alcohol related dementia	0 (0)	0 (0)	2 (2)
Dementia with Lewy Bodies	1 (1)	3 (3)	1 (1)
Unspecified	45 (46)	40 (42)	47 (54)
RUDAS (total score) mean (SD)	6·5 (6·6)	7·5 (6·3)	8·2 (7·0)
CMAI-SF (total score) mean (SD)	27·5 (9·4)	28·2 (10·8)	30·3 (10·4)
Taking medication (yes)[a] *n* (%)	85 (87)	63 (66)	63 (72)
Sensory deficit (yes)[b,c] *n* (%)	83/94 (88)	87/93 (94)	72 (83)
Mobile (yes)[c] *n* (%)	28/91 (31)	25 (26)	35 (40)
Facility care-type environment:[c] *n* (%)			
Secure dementia unit	56 (57)	51/94 (54)	44 (51)
Facility ward/unit	42 (43)	43/94 (46)	43 (49)

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. [a]Includes antidepressants; antipsychotics; anxiolytics and hypnotics; anticonvulsants; analgesics; and anticholinesterase medications. [b]Includes hearing; vision; olfaction; touch/pain/tingling; and other deficits. [c]Data not available for all randomised participants.

Table 2. Effects of PARO, plush toy, and usual care on SenseWear® outcomes after the 10-week intervention

	PARO vs. Plush toy			PARO vs. Usual care			Plush Toy vs. Usual care			
	Adj mean diff (95% CI)	**ES**	***p*=**	**Adj mean diff (95% CI)**	**ES**	***p*=**	**Adj mean diff (95% CI)**	**ES**	***p*=**	**ICC**
SenseWear® daytime										
Step count, * *n*	-178.44 (50.95 to -407.84)		0.127	-268.81 (-37.05 to -500.57)	-0.36	**0.023**	-90.37 (152.30 to -333.04)		0.463	0.012
Phy activity, hrs	-0.61 (-0.07 to -1.14)	-0.42	**0.026**	-0.31 (0.23 to -0.85)		0.253	0.29 (0.86 to -0.27)		0.304	0.047
Awake, hrs	0.06 (0.73 to -0.61)		0.868	0.01 (0.69 to -0.66)		0.970	-0.04 (0.67 to -0.75)		0.903	0.000
Lying down, hrs	-0.56 (0.30 to -1.43)		0.201	-0.33 (0.55 to -1.20)		0.463	0.24 (1.15 to -0.68)		0.610	0.000
Sleep, hrs	-0.21 (0.43 to -0.85)		0.516	-0.14 (0.51 to -0.79)		0.679	0.08 (0.75 to -0.60)		0.827	0.000
SenseWear® nighttime										
Step count, *n*	-64.88 (-7.02 to -122.73)	-0.29	**0.028**	-35.08 (24.11 to -94.27)		0.244	29.80 (89.43 to -29.84)		0.326	0.000
Phy. activity, * hrs	-0.19 (-0.01 to -0.39)		0.065	-0.19 (0.01 to -0.40)		0.066	-0.00 (0.20 to -0.21)		0.969	0.000
Awake, hrs	0.43 (1.38 to -0.53)		0.380	0.56 (1.54 to -0.42)		0.263	0.13 (1.12 to -0.85)		0.794	0.000
Lying down, hrs	-0.46 (0.50 to -1.43)		0.342	-0.55 (0.43 to -1.54)		0.270	-0.09 (0.90 to -1.08)		0.862	0.000
Sleep, hrs	-0.46 (0.51 to -1.42)		0.354	-0.58 (0.40 to -1.57)		0.245	-0.13 (0.87 to -1.12)		0.799	0.000

Adj mean diff = Adjusted mean difference. ES = effect size Cohen's d, interpreted as 0.2 = small; 0.6 = medium; and 0.8 = large. Phy. activity = physical activity. hrs = hours. SenseWear® change scores reflected the difference between the given assessment time-point and the values recorded at week 0 baseline. Interpretation of the direction of the adjusted mean difference and effect size depends on the outcome: positive values are in favour of PARO for daytime awake, and nighttime lying down and sleep; negative values are in favour of PARO for daytime step count, physical activity, lying down and sleep, and nighttime step count, physical activity, and awake.

