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A feasibility study of Dreampad™ on sleep, wandering and agitated behaviors in people living with dementia.

Running title: *Technology to improve sleep, wandering & agitation*

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Highlights

- DreamPad™ is deemed acceptable & feasible for use by people living with dementia.
- Evidence of Dreampad™ effect on sleep, wandering & agitation yet to be established.
- Use of wearable actigraph in research for people with dementia remains challenging.

A feasibility study of Dreampad™ on sleep, wandering and agitated behaviors in people living with dementia.

Running title: *Technology to improve sleep, wandering & agitation in PWD*

Abstract

Background: People living with dementia experience fragmented sleep-wake cycles. Their sleep patterns are shorter, lighter and easily disturbed. Disturbed sleep can lead to behaviors such as wandering and agitation, placing the person at risk of harm and increasing burden of care and pharmaceutical treatment costs.

Methods: This feasibility study examined the acceptability, efficacy and implementation and practicality of Dreampad™, a sleeping device, on sleep disturbance and wandering and agitated behaviors. Four nursing home residents (2 males and 2 females; mean age=89.8 years (*SD*=7.2); mean MMSE scores=9.3 (*SD*=8.7)) used Dreampad™ daily over 4-weeks when they slept. Agitation was assessed before and after the intervention using the Cohen-Mansfield Agitation Inventory - Short Form. Wandering and sleeping patterns were assessed using a wearable actigraphy device over 24 hours at baseline and every week during the intervention.

Results: Dreampad™ was deemed acceptable and feasible for use with people living with dementia by family and care staff. No support for Dreampad™ in improving sleep or behaviors of agitation and wandering was found. Challenges in using the wearable actigraphy device are reported.

Conclusion: Attention is needed to ensure consistent use of Dreampad™ by people living with dementia and their wear adherence of the actigraphy device. Further rigorous research is warranted to address reported limitations in intervention and data collection processes and measurements and can be guided by the study outcomes.

Keywords: Dreampad™, technology, sleep, agitation, wandering, people living with dementia

1. Introduction

Globally, an estimated 50 million people live with dementia, and this number is expected to increase to 131.5 million by 2050 (1). Dementia is one of the top ten leading contributors to disability in people aged 60 years and over, with a rising worldwide cost of US$818 billion in 2015 to an estimated US$2 trillion by 2030 (2). In Australia, prevalence estimates indicate that over 60 per cent of the current population residing in long-term care facilities have dementia (3), and this number is predicted to increase in the coming years. Of these, over one half will display behavioral and psychological symptoms of dementia (BPSD) (4).

Dementia is a clinical syndrome characterized by deteriorations in cognitive, neuropsychiatric and functional skills. Sleep disturbances are common in this population (5). There are well-recognized reports of changes to the sleeping patterns of people living with dementia over and above the typical age-related sleep disturbances (6-8). Besides experiencing sleep which is shorter, lighter and more easily disturbed (6), people living with dementia also have more fragmented sleep-wake cycles, with more sleep occurring during the day and less at night (9), than healthy older people.

Further to alterations in the circadian regulation of sleep and changes in the duration and maintenance of sleep, dementia is linked to a sleep-wake disorder emerging in the late afternoon or evening and is known as *Sundowning*. The severity of cognitive impairment is an important predisposing factor in the development of the symptoms of *Sundowning* (10). *Sundowning* in people living with dementia is defined as increased arousal or impairment characterized by disruptive behaviors such as wandering, agitation, incoherent vocalisation, confusion and disorientation in the late afternoon, evening or at night (11-13). Around 10% to 25% of people living in aged care facilities exhibit signs of *Sundowning* (14). Furthermore,

dementia-related wandering and agitation are common yet distinct behaviors where wandering is considered as a *"locomotion behavior having a frequent, repetitive, temporally-disordered and/or spatially-disoriented nature that is manifested in lapping, random and/or pacing patterns, some of which are associated with eloping, eloping attempts or getting lost unless accompanied*" (15). In contrast, agitation is connected to feelings of tension and unsettledness conveyed via actions and movements but not limited to locomotion (15). These behaviors (i.e. *Sundowning*, wandering and agitation) are difficult to manage and increase the burden of care.

Sleep disturbances have been identified as significant predictors of wandering behaviors (16) and instrumental in the rapid decline in cognitive functioning (17). In more severe cases of a fragmented sleep-wake cycle, people living with dementia have been reported to demonstrate social dysfunction as well as agitated and wandering behaviors as a standard part of their daily routine (18). In residential aged care facilities (RACFs), wandering places the person at risk for falls, increased exposure to environmental hazards such as wet floors, and harmful interactions with other residents. Sustained injuries can occur as a result of the provocation of other residents when the person wanders into others 'personal space' (19).

