PMBC Sleep Program

PROTOCOL NUMBER: VERSION 1.0 (APRIL 2018)

ADMINSTRATIVE INFORMATION

DATA CATEGORY	INFORMATION
Scientific Title	A pilot evaluation of sleep program to improve sleep quality in male psychiatric HDU inpatients
Public Title	PMBC sleep program
Date of Registration	TBC
Primary registary and trial identification number	TBC
Date of Registration in primary registry	TBC
Secondary indentification numbers	TBC
Source of monetary or material support	Fully funded by the Sydney Local Health District ($50,000)
Primary Sponsor	Sydney Local Health District
Contact for public queries	Professor Nick Glozier 02 9515 1596, nick.glozier@sydney.edu.au
Contact for scientific queries	Professor Nick Glozier 02 9515 1596, nick.glozier@sydney.edu.au
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Inpatient male HDU psychiatric patients of all diagnoses
Intervention(s)	Ward-based initiatives and activity groups
Comparator	Routine male inpatient psychiatric HDU patients' length of stay with and without therapy; previous admissions
Inclusion criteria	Males aged 18+ years. Able to give informed written consent. Literacy in English. Inpatient at PMBC psychiatric Male High Dependency Unit (HDU).
Exclusion criteria	Current substance dependence. Severely unwell such that not able to give consent or tolerating participation in group sessions. Severe cognitive impairment or thought disorder. Not

	proficient in English. Recent transmeridian (>2 time zones) travel (within last 1 month).
Study type	Interventional; Allocation: nonrandomized; Masking: none (open label trial)
Primary Purpose	Pilot Study, Feasibility Study
Date of first enrolment	May 2018
Target sample size	N/A (Pilot study, rolling recruitment)
Recruitment status	Recruitment not yet commenced.
Primary outcomes	Actigraphic changes in sleep duration (Respironics Actigraphy data)
Key secondary outcomes	Sleep quality (weekly Visual Analogue Scale (VAS) and Pittsburgh Sleep Quality Index measured at start and end of study) Self-report duration Length of stay in HDU Use of as needed (PRN) sedatives for sleep Sleep efficiency (actigraphy) Engagement in group Autonomy Participant satisfaction
Protocol Version:	Version 1.0, April 2018
Revision Chronology	Version 1.0, April 2018: Original.
Protocol Amendment Number	0
Authors	Peter Xie BE(Hons) BCom MBBS, Melissa Aji BPsych(Hons), Nick Glozier MBBS PhD
Funding	This project is fully funded by the Sydney Local Health District (SLHD).

Roles and Responsibilities

(a) Contributorship

Nick Glozier MBBS RANZCP PhD., Viktoria Sundakov MBChB RANZCP MPH, Peter Xie BE(Hons) BCom MBBS, Abby Moran, Phil Moran, Aaron Schokman, Melissa Aji BPsych(Hons), Ben Cutler

NG is the Principal Investigator. VS, PX, MA AM, AS, BC are investigators. VS, NG, VS conceived the study. NG, VS, AM, PX, RM PM, BC initiated the study design and helped with implementation. NG, PX, AM, MA, AS provided expertise in study design and are conducting the primary analysis. All authors contributed to the development of and approved the final study protocol.

(b) Name and contact information for the trial sponsor

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(c) Sponsor and funder:

The study sponsor and study funding source had no role or authority in the design of this study and will not have any role during its execution, analyses, interpretation of the data, writing the report or decision to submit for publication.

(d) Composition, roles, and responsibilities:

N/A

TABLE OF CONTENT

BACKGROUND

Disease Background and Rationale

Disturbances of sleep are prominent and have a fundamental impact on he course of psychiatric disorders (Benca et al., 1992). Depending on the severity of illness, sleep disturbance occurs in 30 to 80% of patients with schizophrenia, and is associated with positive and negative symptoms, cognitive deficits, poorer outcome, and impaired quality of life. (Chan et al, 2017) Conversely, sleep disturbance is common to patients admitted at acute crisis to a psychiatric hospital. Approximately eight out of 10 patients report clinically significant insomnia. (Haynes et al, 2011) In fact, most medical and psychiatric disorders are associated with disturbed sleep. This is evident by the difficulty initiating and maintaining sleep in most psychiatric disorders and fragmented sleep seen in many medical disorders (Cauter et al, 1991). In addition, patients often take medications which penetrates the CNS and have the potential to alter sleep. Aside from prescription and over-the-counter medications, and herbal preparations, attention must be paid to the amount and timing of alcohol and caffeine consumption. (Jobert et al, 2012)