**There is a significant overall group effect at the level of $p<0.05$. Bolded values indicate statistically significant results at the level of $p<0.05$.*

Table 3. Mean scores and standard deviations for SenseWear® outcomes for PARO, plush toy, and usual care groups at each assessment time-point

	Baseline	Week 5	Week 10	Week 15
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
SenseWear® daytime				
Step count, *n*				
PARO (*n*=67)	323.40 (949.80)	182.66 (494.40)	155.76 (484.90)	153.91 (473.02)
Plush toy (*n*=55)	149.00 (271.88)	152.40 (280.15)	159.80 (341.70)	166.60 (364.02)
Usual care (*n*=53)	385.60 (641.85)	528.81 (1198.58)	486.77 (970.98)	529.17 (1273.05)
Physical activity, hours				
PARO (*n*=67)	2.18 (2.06)	1.79 (2.04)	1.59 (2.04)	1.65 (2.00)
Plush toy (*n*=55)	1.38 (1.49)	1.40 (1.79)	1.40 (1.77)	1.37 (1.79)
Usual care (*n*=53)	2.10 (2.15)	1.86 (1.81)	1.83 (2.11)	1.77 (1.89)
Awake, hours				
PARO (*n*=67)	10.19 (2.21)	10.22 (1.94)	10.28 (2.04)	10.36 (1.73)
Plush toy (*n*=55)	10.45 (1.61)	10.46 (1.73)	10.49 (1.55)	10.24 (1.86)
Usual care (*n*=53)	10.63 (1.38)	10.64 (1.41)	10.71 (1.34)	10.51 (1.46)
Lying down, hours				
PARO (*n*=67)	2.30 (2.90)	2.16 (2.79)	2.00 (2.60)	1.97 (2.32)
Plush toy (*n*=55)	1.86 (2.27)	2.13 (2.49)	2.12 (2.11)	2.35 (2.19)
Usual care (*n*=53)	1.43 (1.51)	1.52 (1.69)	1.45 (1.58)	1.65 (1.74)
Sleep, hours				
PARO (*n*=67)	1.47 (2.09)	1.40 (1.91)	1.36 (1.93)	1.30 (1.70)
Plush toy (*n*=55)	1.12 (1.50)	1.20 (1.71)	1.22 (1.59)	1.43 (1.79)
Usual care (*n*=53)	0.98 (1.27)	1.01 (1.28)	1.01 (1.22)	1.19 (1.46)
SenseWear® nighttime				
Step count, *n*				
PARO (*n*=98)	70.88 (284.98)	25.90 (55.10)	27.98 (71.35)	28.08 (72.94)
Plush toy (*n*=95)	44.62 (103.81)	73.57 (171.24)	66.60 (182.85)	57.52 (151.98)
Usual care (*n*=87)	65.49 (130.03)	65.45 (129.35)	57.68 (121.45)	74.30 (172.63)
Physical activity, hours				
PARO (*n*=98)	0.61 (0.78)	0.53 (0.85)	0.45 (0.72)	0.50 (0.94)
Plush toy (*n*=95)	0.48 (0.61)	0.51 (0.72)	0.51 (0.77)	0.53 (0.79)
Usual care (*n*=87)	0.49 (0.56)	0.51 (0.59)	0.52 (0.80)	0.72 (1.66)
Awake, hours				
PARO (*n*=98)	4.71 (2.75)	5.02 (2.99)	5.27 (3.33)	5.48 (3.12)
Plush toy (*n*=95)	5.09 (3.44)	4.75 (3.01)	5.22 (3.09)	5.56 (2.90)
Usual care (*n*=87)	4.64 (2.70)	4.38 (2.11)	4.65 (2.52)	5.19 (2.75)
Lying down, hours				
PARO (*n*=98)	8.65 (2.56)	8.47 (2.83)	8.16 (3.11)	7.95 (2.99)
Plush toy (*n*=95)	8.37 (3.06)	8.77 (2.75)	8.34 (2.73)	8.12 (2.57)
Usual care (*n*=87)	8.58 (2.59)	8.98 (2.07)	8.65 (2.42)	8.00 (2.77)
Sleep, hours				
PARO (*n*=98)	7.05 (2.77)	6.82 (3.02)	6.53 (3.34)	6.28 (3.12)
Plush toy (*n*=95)	6.66 (3.39)	7.05 (3.01)	6.59 (3.12)	6.24 (2.96)
Usual care (*n*=87)	7.07 (2.75)	7.49 (2.13)	7.13 (2.53)	6.56 (2.75)

