

## ORIGINAL REPORT

## EFFECTIVENESS OF A NOVEL SLEEP CLINICAL PATHWAY IN AN INPATIENT MUSCULOSKELETAL REHABILITATION COHORT: A PILOT RANDOMIZED CONTROLLED TRIAL

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**Objective:** Sleep disturbance in hospital is common. This pilot randomized controlled trial assessed a sleep clinical pathway compared with standard care in improving sleep quality, engagement in therapy and length of stay in musculoskeletal inpatient rehabilitation.

**Methods:** Participants ( $n=51$ ) were randomized to standard care ("control",  $n=29$ ) or sleep clinical pathway ("intervention",  $n=22$ ). Outcome measures included: Pittsburgh Sleep Quality Index (PSQI), Hopkins Rehabilitation Engagement Rating Scale (HRERS), Fatigue Severity Scale (FSS), Patient Satisfaction with Sleep Scale, and actigraphy. Assessment time-points were at admission and before discharge from rehabilitation.

**Results:** No significant differences were found between groups for any outcome measure. As a cohort ( $n=51$ ), there were significant improvements from admission to discharge in sleep quality (PSQI (-2.31; 95% confidence interval (95% CI) -3.33 to -1.30;  $p<0.001$ ), fatigue (FSS (-8.75; 95% CI -13.15 to -4.34;  $p<0.001$ ), engagement with therapy (HRERS-Physiotherapists (+1.37; 95% CI 0.51-3.17;  $p=0.037$ ), HRERS-Occupational Therapists (+1.84; 95% CI 0.089-2.65;  $p=0.008$ )), and satisfaction with sleep (+0.824; 95% CI 0.35-1.30;  $p=0.001$ ). Actigraphy findings were equivocal.

**Conclusion:** The sleep clinical pathway did not improve sleep quality compared with standard care. Larger studies and studies with alternate methodology such as "cluster randomization" are needed.

**Key words:** sleep; rehabilitation; clinical pathway; actigraphy; randomized controlled trial; musculoskeletal.

## LAY ABSTRACT

Sleep disturbance in hospital is common. This study examined the effectiveness of "sleep clinical pathways" to help sleep in rehabilitation ward patients after hip and knee replacements. Fifty-one patients were divided randomly into 2 groups. One group received usual care, whilst the other group received care from doctors who were guided by these "pathways". The pathways prompted the doctors to look for conditions that could affect sleep and gave them suggestions on how to manage these conditions. However, the results showed that using these pathways did not improve the sleep of patients compared with the usual care control group. Sleep improved in all patients over the course of the study.

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Sleep is commonly disturbed in hospital. In rehabilitation, poor sleep can affect engagement with therapy and functional recovery, prolonging hospital stay (1). Despite this, existing guidelines provide limited information, and only address sleep-disordered breathing (2); or exclude sleep (3).

Common sleep disorders include insomnia (difficulty initiating or maintaining sleep), hypersomnia (excessive

daytime sleepiness), sleep apnoea and circadian rhythm sleep disorders (4). Other factors that affect sleep include psychological (e.g. anxiety), medications (e.g. benzodiazepines), neurological disorders (e.g. stroke) and other sleep disorders (e.g. periodic leg movements) (5–7). Patients with musculoskeletal conditions may have pain from surgery and from arthritic joints. Sleep deprivation further decreases pain threshold, thus increasing pain (8). Hip precautions restrict sleep positions, worsening discomfort. The hospital environment also disrupts sleep, due to factors such as noise, light, frequent intervention, co-habitation with other patients, imposed schedules, deprivation of normal sleep habit and an unfamiliar bedroom environment.

Poor sleep can spiral into a vicious cycle and be associated with negative thoughts and emotions, such as the fear of not sleeping. Poor sleepers may spend more time in bed, have irregular sleep-wake schedules and further fragmented sleep. Napping can worsen night-time sleep (9). Functional recovery for up to 3 months is poorer in orthopaedic rehabilitation inpatients ( $n=245$ ) with more daytime sleep (10).

Treatment of insomnia can be divided into pharmacological and non-pharmacological interventions (e.g. cognitive behavioural therapy (CBT), sleep restriction, stimulus control, sleep hygiene) (4). Pharmacological interventions remain the mainstay treatment despite evidence suggesting that: (i) non-pharmacological options (such as CBT) are superior (11); and (ii) the risks (falls) in older patients outweigh the benefits (12). Furthermore, a study in which 40% of rehabilitation inpatients received benzodiazepines for sleep showed no improvement in sleep according to staff and patients (13).