The assessment of sleep disturbance includes face-to-face interview, self-report questionnaire, sleep diary, actigraphy, and polysomnography (PSG). PSG is an objective method to derive quantitative sleep measures and records electroencephalogram (EEG), electro-oculo-gram (EOG) and electromyogram (EMG). (Chan et al, 2017) Compared to healthy controls, patients with schizophrenia were shown to have significantly lower Total Sleep Time (TST) and Sleep Efficiency (SE), longer Sleep Onset Latency (SOL) and Total Awake Time (TAT). (Chan et al, 2017)

The treatment of sleep disturbances has shown to reduce psychological distress and psychotic experiences including delusions and hallucinations (Freeman et al. 2015; Freeman et al., 2017; Myers et al., 2011). Presently, hypnotic pharmacotherapy remains the mainstay management for sleep disturbances in inpatient and outpatient settings. (Buysse 2013, Winkler A 2009)

Research has shown that the sleep-wake cycle is strongly linked to the environment (Czeisler et al. 1980; Rea et al. 2008) and disruptions to this cycle may result in sleep disturbances as well as negative cognitive and psychological consequences (Lane & East, 2008). Hospital environments tend to report low lighting levels which may distort the normal circadian sleep-wake rhythms. Bendetti et al. (2001) assessed an inpatient hospital setting over 2 years and reported an average reduction of 3.67 days in admission in those rooms facing east compared to rooms facing the west. The addition of increased outdoor activities and light glasses in the current study increases exposure to light which can assist in stabilising the circadian rhythm.

Moreover, evidence-based interventions such as cognitive behavioural therapy for insomnia (CBT-I) has shown promising results within clinical settings involving patients with schizophrenia, psychosis and patients in acute care (Freeman et al., 2015; Sheaves et al., 2017).

This study has 2 goals. The first goal is a pilot study of an integrated, ward-based behavioural therapy (the Sleep Program) to improve the quality sleep of psychiatric inpatients in order to determine its effect, variance of effect and feasibility. The second is to describe the characteristic of sleep, activity and light exposure of patients in a high dependency psychiatric unit using wrist actigraphy.

Actigraphy

Wrist actigraphy has been used to measure sleep rhythms for over 25 years (Kripke et al., 1978, Mullaney et al., 1980). Actigraphs are watch like devices generally placed on the wrist to record movement. Most are based on weighted activity (accelerometry) counts in a given epoch of time which detect sleep/wake according to threshold values. Activity data is then processed and analysed by computer software programs and specialized algorithms are used to estimate sleep and activity parameters. The analysis utilises algorithms which have been developed, compared and validated since the original use of actigraphs (Cole et al., 1992, Sadeh et al., 1994, Jean-Louis et al., 2001, Tryon, 2005, Kripke et al., 2010). As actigraphic devices have evolved, so too has the number of channels used to collect additional data streams (light, event markers, subjective scores, and off-wrist capacitance). (Ancoli-Israel et al, 2003)

Polysomnography (PSG) is the gold standard technology for assessing sleep. It is objective, but it is also expensive and limited to just a few nights of data collection in a lab setting which would impede its ability to document sleep problems in a inpatient psychiatric ward. The polysomnography testing process can also interfere with sleep, especially on the first night. Benefits of actigraphy over traditional polysomnography is that you can record continuously for 24 hours per day for days, weeks or longer. Conversely, patient-reported sleep questionnaires are low cost, can be used for multiple nights, and likely do not interfere with sleep. However, they are imprecise and subjective. The subjective nature of questionnaires can be useful if the subjective sleep assessment is the therapy target but can be a problem if you want to detect changes in small Phase 2 or pilot studies. Monk et al. compared both actigraphs and sleep diaries to PSG during space flight. Predicted values of actigraphy were clearly superior to those of diaries for sleep onset and offset, sleep duration, and sleep efficiency.