Table 4. Short-term and long-term effects of PARO, plush toy, and usual care on SenseWear® outcomes

	PARO vs. Plush toy			PARO vs. Usual care			Plush Toy vs. Usual care		
	Adj mean diff (95% CI)	**ES**	***p*=**	**Adj mean diff (95% CI)**	**ES**	***p*=**	**Adj mean diff (95% CI)**	**ES**	***p*=**
SenseWear® daytime									
Step count, *n*									
Week 5	-144.15 (29.63 to -317.92)		0.104	-283.95 (-11.85 to -556.06)	-0.40	**0.041**	-139.81 (71.70 to -351.31)		0.195
Week 10	-178.44 (-21.06 to -335.83)	-0.01	**0.026**	-268.81 (-27.33 to -510.29)	-0.45	**0.029**	-90.37 (96.93 to -277.67)		0.344
Week 15	-187.09 (-20.49 to -353.69)	-0.03	**0.028**	-313.06 (29.86 to -655.98)		0.074	-125.97 (186.29 to -438.22)		0.429
Physical activity, hours									
Week 5	-0.34 (0.25 to -0.94)		0.258	-0.10 (0.34 to -0.53)		0.663	0.25 (0.84 to -0.34)		0.415
Week 10	-0.54 (-0.00 to -1.08)	0.10	**0.048**	-0.27 (0.35 to -0.89)		0.397	0.27 (0.91 to -0.37)		0.404
Week 15	-0.45 (0.34 to -0.93)		0.068	-0.15 (0.43 to -0.72)		0.618	0.30 (0.84 to -0.23)		0.266
Awake, hours									
Week 5	0.02 (0.44 to -0.39)		0.917	0.02 (0.44 to -0.39)		0.915	0.00 (0.53 to -0.53)		0.998
Week 10	0.06 (0.50 to -0.38)		0.801	0.01 (0.28 to -0.25)		0.924	-0.04 (0.46 to -0.55)		0.865
Week 15	0.39 (1.07 to -0.30)		0.270	0.29 (0.67 to -0.09)		0.138	-0.10 (0.61 to -0.81)		0.785
Lying down, hours									
Week 5	-0.41 (0.25 to -1.06)		0.224	-0.24 (0.41 to -0.88)		0.477	0.17 (0.82 to -0.48)		0.606
Week 10	-0.56 (0.06 to -1.19)		0.077	-0.33 (0.14 to -0.79)		0.168	0.24 (0.88 to -0.41)		0.470
Week 15	-0.81 (0.17 to -1.80)		0.106	-0.55 (0.13 to -1.24)		0.114	0.26 (1.07 to -0.55)		0.530
Sleep, hours									
Week 5	-0.15 (0.27 to -0.57)		0.494	-0.10 (0.32 to -0.53)		0.636	0.04 (0.53 to -0.44)		0.857
Week 10	-0.21 (0.25 to -0.67)		0.368	-0.14 (0.17 to -0.44)		0.381	0.08 (0.59 to -0.44)		0.774
Week 15	-0.47 (0.19 to -1.14)		0.161	-0.37 (0.10 to -0.84)		0.121	0.10 (0.70 to -0.50)		0.734
SenseWear® nighttime									
Step count, *n*									
Week 5	-73.93 (-22.77 to -125.09)	-0.38	**0.005**	-44.93 (2.35 to -92.22)		0.063	28.99 (53.58 to 4.41)	0.05	**0.021**
Week 10	-64.88 (-16.02 to -113.74)	-0.28	**0.009**	-35.08 (18.04 to -88.21)		0.196	29.80 (27.26 to -11.67)		0.159
Week 15	-55.69 (-8.97 to -102.41)	-0.25	**0.019**	-51.60 (-0.86 to -102.34)	-0.36	**0.046**	4.09 (39.74 to -31.56)		0.822
Physical activity, hours									
Week 5	-0.11 (0.05 to -0.27)		0.181	-0.09 (0.03 to -0.21)		0.127	0.02 (0.15 to -0.12)		0.830
Week 10	-0.19 (-0.03 to -0.35)	-0.08	**0.021**	-0.19 (-0.03 to -0.35)	-0.10	**0.018**	-0.00 (0.18 to -0.19)		0.965
Week 15	-0.16 (0.04 to -0.37)		0.125	-0.34 (-0.06 to -0.61)	-0.16	**0.015**	-0.18 (0.10 to -0.45)		0.214