Clinical pathways are “standardized, evidence-based multidisciplinary management plans, which identify an appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for a homogenous patient group” (14). Current sleep pathways are restricted to diagnosis and management of obstructive sleep apnoea (15), but could be expanded within inpatient rehabilitation to improve sleep in general.

This randomized controlled trial aimed to assess the effectiveness of a sleep clinical pathway in improving sleep quality, fatigue, patient engagement in therapy and length of hospital stay in an inpatient rehabilitation musculoskeletal cohort. It was hypothesized that using the clinical pathway would improve these outcome measures more than standard care alone.

## METHODS

This study followed the Consolidated Standards of Reporting Trials (CONSORT) criteria and was approved by the Melbourne Health Human Research and Ethics Committee (HREC 2016.263).

### Participants and setting

Participants were recruited from a single Australian rehabilitation inpatient unit.

Inclusion criteria were:

- age above 18 years;
- ability and willingness to give informed consent;
- poor sleep quality ( $\geq 5$  on the Pittsburgh Sleep Quality Index after answering “no” to the initial screen “do you currently sleep well?”);
- musculoskeletal diagnosis (main reason for rehabilitation admission);
- length of stay > 1 week.

Exclusion criteria were:

- severe cognitive, communication or behavioural deficits (unable to complete questionnaires).

All consecutive patients were invited to participate by an independent researcher (JH) who sought informed consent.

### Randomization

Participants were randomized in a 1:1 ratio to control or treatment groups using stratified block randomization based on diagnosis (orthopaedic vs amputation). Treating doctors were e-mailed the names of participants in the intervention group. Therapists remained blinded.

### Assessment interviews

Assessment time points were: baseline (within 72 h of admission) (T0) and within 72 h before discharge (T1). The blinded assessor received training in assessments. Baseline assessments included clinical and sociodemographic data (age, sex, medication), self-rating of sleep at home (4-point Likert scale: very bad to very good), standardized measures (see below) and actigraphy. The treating physiotherapist (PT) and occupational therapist (OT) completed the Hopkins Rehabilitation Engagement Rating Scale (HRERS).

Assessments at T1 included all outcomes and length of inpatient stay. Identified issues and interventions used as a result of the pathway were documented (evidence of compliance).

### Intervention

The sleep clinical pathway was developed collaboratively by senior rehabilitation and sleep clinicians at the hospital, based on existing evidence and expert opinion. It consisted of 2 parts: (A) simplified pre-hospitalization sleep history; and (B) sleep optimization strategies (see Appendix I for details).

Junior doctors received orientation on the use of the clinical pathway. Sleep hygiene written educational material was sourced from the National Sleep Foundation (16). The pathway was used by the doctors once for each patient during the first week of stay.

Control patients received standard care. At the time of the study, patients were not consistently asked about their sleep and no educational materials were provided.

### Measurement

The following validated outcome measures were used:

**Pittsburgh Sleep Quality Index (PSQI).** The PSQI (17) is a 19-item reliable and validated self-report questionnaire measuring sleep disturbance in the preceding month (18). Each of the 7 components (e.g. subjective sleep quality, sleep duration) are scored from 0 to 3. Scores are summed (range 0–21); lower scores reflect better sleep and >5 indicates poor sleep quality. A 3-point change is clinically significant.

**Fatigue Severity Scale (FSS).** FSS (19) has 9 items scored on a 7-point Likert scale (1=strongly disagree to 7=strongly agree) measuring the impact of fatigue on work, family or social life. A higher score indicates more fatigue. The FSS has excellent validity and reliability (20).

**Patient Satisfaction with Sleep Scale.** Patient satisfaction with sleep was measured with the 5-point Likert Patient Satisfaction with Sleep Scale (very dissatisfied to very satisfied).

**Hopkins Rehabilitation Engagement Rating Scale (HRERS).** The HRERS is a 5-item, clinician-rated measure quantifying engagement in therapy (21). Higher scores represent greater engagement. It has good validity, internal consistency and inter-rater reliability (21). Clinicians scored patient engagement in the previous 72 working hours.