Effective strategies to improve sleep in people living with dementia and particularly in those who are living in RACFs are needed. However, to date, there have been limited options available apart from pharmacological treatment. A literature review of sleep in residential aged care reported the limited benefits and concerning side effects in the pharmacological treatment of sleep disturbances (20). The review also indicated that although there is promising support for psychosocial interventions such as exercise, music therapy, light therapy, aromatherapy, cognitive behavioral therapy, acupuncture, yi-gan san, valerian, melatonin and ramelteon; outcomes and protocols have been inconsistent. Further research is required to identify optimal

treatments with feasibility and pilot testing, followed by rigorous testing to verify beneficial outcomes.

Insert Figure 1.

1.1 Dreampad™

Dreampad™ is a sleeping device in the form of a customised, removable, washable, quilted cover, which is placed over a pillow that connects to a music player (e.g. MP3 or smart device) directly or via Bluetooth. Developed in the United States of America, Dreampad™ delivers bone-conducted, low frequency-rich music through a gentle, calming vibration, which is carried internally by the cranium to the cochlea, that only the user can hear (refer to Figure 1). Human bones are natural conductors. When a person speaks, the vibration caused by his/her voice is carried by the bone to the inner ear. According to its developer (21), the *Intrasound Technology*™, embedded in Dreampad™, replicates this natural process by using electromechanical transducers to convert the properties of sound to gentle vibration that is audible only to the user. When a user's head is in contact with Dreampad™, the vibration is carried to the middle and inner ear, which is the home of the cochlear/vestibular apparatus, which governs one's ability to hear and filter out unwanted noise (related to auditory hypersensitivity). It is also an area that is connected to the parasympathetic branch of the nervous system, which facilitates a relaxation response through the vagus nerve. It is believed that physiological and cognitive processes are slowed down due to an increase in the parasympathetic nervous system activity induced by the vibrations (22). Hence, the use of Dreampad™ brings about a relaxation response from the body and mind which has been aptly described by the developer as a "massage to the nervous system'" to reduce stress, improve sleep (i.e. falling and staying asleep), and decrease audio hypersensitivity (21).

Users can listen to their preferred music; however, Dreampad™ recommends and provides a list of pre-selected music designed to emphasize frequencies of the auditory spectrum most conducive for relaxation and sleep. Dreampad™ music, which consists of nature sounds, instrumental and classical music with no vocals, is available either on a pre-loaded MP3 player or can be downloaded via the Dreampad™ sleep supplication on both android and apple platforms (21). While sound volume can be adjusted to the preference of users, Dreampad™ works differently to conventional speakers in that music travels through vibrational soundwaves, which resonate through the pillow, rather than airwaves.

The limited research to date on the use of Dreampad™ has shown promising results (23) in improving sleep, behaviors, attention and quality of life in children with Attention Deficit Hyperactivity Disorder (ADHD) and the device was deemed acceptable and feasible for use by parents (24, 25). Dreampad™ was also found to reduce night-time awakening when compared to other sleep interventions such as meditation and sleep hygiene in people aged 25 to 65 year with self-reported poor sleep (26) and improve sleep quality in people with insomnia (27). However, there is no published study examining the use of Dreampad™ with people living with dementia. This project expands existing research on Dreampad™ and aims to determine the feasibility of using Dreampad™ to improve sleep, wandering and agitated behaviors in people living with dementia in RACFs.

2. Materials and Methods

2.1 Design & Setting

A mixed-methods approach involving (a) data on sleeping patterns, wandering and agitated behaviors of people living with dementia, assessed before and after the Dreampad™

intervention, as well as (b) post-intervention semi-structured interviews were used to determine the feasibility of using Dreampad™.

Residential aged care facilities were eligible for inclusion if they were Australian government approved and accredited within a 60kms radius of the Brisbane central business district and provided care for people living with dementia. The two RACFs from the same aged care organization where this study took place were known to the researchers, and their care director expressed an interest to be involved in this study. Ethics approval for this study was received from *(blinded for review)* (#2016/225), and approval was obtained from individual facility managers.

2.2 Participants

Residents who had: (a) no auditory impairments; (b) a diagnosis of dementia or a Mini-Mental State Examination (MMSE) score of 24 or less that was indicative of mild dementia (28); and (c) a recent history reported by care staff and/or family of sleep disturbance and wandering and agitated behaviors were recruited for this study. A senior staff member from each participating RACF assisted with recruitment by identifying potential participants, who met the inclusion criteria and providing them and their families with informed consent materials. When interest to participate in the study was indicated, a member of the research team then met with the person with dementia and his/her family to discuss the study, answer questions and demonstrate the use of Dreampad™ before seeking their signed informed consent.