Awake, hours						
Week 5	0.67 (1.47 to -0.14)	0.104	0.59 (1.54 to -0.36)	0.226	-0.08 (0.72 to -0.88)	0.843
Week 10	0.44 (1.30 to -0.41)	0.306	0.57 (1.43 to -0.28)	0.191	0.13 (1.03 to -0.77)	0.781
Week 15	0.31 (1.21 to -0.58)	0.492	0.24 (1.21 to -0.73)	0.625	-0.07 (0.81 to -0.96)	0.871
Lying down, hours						
Week 5	-0.58 (0.03 to -1.18)	0.061	-0.57 (0.28 to -1.43)	0.189	0.00 (0.71 to -0.71)	0.994
Week 10	-0.46 (0.37 to -1.30)	0.277	-0.55 (0.38 to -1.49)	0.246	-0.09 (0.84 to -1.02)	0.854
Week 15	-0.45 (0.43 to -1.33)	0.314	-0.12 (0.95 to -1.18)	0.827	0.33 (1.44 to -0.78)	0.558
Sleep, hours						
Week 5	-0.63 (0.15 to -1.41)	0.115	-0.65 (0.30 to -1.59)	0.178	-0.02 (0.81 to -0.85)	0.958
Week 10	-0.46 (0.39 to -1.31)	0.287	-0.59 (0.29 to -1.47)	0.188	-0.13 (0.77 to -1.03)	0.781
Week 15	-0.36 (0.48 to -1.20)	0.398	-0.27 (0.69 to -1.23)	0.581	0.09 (0.98 to -0.80)	0.841

Adj mean diff = Adjusted mean difference. ES = effect size Cohen's d, interpreted as 0.2 = small; 0.6 = medium; and 0.8 = large.
SenseWear® change scores reflected the difference between the given assessment time-point and the values recorded at week 0 baseline. Interpretation of the direction of the adjusted mean difference and effect size depends on the outcome: positive values are in favour of PARO for daytime awake, and nighttime lying down and sleep; negative values are in favour of PARO for daytime step count, physical activity, lying down and sleep, and nighttime step count, physical activity, and awake
Bolded values indicate statistically significant results at the level of p<0.0