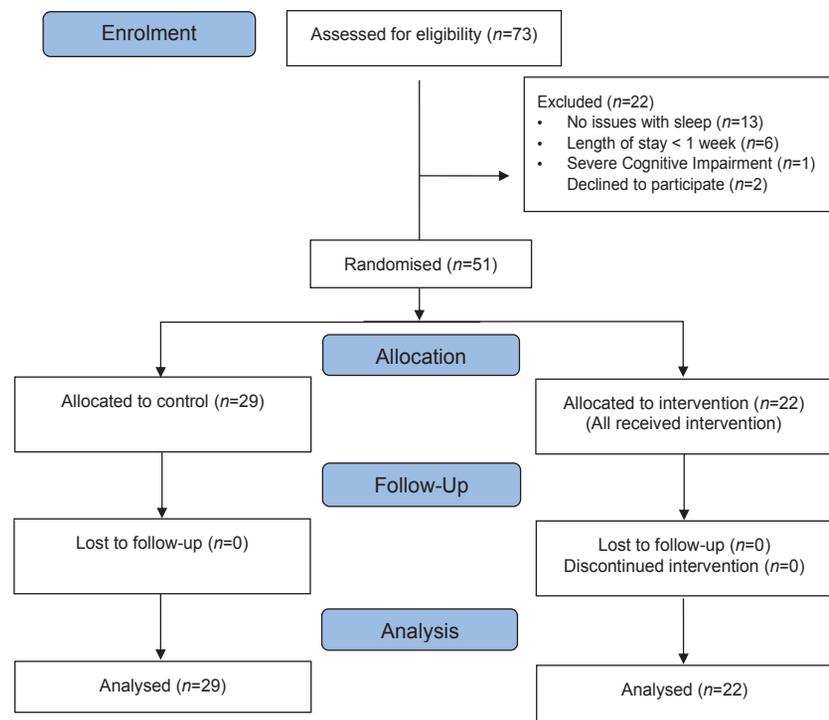
#### Actigraphy

Actigraphy provided an objective measure of sleep-wake parameters (22). This non-invasive method is based on accelerometer data that assesses movement as an analogue of sleep. The SenseWear BodyMedia Armband (BodyMedia, Inc. Pittsburgh, Pennsylvania, USA) was used. Commonly worn mid-humerus or on the wrist, these devices also record skin temperature, heat flux and galvanic skin response (23). Sleep is determined by a propriety algorithm. Devices were donned for 72 h, and doffed only for showering and hydrotherapy (not water-resistant). Actigraphy is a valid and reliable for measuring sleep quality, both in healthy people and in those with suspected sleep disorders (24). The supply of devices was limited because they were expensive; hence they were applied based on availability.

#### Statistical analysis

The primary outcome was defined as the impact of the intervention on PSQI. An overall sample of 50 participants (25 participants in each arm) was needed to provide 80% power to detect a minimal clinically significant effect size of 3 points (SD 4.57) based on analysis of covariance for PSQI from baseline (T0) to discharge (T1) (17).

Patient demographics, clinical information and sleep interventions were presented in a descriptive manner. Shapiro-Wilk test was used to determine normality of data-sets. Two-sample *t*-test was used to compare PSQI, FSS, HRERS-OT/PT and sleep satisfaction and sleep efficiency (the last 2 measures are derived from PSQI) between study arms at baseline and at follow-up, while the Mann-Whitney *U* test was used for sleep efficiency components (total sleep time, time in bed and sleep latency) derived from PSQI. Pre-post analyses were assessed using  $2 \times 2$  analysis of variance (ANOVA) for PSQI, FSS, HRERS-OT/PT, sleep satisfaction, sleep efficiency and Friedman test for total sleep time, time in bed and sleep latency. Patient satisfaction with sleep was analysed using  $\chi^2$  test. A value of  $p < 0.05$  was considered statistically significant. All data analysis (other than actigraphy data) was performed using IBM SPSS Statistics Desktop 22.0 (SPSS Inc., Chicago, IL, USA). Actigraphy data were analysed



**Fig. 1** Participants flow through the study.

using SenseWear Professional Software version 8.0.0.2903 with sampling in 1-min epochs.