With four available Dreampad™, only a total of four residents aged 65 years and over (i.e. three from one RACF and one from a second RACF) were identified, approached and successfully recruited while they continued their routine pharmaceutical treatments throughout

the study. All participants, if capable as indicated by the RACFs, or their next-of-kin provided written informed consent at the time of enrolment into the study. A family member who visited regularly or a care staff member who had regular contact for each participant was also recruited. Family member and care staff provided written, informed consent for their participation.

2.3 Intervention

Participants were asked to use Dreampad™ daily over a 4-week intervention period when they slept during the day and at night. Previous studies examining the effect of Dreampad™ on sleep had an intervention period ranging from 2 to 4 weeks (24, 26, 27). However, as no study has been conducted with people living with dementia, a conservative approach of a 4-week intervention was adopted in this study to ensure the feasibility of using Dreampad™ to improve sleep, wandering and agitated behaviors were adequately assessed.

Care staff placed Dreampad™ over each participants' usual pillow together with a protective waterproof pillowcase over it that was washed and replaced with a substitute backup when soiled. Regardless of when sleep occurs, the same playlist of five Dreampad™ music, set on a repeating mode for the recommended 2 hours of playing, was delivered via an MP3 device by care staff while participants slept. If participants indicated their refusal to use Dreampad™ for any reason (e.g. annoyance with the music) when sleeping, the MP3 device was removed with an attempt to use it again at the participants' next sleep. Besides facilitating the use of Dreampad™ by care staff that included the completion of an intervention checklist, a research assistant visited participating RACFs weekly to check and encourage usage as well as to address any usage issues raised by participants and care staff.

2.4 Data Collection

Using an adapted version of the Bowen Feasibility Framework (29), Dreampad™ was examined in terms of its acceptability, efficacy as well as implementation and practicality as reflected in Table 1. Different sources of data were used to present triangulated information to enhance the credibility and robustness of findings (30).

Insert Table 1.

2.4.1 Demographic, Sleep, Wandering & Agitation

Participants' demographic data, which included age, gender, type of dementia and length of time in residential care, were collected at baseline.

Insert Figure 2.

An actigraph called SenseWear® Professional 8.0 activity armband (Temple Healthcare, BodyMedia, Inc.) (refer to Figure 2) was placed every Tuesday on each participant for one 24-hour period at Week 0 (i.e. baseline – one week before the start of the Dreampad™ intervention) and once a week during each of the 4-week intervention periods totalling 120 hours per participant. Participants were asked to wear the armband continuously for 24 hours, removing only for bathing. The armband was placed and removed from participants by a research assistant. However, care staff were also trained on how to place the armband on participants if it was removed. SenseWear® is a slim, nonintrusive armband. Several sensors are incorporated into the device which is worn on the back of the upper right arm over the tricep muscle and held in place by a Velcro armband. Accelerometry is measured using a two-axis micro-electronic mechanical sensor, and the device has a built-in algorithm that can identify the physical activity, sleep and wakefulness based on arm movement (31). SenseWear® was used to assess wandering (i.e. step count) as well as sleep type (i.e. non-Rapid Eye Movement [REM] sleep), deep (i.e. from non-REM to REM sleep), and very deep

sleep (i.e. REM sleep)) and duration of participants. SenseWear® has been used in other studies of similar duration (i.e. 24 hours) with people living with dementia (32, 33).

Care staff were asked to review each participant's state of agitation over the previous fortnight using the Cohen-Mansfield Agitation Inventory-Short Form (CMAI-SF) (34) before (i.e. baseline) and after the end of the intervention. The CMAI-SF has established reliability and validity and uses a 5-point scale to indicate participants displayed agitated behaviors during the previous 2 weeks. A total score ranges from 14 to 70, with higher scores indicating greater levels of agitation.

2.4.2 Interviews

Semi-structured interviews were conducted at the facility within four days of the end of the intervention to seek care staff and family's perceptions of the feasibility of Dreampad™ and its effect on participant's sleeping patterns and the behaviors of wandering and agitation. Interview questions included: *"Tell me your initial perceptions of the Dreampad™? Did these perceptions change at any time after residents started using the Dreampad™?"*; *"Did you notice any improvement or decline in residents' sleep patterns and behaviors of wandering or agitation?"*; *"What benefits/limitations do you see of the Dreampad™? Why? Tell me more about that."*; *"Do you have any concerns about the use of the Dreampad™? What are these concerns?"*; *"The Dreampad™ costs $530. What are your perceptions about the cost of the Dreampad™? "*; and *"Should facilities purchase Dreampad™? Could families be asked to contribute to the cost?"*. All interviews were digitally recorded and transcribed before analysis.