FIGURE LEGENDS

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

Figure 2. Trial profile

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

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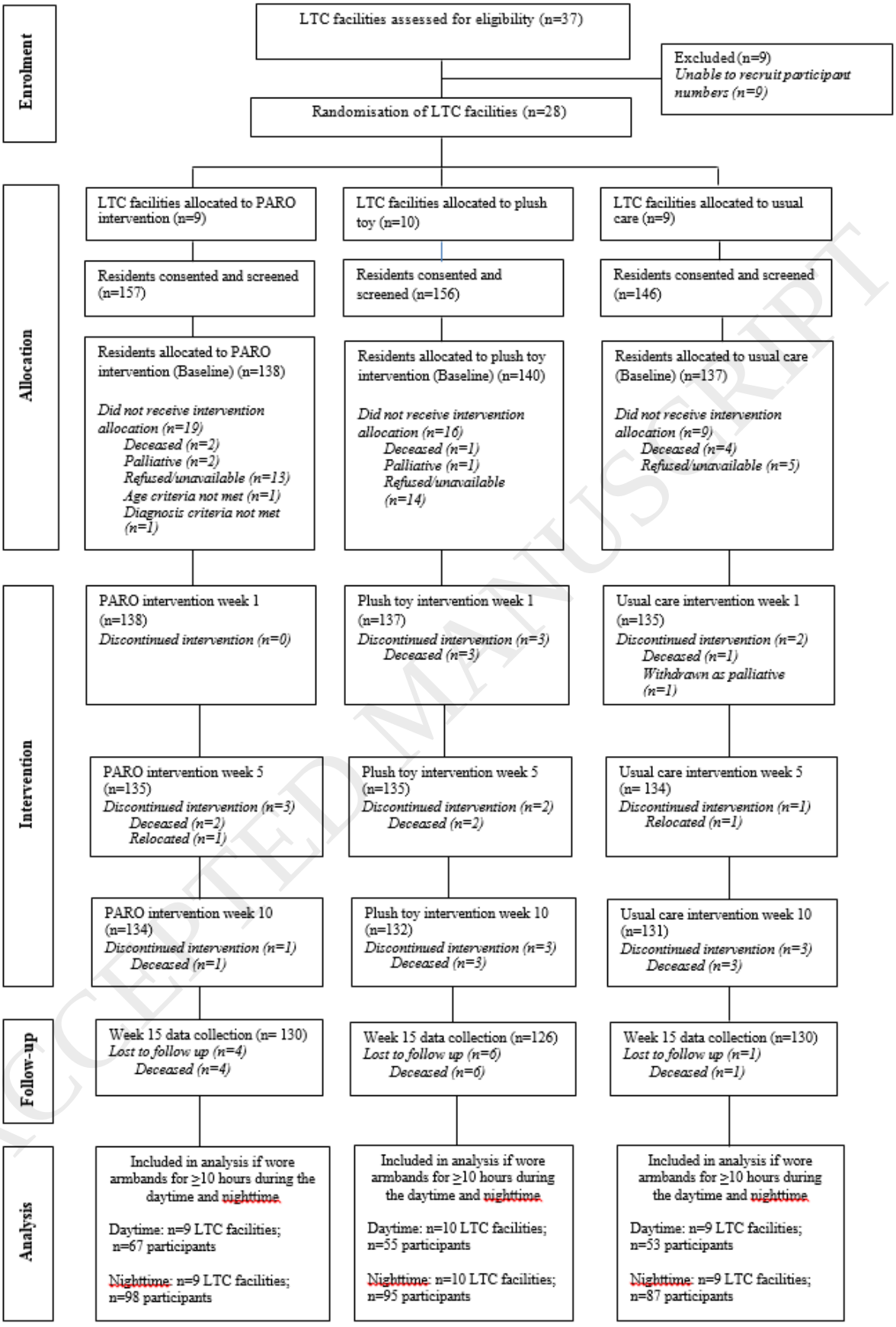

Figure 2 Trial profile