## RESULTS

Of the 73 patients (90% orthopaedic, 10% amputation) admitted during the study period, 13 had no sleep issues, 7 did not meet the criteria and 2 declined to participate (reasons unknown). The remaining 51 patients consented to partici-

**Table I.** Socio-demographic characteristics of participants ( $n = 51$ )

Characteristics	Control group ( $n=29$ )	Intervention group ( $n=22$ )	<i>p</i> -value
Age, years, mean (SD)	61.7 (17.2)	63.4 (13.8)	0.434
Sex, $n$ (%)			
Male	16 (55.1)	9 (40.9)	0.234
Female	13 (44.9)	13 (59.1)	
Admission type, $n$ (%)			
Orthopaedic	26 (89.7)	20.0 (91)	0.632
Amputation	3 (10.3)	2.0 (9.0)	
Length of stay, days, median (IQR)	14.0 (11.0)	14.5 (24.3)	0.651
Medications, $n$ (%)			
Paracetamol	22 (86.2)	17 (77.2)	1.000
NSAIDS	6 (20.6)	3 (13.6)	0.714
Opioids	25 (86.2)	22 (100.0)	0.124
Steroids	4 (13.7)	1 (4.5)	0.375
Benzodiazepines	5 (17.2)	4 (18.2)	0.526
Melatonin	1 (3.4)	0	0.431
Antidepressants	4 (13.7)	2 (9.0)	0.688
Antipsychotics	1 (3.4)	1 (4.5)	1.000
Gabapentin	15 (51.7)	10 (34.4)	0.779
Thyroxine	3 (10.3)	4 (18.1)	0.447
Diuretics	0	0	0
Tricyclic antidepressants	3 (10.3)	7 (31.8)	0.079
Self-rating of sleep at home (mode)	2 (fairly good)	2 (fairly good)	1.000

IQR: interquartile range; number; SD: standard deviation; NSAIDS: non-steroidal anti-inflammatory drugs.

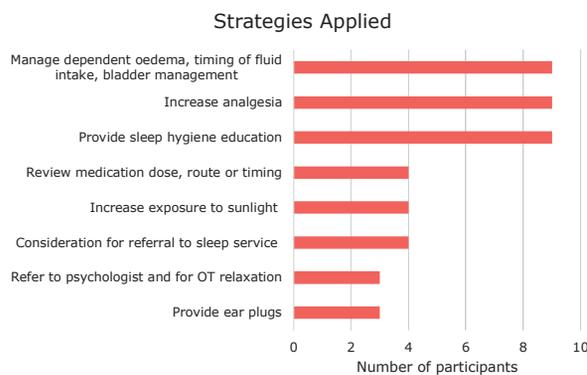


**Fig. 2.** Sleep issues identified using the clinical pathway ( $n=22$ ). \*Participants could have more than 1 issue. \*\*Pre-existing diagnosis of obstructive sleep apnoea and had a Continuous Positive Airway Pressure machine.

pate in the study and were allocated to control ( $n=29$ ) and intervention ( $n=22$ ) arms. There were no drop-outs. **Fig. 1** shows the study flow diagram.

Baseline characteristics for participants are summarized in **Table I**. The mean age of participants was 62.5 years (range 22.3–88.1 years) with a 1:1 female to male ratio. There were no statistical differences in medication use between groups. As expected, analgesics, most commonly paracetamol, opioids and gabapentin (75%, 92% and 49% of entire cohort, respectively) were widely prescribed. One patient (control group) was already on melatonin on admission, which was ceased at discharge. Nine patients were on benzodiazepines on admission; 4 ceased benzodiazepines during their stay and 3 were discharged home on benzodiazepine. Both groups rated their sleep, on average, as “fairly good” prior to admission to hospital. The baseline scores for PSQI, FSS, sleep satisfaction, and HRERS were similar between the 2 groups at T0.

Clinical pathways were completed for all participants in the intervention group. A number of issues (**Fig. 2**) affecting sleep were identified, most commonly pain, poor sleep hygiene, nocturia and environment (45%, 41%, 41%, and 36% of intervention group, respectively). Three participants had known sleep apnoea; only one actively used Continuous Positive Airway Pressure (CPAP) (1 had a broken machine, one was non-adherent). A further participant was suspected to have sleep apnoea from symptomatology, but declined



**Fig. 3.** Sleep strategies applied using the clinical pathway ( $n=22$ ).

referral to the sleep clinic. All 22 intervention-group participants had at least one issue identified: 6 had one issue; 9 had 2 issues; 6 had 3 issues; and 1 had 4 issues. All identified issues were addressed through the suggested strategies on the clinical pathway (**Fig. 3**).