Actigraphy has been used to investigate movement and sleep disturbance in psychiatric patients. Dursun et al. conducted a descriptive study of wrist actigraphy estimation of sleep in outpatients with schizophrenia prescribed risperidone compared to those on “typical” antipsychotics, and to normal controls. They found a greater degree of nighttime wrist movement (i.e., higher movement index) in patients on a typical antipsychotic compared to those on risperidone. Lemke et al. used wrist actigraphy to estimate mean activity levels in psychiatric unit inpatients with major depressive disorder (evidence level 4C-b).153 They found that subjects whose Pittsburgh Sleep Quality Index indicated poor sleep had higher mean nighttime motor activity levels that those who reported good sleep. In addition, subjects with fewer depressive symptoms had lower mean nighttime motor activity levels than those with greater depressive symptomatology.

In conclusion, scientific research suggests that in the clinical setting, actigraphy is reliable for evaluating sleep patterns in patients with insomnia, for studying the effect of treatments designed to improve sleep, in the diagnosis of circadian rhythm disorders (including shift work), and in evaluating sleep in individuals who are less likely to tolerate PSG, such as inpatient psychiatric patients. While actigraphy has been used in research studies for many years, it is only recently that the methodological issues have been systematically addressed in clinical research and practice. With those issues addressed, the use of actigraphy is now being applied to clinical practice. (Ancoli-Israel et al, 2003).

STUDY OBJECTIVES

Primary Objective

To evaluate the effect of the Sleep Program on duration of admission in HDU (compared to controls) and sleep duration (Actigraphy data), in male psychiatric HDU inpatient participants.

Secondary objectives

1. Sleep quality - improvement in the Pittsburgh Sleep Quality Index
2. Sleep efficiency- percentage time in bed vs percentage time asleep
3. To test the engagement (tolerability and practicality) with a structured Stimulus Control Therapy Program
4. Impact on use of as needed (PRN) hypnotics
5. To describe the characteristic of sleep, activity and light exposure of patients in a high dependency psychiatric unit using wrist actigraphy.

Hypotheses

- We hypothesise that a structured stimulus control program for sleep will shorten duration of admission at psychiatric HDU.
- There will be an improvement in the sleep duration and efficiency
- There will be an improvement in the quality of sleep via a reduction of the self-rated Pittsburgh Sleep Quality Index score, measured at the beginning and end of the study.
- Participants in the Bright Light Study will engage in a structured stimulus control therapy program and it will be well-tolerated.

STUDY DESIGN

Design, Study Groups, Number of Participants

This is a pilot study for a complex intervention and we do not know the effect of variance. We seek to test our methodology, exterminate recruitment and retention rates, feasibility and finally, determine the sample size. We also seek to highlight any issues with acceptability, compliance, and delivery of our interventions.

Number of centres

Single-centre, at Professor Marie Bashir Centre, male High Dependency (psychiatric) Unit

Duration

We foresee the duration of the pilot study of approximately 6 months. Recruitment is on a continuous basis; with approximately 4-6 patients recruited at any given time.

Initial recruitment phase is one week, where patients are identified (see recruitment procedures). Initial recruitment will be 4-6 patients. The patient is recruited for as long as they are an inpatient at the HDU and discontinued at their discharge (or at their request). Subsequent patients are then recruited in the same process to maintain 4-6 patients at any given time in the program for the duration of the pilot study.

PARTICIPANTS

Inclusion Criteria

1. Males 18+ years.
2. Inpatient in psychiatric Male HDU at PMBC
3. Willingness to give informed written consent and willingness to participate to and comply with the study.
4. Literacy in English.

Exclusion Criteria

1. Current substance dependence.
2. Severe cognitive impairment or thought disorder that does not allow participants to consent or follow treatment instructions.
3. Recent time-zone travel (within last 1 month).

Interventions

The intervention is an integrated Sleep Program. It comprises of two main components, thrice weekly group sessions and ward environmental initiatives. The overarching aim is to improve sleep through;

1. **Increase daytime activity**, particularly in the morning if possible, with use of the balcony and outdoor areas. It has the ultimate aim of establishing routine. Many patients in a hospital setting experience a lack of activity. For example, patients may spend a lot of time in bed watching TV or napping throughout the day.
2. **Setting regular rhythms** – enhanced light/dark exposure to stabilize circadian rhythms.
3. **Stimulus control and relaxation** – simple breathing techniques, relaxing music through headphones, relaxation on bean bags
4. Encourage patient-driven management through **psychoeducation,** ongoing sleep quality monitoring and feedback, and driving behavioural change in the ward milieu.