2.4.3 Intervention Checklist & Research Team Observation Notes

Each evening during the 4-week intervention period, care staff were also asked to indicate on a checklist whether the participant has gone to bed using the Dreampad™ and to note any sleep-related behaviors or concerns and the known or possible reasons for these issues (refer to Table 2). A record of technical difficulties (i.e. type and frequency) and the steps taken to address them, if any, were kept. Also, observation notes on issues that may have impacted on the intervention and influenced the experience of participants and perceptions of family and staff were recorded.

Insert Table 2.

2.5 Data Analysis

All data collected were analyzed using IBM SPSS Statistics for Windows Version 24.0 (Armonk, NY: IBM Corp.). Besides descriptive statistics, paired sample t-tests were conducted to determine pre- and post- intervention outcomes with a significant alpha level set at $p<.05$. Thematic analysis was used to explore the qualitative interview to reveal key issues of importance (35). The process of analysis involved two members of the research team first reading the interview transcripts and conducting a line-by-line analysis to compare with and between transcripts. Similar and dissimilar key issues were identified, followed by a clustering of key issues. Finally, transcripts were re-read to check the credibility of key issues (35).

3. Results

Residents, family and care staff participants served as the main identifiers of feasibility. **A** convenience sample of care staff (n=3; *all female enrolled/registered nurses*) engaged in the care of the participants and a family member (n=1; *wife*) who regularly visited her care recipient were interviewed, which ranged from only 6.0 to 12.1 minutes (M=8.5), while four residents participated in the use of Dreampad™. As reflected in Table 3, the mean age of the four

participants (i.e. 2 males and 2 females) was 89.8 years (*SD*=7.2) with an average MMSE score of 9.3 (*SD*=8.7). Three participants lived in a secure dementia unit with either vascular dementia (n=2) or Alzheimer's disease (n=1). The remaining participant resided in a low care area and had mild to moderate dementia, as reflected by her MMSE score.

Insert Table 3.

3.1 Feasibility Indicators

3.1.1 Acceptability

Both family and care staff accepted the use of DreamPad™, and they welcomed the trial of DreamPad™ as they wanted to improve opportunities for participants to enhance sleep and reduce wandering and agitation. Family and care staff found the cost of DreamPad™ (i.e. $530 inclusive of the MP3 player) to be of a *'fair price'* and could be covered by either the family or nursing home if it was found to be effective in improving sleep, wandering and agitated behaviors. No concerns were reported on the use of DreamPad™ at the end of the intervention period. While the use of DreamPad™ was reported to be *'pretty easy and straightforward'*, perceptions of the use of DreamPad™, including SenseWear®, by residents and the associated change in their sleep, wandering and agitated behaviors were mixed (refer to Table 4). Generally, care staff interviewed believed that the effects of DreamPad™ would vary among residents and that the device was less likely suited for those highly agitated or with severe cognitive impairment.

Insert Table 4.

3.1.2 Efficacy

Paired sample t-test revealed no significant difference in CMAI-SF scores (p=.47) before (M=28.3; SD=2.9) and after the intervention (M=31.3; SD=8.3). Table 3 reflects the CMAI-SF

scores for each participant pre- and post DreamPad™ intervention at baseline and across the 4-week intervention period. Additionally, on average, participants only wore SenseWear® for a total of 74.1hrs (*SD*=28.5), ranging from 34.3 to 96.1 hours, out of a maximum of 120 hours. This reflects that the total average wear adherence of SenseWear® by participants was 61.7% (*SD*=23.7). A further detailed breakdown of each participant's use of Dreampad™ and SenseWear® is reported in Table 3. The significantly large amount of missing data (i.e. step count and sleep type and duration), due to non-wear adherence of SenseWear® by all participants, as reported in Tables 3 and 4, did not permit any meaningful analysis or interpretation of the recorded data. Therefore, participants' step count trends over 24 hours, as recorded by SenseWear®, during baseline and the 4-week intervention period are presented in Figure 3. Similarly, participants' sleep type and duration trends during baseline and the 4-week intervention period are presented in Figure 4. Trends of step count and sleep type and duration are varied between participants.

Insert Figures 3 & 4.

3.1.3 Implementation & Practicality

Basic training, together with an instruction and troubleshooting guide, were provided for care staff in the operation of the Dreampad™ and the MP3 player as well as the charging of the MP3 player (i.e. 10 hours playtime per full charge) and SenseWear® (i.e. 4 days of recording per full charge). There were no reported challenges during training or difficulties in the operation and charging of Dreampad™, the MP3 player and SenseWear® during the intervention period.