At discharge from the rehabilitation ward, there were no significant differences between groups in PSQI (primary outcome measure) (**Table II**). Mean (SD) changes in PSQI for the control group was  $-2.76$  (2.54) and  $-1.72$  (4.67) points for the intervention group ( $p=0.318$ ). The control group spent statistically significantly more “time in bed” ( $+1.19$  h in bed compared with the intervention group:  $-0.43$  h in bed;  $p=0.022$ ), and self-reported more sleep (median (IQR) of  $+1.5$  (0.5–3) h vs.  $+0.5$  ( $-1.5$  to 2) h for the intervention group ( $p=0.033$ )). Actigraphy data were similar to patient-reported data, but the difference between groups was not significant ( $p>0.05$ ) (data not shown). There were no significant differences between groups for sleep latency ( $p=0.954$ ) or “sleep efficiency” ( $p=0.728$ ). The FSS scores decreased by a mean of  $-5.7$  for control (SD 16.49) and  $-12.7$  (SD 13.87) for intervention ( $p=0.115$ ), but there were no significant differences between groups. No significant differences were found in sleep satisfaction ( $p=0.854$ ) and engagement with OT ( $p=0.769$ ) or PT ( $p=0.573$ ). There was no significant difference in the median (IQR) length of inpatient rehabilitation stay between the control ( $14.0 \pm 10.5$ ) and the intervention groups ( $14.5 \pm 22.60$ ).

The proportion of patients who were either somewhat or very satisfied with their sleep increased from 31.8%

**Table II.** Summary of group sleep outcomes measures ( $n=51$ )

Scales	Control group ( $n=29$ )		Intervention group ( $n=22$ )		Mean change in scores		
	T0 (Admission)	T1 (Discharge)	T0 (Admission)	T1 (Discharge)	Control	Intervention	$p$ -values
PSQI, mean (SD)	10.9 (2.9)	8.2 (3.0)	10.5 (4.0)	8.8 (3.2)	-2.76 (2.54)	-1.72 (4.67)	0.318
FSS, mean (SD)	34.2 (16.4)	28.5 (14.5)	38.9 (14.1)	26.1 (14.9)	-5.7 (16.49)	-12.7 (13.87)	0.115
HRERS OT, mean (SD)	24.4 (3.4)	25.6 (4.5)	25.2 (3.9)	26.8 (3.8)	+1.21 (4.82)	+1.60 (4.31)	0.769
HRERS PT, mean (SD)	24.1 (5.2)	26.3 (4.9)	24.9 (3.8)	26.3 (5.0)	+2.17 (4.86)	+1.41 (4.63)	0.573
Sleep latency, min, median (IQR)	25.0 (52.5)	15.0 (20.0)	20.0 (50.0)	27.5 (35.1)	0.00 (32.5)	-2.00 (42.5)	0.954
Total sleep time, h/24h, median (IQR)	5.0 (2.25)	6.5 (1.75)	6.0 (3.25)	6.2 (1.7)	+1.50 (2.50)	+0.50 (3.63)	0.033
Time in bed, h/24h, median (IQR)	8.5 (2.5)	9.5 (2.5)	8.75 (2.5)	8.5 (1.1)	+1.00 (2.88)	0.00 (1.94)	0.022
Sleep efficiency, %, mean (SD)	68.1 (35.0)	72.8 (18.5)	73.3 (22.0)	73.5 (17.6)	+4.69 (32.47)	+0.14 (22.15)	0.728

PSQI: Pittsburgh Sleep Quality Index; FSS: Fatigue Severity Score; HRERS: Hopkins Rehabilitation Engagement Rating Scale; IQR: interquartile range;  $n$ : total number; SD: standard deviation.

to 63.6% and from 34.5% to 65.5% in the intervention and control groups, respectively. In general, 62.1% of the controls and 54.5% of the intervention patients reported an improvement in sleep satisfaction levels ( $p=0.585$ ).