The total duration of a patient's participation in the Program is flexible. However, we consider a 2-week duration as the minimum dose.

Ward environmental initiatives

A number of initiatives are adopted, these are summarised below. They are specific to the participants of the study. Bean bag and visual cues (ward posters) are made available to the participants in their own rooms; while headphones are pre-existing equipment available to all patients in the HDU.

	Ward environmental initiatives
Stimulus Control Therapy	• Consistent wake time at 7am encouraged by ward staff • Beanbags: an alternate place to sit other than the bed
Sleep Psycho-education	• Visual cues regarding specific sleep hygiene strategies around patient room and ward area. • Reinforcement, encouragement and further psychoeducation provided by nursing staff
Increased light exposure (regulating circadian rhythm)	• Using available open spaces wherever possible enhanced with early morning Retimer™ blue-green light goggles for those with sleep-phase delay
Relaxation	• Calming music during wind down • Quiet space with dim lights and beanbags

Activity Groups

Each participant will be invited to participate in thrice-per-week, 30-minute workshops in the program, which aim to provide psychoeducation about sleep, debriefing and sleep-promotion related

activities. It is also aimed at increasing daytime activity and enforcing a regular circadian rhythm. This is conducted on a repeated weekly cycle as outlined below. These sessions will take place on the outdoor area of the HDU (the balcony) where possible such that participants will receive continuous daylight exposure during these sessions. Each session will take place in mid-morning to lunchtime.

Session 1

Session 1 are on Mondays. They are facilitated by a senior Occupational Therapist and a peer-support worker and is designed to instil a routine of activity (via a Cooking group). Initial consenting and program information will be provided to a patient who is commencing. As well, actigraph watch and sleep diary will be provided to the commencing participant, allowing for ongoing record and feedback of their sleep parameters throughout their time in the program. Qualitative feedback regarding sleep will be collected during these sessions.

Session 2

Second sessions are held on Wednesdays, on the balcony of the HDU. They are facilitated by two psychiatry registrars. Prior to the sessions, participants' actigraph watches are collected and sleep data analysed by the research assistant. A visual representation of sleep duration and activity for each patient will be printed prior to the session and given to the registrars, and printouts are identifiable only by participant IDs.
These sessions are held as a mini picnic with healthy snacks. During these sessions, printouts will be discussed individually with participants, especially with respect to their self-evaluation in their Sleep Diaries. This aims to increase insight and empower the participants to take a proactive role in their management.

As a group, the registrars will give further psychoeducation about sleep, with a focus on sleep hygiene, and addressing specific stimuli which affect sleep.

Wednesday sessions are also repeated in a weekly cycle. Patients in their initial and final weeks of the program will be asked to complete the Pittsburgh Sleep Quality Index, modified to reflect the quality of sleep within one week.

Session 3

Session three are held on Fridays and are repeated on a weekly basis. It is split into two components. Firstly, the morning session is in the form of a breakfast barbeque – which is open to the entire ward to participate. Facilitators of sessions 1 and 2 are able to join. This session is an informal way for participants and clinicians to freely exchange ideas and feedback, as well as to reinforce sleep psychoeducation provided in earlier sessions.

Secondly, there will be a booster session on Friday evenings, which is self-directed by the participants and is optional. It entails participants making use of the ward measures made available to them – to enhance relaxation and stimulus control.

Summary table of sessions

Session	Day and time	Content	Measurement tools	
			Sleep diary	Actigraphy
1	Monday 11:30am – 12pm	• Cooking group • Preliminary psychoeducation • Program information and obtaining consent • Providing actigraph watch and diary for participant	X	X
	Tuesday	Nil active intervention for Day 2 participants complete diary +/- nurse Day8 participants - maintain stimulus control and am light goggles	X	X
2	Wednesday (Pre-session)	• Collecting watches + analysing actigraphy	X	X
	Wednesday 11:30am – 12pm	• Outdoor session with snacks • Psychoeducation about • Stimulus Control Therapy, Sleep Hygiene • Present sleep results • Administer PSQI and one-item Sleep Quality measure (start and terminating session only)		
	Thursday		X	X
3	Friday AM	• Outdoors session with bacon and eggs	X	X
	Friday PM 9 - 9:30pm	• Booster session • Wind down with beanbags • Headphones provided for relaxing music • Reinforcing stimulus control therapy	X	X