Overall, participants recorded an average usage adherence of Dreampad™ of 82.1% (*SD*=8.2) usage of Dreampad™, ranging from 21 to 25 days use out of 28 days (*M*=23; *SD*=2.3), as

indicated on the intervention checklist. Reasons for non-usage of Dreampad™ by participants as indicated on the intervention checklist included irritation with the sound/music (n=5), not sleeping due to being unwell (n=1) and unable to locate the MP3 player (n=1). It was noted that 65% of Dreampad™ usage omissions (i.e. 13 out of 20 days across all participants), reflected on the intervention checklist, were not accompanied by an explanation. It was unclear if these omissions were due to usage refusal by participants, usage oversight by care staff or an uncharged MP3 player.

4. Discussion

This study aimed to assess the feasibility of using Dreampad™ to improve sleep, wandering and agitated behaviors in people living with dementia in RACFs. Findings of our study found that family and care staff deemed Dreampad™ to be acceptable for use with people living with dementia and they may successfully implement Dreampad™ for people with dementia in RACFs. However, there is no established support that sleep, wandering, and agitated behaviors of people living with dementia are improved via the use of Dreampad™.

In this study, the use and cost of Dreampad™ were found to be acceptable to family and care staff, and it was found to be generally feasible for use by people living with dementia. The overall average usage adherence of Dreampad™ by people living with dementia was relatively high (i.e. over 80%). Although two out of the four people living with dementia who took part in this study did, at times, express their irritation with the music heard through their pillow, they continued with the use of Dreampad™ during the intervention. Nevertheless, this may suggest the possibility of some people living with dementia who may resist the use of DreamPad™. A larger sample study will help us to understand this issue.

This feasibility study did not demonstrate evidence to support the use of DreamPad™ to improve sleep in people living with dementia. This preliminary result is not in concordance with the promising effect on sleep found in children with ADHD; people aged 25 to 65 year with self-reported poor sleep (26), and patients with insomnia (27). Furthermore, the influence of DreamPad™ on behaviors of agitation and wandering in people with dementia remains unclear due to the mixed results found in this study. These outcomes may be, in part, be explained by the intervention and data collection processes as well as the measurements used in this study.

Several limitations need to be considered when reading the efficacy results from this feasibility study. First, challenges were experienced with the use of SenseWear® to assess wandering (i.e. step count) as well as sleep type and duration of participants in this study. Similar to other studies involving people living with dementia (32, 33) where some did not tolerate wearing SenseWear®, participants in this study exhibit similar responses where they either refused to wear or removed the device with reported agitation in one participant by care staff. This is reflected by the poor overall average wear adherence of SenseWear® by participants (i.e. slight over 60%). Consequently, data on step count and sleep type and duration were either incomplete or missing, and it proscribes any meaningful analysis or interpretation of the limited data captured via SenseWear®. Additionally, there were concerns with the reliability of the recorded data. For example, SenseWear® has been shown to under- and over-estimate step count (36). There are concerns about the adequacy of capturing data over 24 hours per week as was undertaken in this feasibility study due to resource constraints when a minimum recording of 72 hours is recommended (37, 38). Therefore, the promise of sleep improvement, as well as reduction in wandering and agitation when using Dreampad™, could not be robustly ascertained. It is acknowledged that wearable activity-focused devices, such as SenseWear®,

have distinct benefits in providing an objective measure of physical activity (e.g. step count relating to wandering) as well as sleep type and duration of individuals. However, results from this feasibility study and other earlier studies (32, 33) serve to identify some of the existing issues of wearable activity-focused devices when used with people living with dementia. Future study may need to consider (a) the use of other actigraphy, with regards to wear adherence as well as modifications to the comfort, size, placement, and tolerability of wearable activity-focused technologies, or (b) the possibility of polysomnography to assess sleep over a minimum 3-day aggregate.

Second, while usage adherence of Dreampad™ by participants in this feasibility study was relatively high, observed agitation when using Dreampad™ was reported in some participants. Future larger scale studies can provide insight into the extent of this issue for people living with dementia and whether Dreampad™ will further intensify agitation for those who are already moderately to highly agitated or with severe cognitive impairment. Third, the role of care staff in the usage adherence of Dreampad™ by people living with dementia, particularly for those who refused Dreampad™ together with the frequency and associated reasons need to be documented in future studies. Lastly, medications taken by participants may have influenced their sleep and behaviours. The lack of a medication audit did not permit any further investigation of the influence of medications on the effects of the Dreampad™ intervention, and this should be considered in future studies.