As a cohort (all participants), there were significant improvements in sleep quality from baseline to discharge (PSQI decreased by 2.31 points ( $p<0.001$ )), fatigue (FSS decreased by 8.75 points ( $p<0.001$ )) and engagement in both OT and PT (OT:  $p=0.037$ , PT  $p=0.008$ ). There was a mean increase of 0.833 h slept ( $p=0.05$ ) and overall patient satisfaction with sleep increased from “2 = neither satisfied nor dissatisfied” to “3 = somewhat satisfied” ( $p=0.001$ ).

Actigraphy was well-tolerated and results were obtained for 25% of the entire cohort (5 from control, 9 from intervention). The mean nocturnal sleep recorded by actigraphy at baseline was 5.08 h, compared with the 5.68 h of self-reported sleep. At discharge from the ward, actigraphy recorded a mean of 5.04 h compared with 6.46 h of self-reported sleep. Sub-group analysis revealed that, at baseline, the control group’s actigraphy was 4.70 h compared with self-reported 4.30 h. The intervention group’s actigraphy at baseline was 5.29 h vs. 6.44 self-reported hours. At discharge, the control group’s actigraphy was 5.00 h compared with self-reported 5.80 h. The intervention group’s actigraphy at baseline was 5.07 h vs. 6.83 h self-reported.

## DISCUSSION

To our knowledge, this is the first randomized controlled trial of a sleep clinical pathway in an inpatient rehabilitation setting compared with standard care. The results showed a significant improvement in sleep quality in both intervention and control groups, suggesting that the use of a sleep clinical pathway is no more effective than standard care in improving these outcomes. However, due to the lack of comparative data, these findings should be interpreted with caution. Actigraphy results were equivocal and participants reported more sleep than was objectively measured. There were no significant baseline differences between groups, and participants were similar to other studies with an inpatient rehabilitation cohort in terms of age, sex and clinical characteristics (25, 26).

Studies involving clinical pathways and sleep typically address sleep apnoea diagnosis (15) and monitoring (27, 28). Within rehabilitation, studies have focused on sleep interventions, such as CBT, for neurological conditions, such as stroke (29) and acquired brain injury (30). With no other studies addressing sleep clinical pathways for musculoskeletal patients in rehabilitation, it has not been possible to compare our findings. Clinical pathways can support clinicians in timely and safe decision-making, as well as reduce the variability of care (31). This becomes particularly useful when there is a turn-over of staff,

which is common with junior doctors-in-training. Use of the pathway was feasible, as supported by excellent clinician compliance.

Unsurprisingly, pain and the hospital environment affected sleep, but interestingly, one of the most frequent issues reported was nocturia. The reasons for this are unclear, even accounting for age (32). Factors such as caffeine intake and reduction in physical activity leading to lower extremity fluid retention should be considered. Undiagnosed sleep apnoea or poor compliance with CPAP can also cause nocturia; however, the study had not been designed to detect these, and the single participant with poor compliance with CPAP did not have nocturia. Future studies should consider screening patients for obstructive sleep apnoea using high-resolution pulse-oximetry (33).

All participants had significantly improved sleep, which was associated with improvement in therapy engagement. However, no between-group differences were seen. This is most likely because of the bias introduced by 2 particular elements of the study: (i) bias due the same clinicians treating both control and intervention patients; (ii) raising awareness of sleep issues with all participants (through asking about sleep) may have increased engagement by the patients with treating clinicians about their sleep issues.

Other factors that may have contributed to negative findings include:

- The non-inclusion of interventions with a strong evidence-base, such as multicomponent CBT (34, 35), and sleep restriction (36) within the clinical pathway. Future clinical pathways should include CBT delivered by trained clinicians and sleep restriction.
- Clinicians were orientated to the clinical pathway, but not specifically educated about sleep issues and management strategies. Formal education should be provided to improve clinicians’ knowledge and understanding of sleep management.
- Some of the strategies may have been logistically difficult to implement, such as switching patients out of noisy environments. There should be action from hospitals to address noise.

The clinical implications of this study suggest that sole use of this clinical pathway, whilst feasible, is not recommended. Empowering patients to raise issues relating to sleep and providing education on sleep hygiene is likely to improve patient engagement and better self-management. Increasing the focus on sleep as a priority through having “sleep nurse champions” might further raise awareness. In addition, reminders from clinicians about sleep hygiene, more aggressive pain management, having education material easily available, referral to clinicians including allied health proficient in CBT, sleep restriction and stimulus control are all relevant. As the evidence-base builds for non-pharmacological interventions (34–36), they should be incorporated into best evidence-based practice.