Overall, the study limitations include (a) the small sample size; (b) poor wear adherence of the SenseWear® device by participants leading to significant missing or incomplete data; (c) the accuracy of step count recordings using SenseWear®; (d) the adequacy of using SenseWear® and only for 24 hours per week; (e) a lack of insight into what participants were doing over the

24 hours when the data was objectively assessed as well as during the intervention period, for example, participation in exercises and activities or being unwell and recuperating in bed can skew the data captured; (f) the influence of medications; and (g) possible inconsistent or irregular use of Dreampad™ during the intervention period, which may be possibly due to care staff oversight or different care staff on duty when participants were sleeping during the day or at night.

5. Conclusions

Quality sleep is essential for health and wellbeing, and when individuals do not get adequate sleep, this can result in agitation and restlessness. To improve the quality of life for people living with dementia and their carers, safe, effective and acceptable strategies to improve sleep for people living with dementia are needed. This study assessed the feasibility of a new technological option (i.e. Dreampad™) on sleep and behaviors of agitation and wandering in people living with dementia that may indirectly improve outcomes for their carers.

The use and cost of Dreampad™ appear acceptable to family and care staff. The device is also feasible for use by people living with dementia and can potentially be incorporated into daily use if its efficacy is established. Study outcomes have yet to demonstrate any support for Dreampad™ as a promising non-pharmacological intervention to improve sleep or reduce behaviors of agitation and wandering in people living with dementia due to intervention and data collection processes as well as the limitations of the measurements reported in this feasibility study. There continue to be challenges in using wearable actigraph technologies with people living dementia. Attention should be placed on the role of care staff in the consistent and regular use of Dreampad™ as well as data collection, including the wear adherence of activity-focused devices in future research endeavors. This feasibility study can be used to

guide a more rigorous study of Dreampad™ in people living with dementia to improve their sleep and behaviors of agitation and wandering.

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* http://www.icmje.org/recommendations/

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Table 1. Feasibility framework (focus areas, questions, and data sources)

Focus areas	Questions	Data sources
Acceptability	Is Dreampad™ deemed to be suitable for use by participants in residential aged care facilities?	• Interviews with family & staff • Research team observation notes & reflections
Efficacy	Does Dreampad™ show promise of improving sleep, wandering and agitated behaviors in participants?	• SenseWear® • Cohen-Mansfield Agitation Inventory – Short Form
Implementation, and practicality	Can Dreampad™ be successfully implemented with participants?	• Intervention checklist • Research team observation notes & reflections

Table 2. SenseWear® and Dreampad™ usage checklist

Participant ID: _____

Completed by: _____

Start Date: _____

*(*SenseWear® *[SW] to be worn for 24hrs per week – Tues 12pm to Wed 12pm)*

Week 1 Date:	Mon	Dreampad™ used: Yes/No Time on:	*Notes:*
	Tues	SenseWear® used: Yes/No Time on: Dreampad™ used: Yes/No Time on:	*Notes:*
	Wed	SenseWear® (SW) removed: Yes/No Time off: Data downloaded and SW charged: Yes/No Dreampad™ used: Yes/No Time on:	*Notes:*
	Thurs	Dreampad™ used: Yes/No Time on:	*Notes:*
	Fri	Dreampad™ used: Yes/No Time on:	*Notes:*
	Sat	Dreampad™ used: Yes/No Time on:	*Notes:*
	Sun	Dreampad™ used: Yes/No Time on:	*Notes:*

Table 3. Participants' demographic characteristics, Dreampad™ usage and CMAI-SF scores (n=4)

	Participant A[^]	Participant B[^]	Participant C[#]	Participant D[^]
Age (years)	99	87	82	91
Gender	Female	Male	Male	Female
Time in facility (years)	4 to 6	1 to 3	1 to 3	1 to 3
Type of Dementia	Mild-Moderate Dementia	Alzheimer's Disease	Vascular Dementia	Vascular Dementia
MMSE	21	9	7	0
Dreampad™ Usage (days out of 28)	21	21	25	25
SenseWear® Usage (hours)*	18.6	14.5	19.2	6.9
Baseline	15	14.3	23.8	22.9
Week 1	23.9	23.8	19.4	2.4
Week 2	13.2	23.7	16.8	1.4
Week 3	17.1	10.9	23.8	1.7
Week 4	24	0	12.3	5.9
CMAI-SF				
Pre	25	28	32	28
Post	20	40	32	33

**Average 24 hours wear time across 5 weeks (i.e. baseline and weeks 1 to 4)*

[^] *Participants A, B & D were from facility one*

[#] *Participant C was from facility two*

Table 4. Summary of family and care staff perceived used of DreamPad™ and SenseWear® and change in sleep, wandering and agitated

	DreamPad™ use	SenseWear® use	Sleep, wandering & agitation
Participant A (PA)	• PA found DreamPad™ *"annoying"* and *"disturbing"* and on some occasions *"took the MP3 player out of her pillow"*.	• PA wore SenseWear® as scheduled but did attempt to remove it over the 24-hour wearing period – leading to missing data on sleep & step counts.	Care staff reported: • noticeable improvement in PA's night-time sleep and a reduction in her behaviors of wandering and agitation (as reflected in CMAI-SF scores and SenseWear® data trends). • PA slept well on the nights DreamPad™ was used. • PA was observed to be awake and sitting on her bed at night when DreamPad™ was not used and looking *"depressed"* during the day when she had inadequate sleep.
Participant B (PB)	• PB complained about DreamPad™ and *"hearing noises through his pillow"* when in bed.	• The use of SenseWear® *"exacerbated his agitation"* leading to PB's refusal to wear it – leading to missing data on sleep & step counts particularly in Week 4.	Care staff reported: • no observable differences in PA's sleep, wandering or agitation (as reflected in CMAI-SF scores and SenseWear® data trends).

Participant C (PC)	• PC was unwell with a cold prior to the start of the intervention which affected his mobility, sleep and use of DreamPad™ at baseline and in Week 1 (i.e. constant coughing fits disrupting sleep) – subsequent sleep improvement trend may be due to poor sleep at baseline due to sickness.	• PC wore SenseWear® as scheduled but did attempt to remove it at times – leading to missing data on sleep & step counts.	Wife reported: • no observable differences in wandering or agitation (as reflected in CMAI-SF scores and SenseWear® data trends).
Participant D (PD)	• No problem reported with PD's use of DreamPad™.	• PD often refused to wear or removed the SenseWear® device – leading to missing data on sleep & step counts.	Care staff reported: • no observable differences in PA's sleep, wandering or agitation (as reflected in CMAI-SF scores and SenseWear® data trends).

Figure 1. Dreampad™

Figure 2. SenseWear®

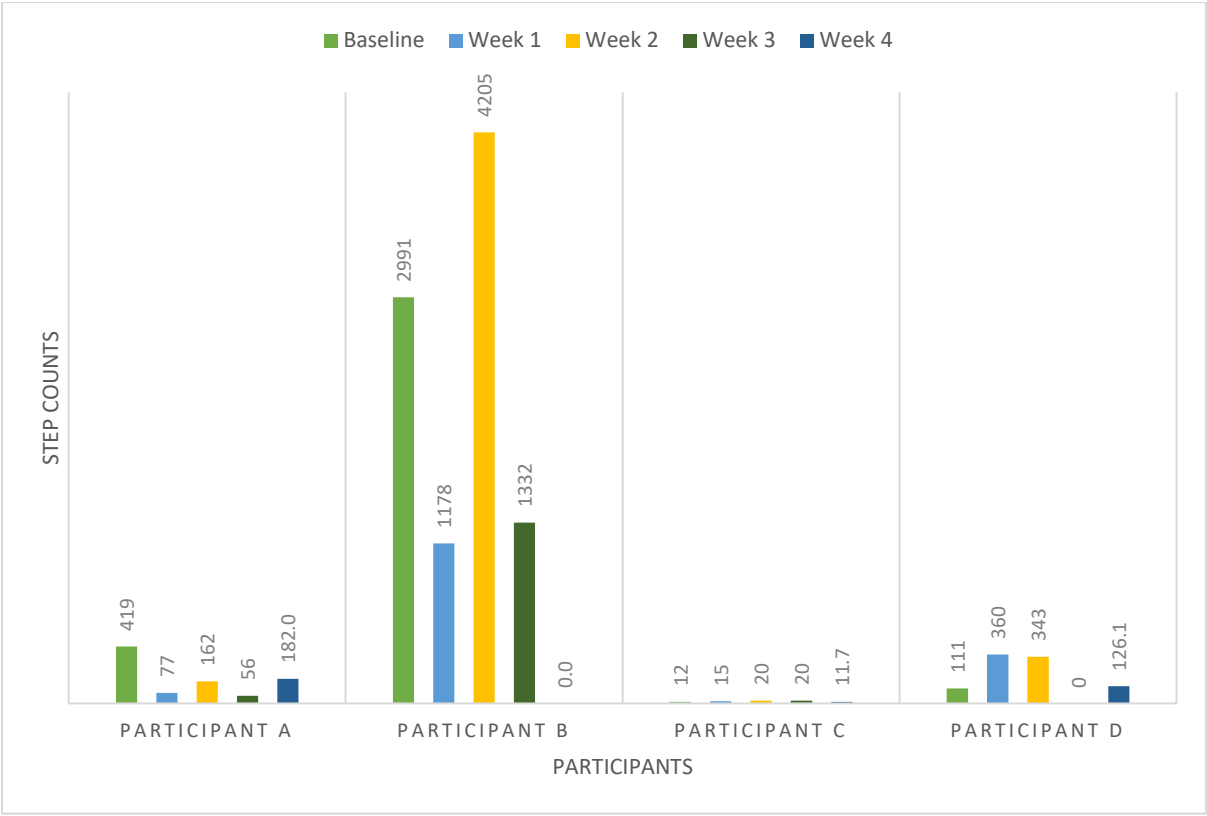

Figure 3. Participants' step count over 24 hours during baseline and weeks 1 to 4 *(standardised across wear time over a 24-hour period)*