### Study limitations

The limitations of this study included: (i) the results cannot be generalized to other rehabilitation populations, especially where sleep apnoea is common (such as in stroke populations) (37) or to traumatic brain injury, where the structural damage itself can cause insomnia (38, 39); (ii) the cohort was recruited from a single tertiary centre; (iii) data related to interventions within the control group were not collected; hence it was not possible to determine whether the control group received similar levels of interventions for sleep optimization compared with the intervention group; (iv) there was some unintended unevenness in group allocation; however, it is unlikely that this would have changed the results; (v) the follow-up duration was short; (vi) the number of patients who had actigraphy was small.

### Conclusion

Sleep disturbance in a rehabilitation hospital population is common, and affects recovery and participation. This study supports the feasibility, but not the efficacy, of a sleep clinical pathway programme in an inpatient rehabilitation unit. Further research is required to develop best practice in sleep optimization in rehabilitation patients. Studies should consider larger sample sizes, longer follow-up duration, and alternate methodology, such as cluster randomization, incorporating multiple centres, other patient cohorts (neurological) and focussing on non-pharmacological sleep strategies.

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**Appendix I.** The sleep clinical pathway

Sleep Assessment and Management Clinical Pathway

Part A

Bed time \_\_\_\_\_ am/pm

Wake time \_\_\_\_\_ am/pm

Sleeping tablets No  Yes

I would generally rate my sleep as (please circle)

Poor average excellent

How often do you wake refreshed? (please circle)

Never rarely occasionally mostly always

Have you ever been diagnosed with any of the following sleep conditions?

Sleep apnoea

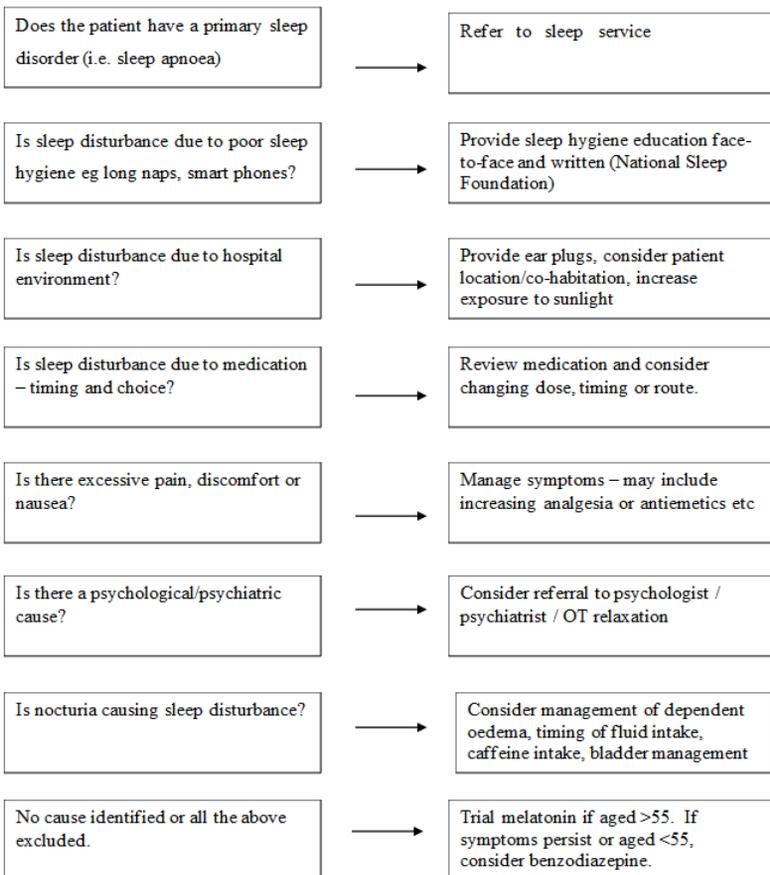
Insomnia

Restless legs syndrome

Shift work sleep disorder

Part B

Patient admitted to the ward - Implement optimal sleep management strategies. Consider the following and circle strategies used:



Melatonin referred to is slow release melatonin (Circadin 2 mg) OT: occupational therapist.