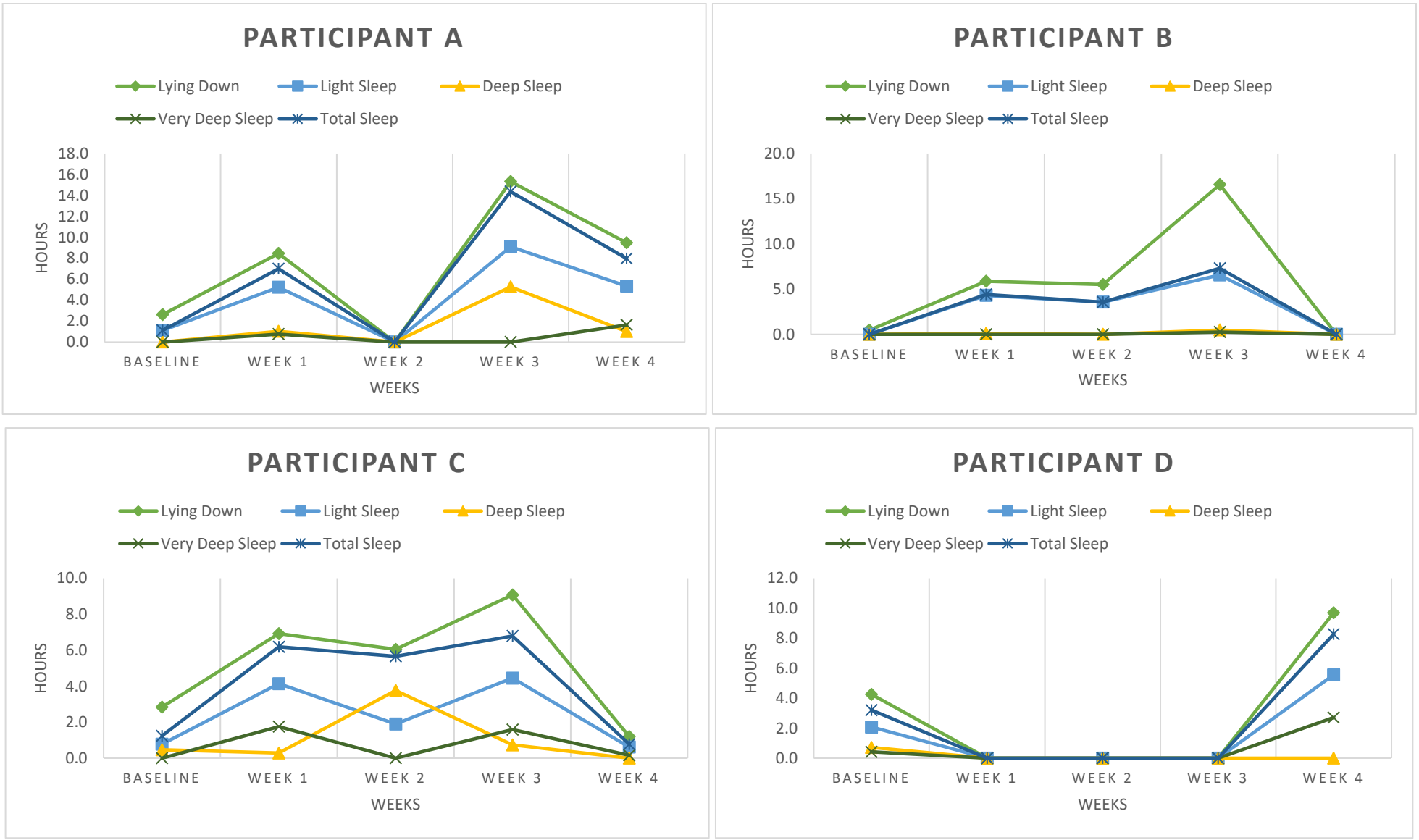

Figure 4. Participants' lying down and sleeping patterns during baseline and weeks 1 to 4 *(standardised across wear time over a 24-hour period)*