Participant Time Line

Time Frame for Activity	Screen	Program cycle		
		At recruitment	Weekly	At discharge
Initial screening in handovers by clinical staff	X			
Initial medical assessment for appropriateness	X			
Self-report measures		X	x	X
Sleep Diary			X	
Qualitative evaluation Questionnaire				X
Ward initiatives		X	X	
Retimer™ Light goggles			X	
Actigraphy data		X	X	
Sleep Program groups		x	X	
Psychoeducation about sleep hygiene		X	X	
Program usage		X	X	X
Adverse event monitoring		X	X	X

1. Skin damage due to photosensitivity
   Some medications, notably Chlorpromazine, are known to increase the photosensitivity of the skin. The Program entails exposure to natural and low intensity artificial light, which may cause irritation and minor sunburns.
2. Headache from tightness or poor fit of light spectacles
   The Retimer™ light goggle is made from rigid plastic and are not adjustable for size of head. Therefore, it is possible that participants may experience discomfort on the ridge of their nose, or sections of the skin around the auricle which makes contact with the goggle.
3. Discomfort from artificial light
   The Retimer light goggle emits light in two different intensity settings, which is projected upwards towards the light. Whilst the light intensity is safe, it may still be a source of discomfort and annoyance to the patient.
4. Sleep disturbance
   The Program is an evidence-based intervention aimed to reset and align the circadian rhythm to normal daylight hours. However, there is a risk that the integrated intervention does not improve sleep quality and quantity, or indeed, may worsen them.
5. Psychological harm: wearing a watch which constantly collects data might further enhance persecutory or paranoid ideations in the sub-population of participants who are experiencing psychotic symptoms. However, given the study requires informed consent, the likelihood of a paranoid patient consenting to participate is small.

Given the non-invasive, interactive and patient-driven nature of the intervention, it is expected that participants will have minimal risks in the following domains:

- disclosure of sensitive personal information
- exposure of illegal activity
- economic harm
- discrimination, stigma or other social harm
- devaluation or harassment
- familial distress
- harm to any member of a vulnerable population
- reputational harm

Informed Consent Process

There is a one-stage consent process to entry into the study. The Senior occupational therapist, Abby Moran (investigator in this study) will introduce the study and discus the main aspects to potential eligible participants in person in the first instance to reduce medical-patient power imbalance.

Participants will receive the study information sheets in hard copy. Research clinicians will discuss the study with participants in light of the information provided to them. The research clinician will obtain written content from patients willing to participate.

A potential participant has one week to consider their participation; however, they may defer that decision up until two weeks prior to their expected discharge date from the HDU - given a meaningful study period is defined as a minimum of two weeks of participation.

Enrolment Procedure

The participant will be enrolled into the study after the informed consent process has been completed and the participant has met all inclusion criteria and none of the exclusion criteria.

Participants need to be inpatient at HDU North (male) in PMBC, Royal Prince Alfred Hospital.

Participants are first identified as potential (candidate) participant by medical/OT/SW/RN from Multi-Disciplinary Team (MDT) meeting, satisfying inclusion and exclusion criteria.

The participant will receive a study enrolment number (Participant ID number), and this will be documented in secure and confidential register, as well as in the medical records.

Capacity

Potential (candidate) participants are clinically assessed for the ability to understand and capacity to give consent. The consultant in the treating team must deem the candidate participant as having capacity to consent; and this must be a consensus impression by the rest of the MDT. Further, it must be verifiable by demonstrated understanding and engagement with the Sleep Program. Mental state is monitored on an ongoing basis as per standard care. In cases where a participant deteriorates or loses capacity to consent and participate altogether: their involvement in the study will cease. This is outlined under *Early Terminations*.

Randomisation Procedure

Not applicable

Adverse Event Reporting

An adverse event is defined as any untoward medical occurrence in a participant which does not necessarily have a causal relationship with the study treatment. All adverse events will be collected after the participant has provided consent and enrolled into the study. If subject experiences an adverse event after the informed consent document is signed (entry) but the participant has not started to receive study intervention, the event will be reported as not related to stimulus control therapy.

All adverse events occurring after entry into the study and until hospital discharge will be recorded.

If treatment is discontinued as a result of an adverse event, study personnel will document the circumstances and data leading to discontinuation of treatment.

The study will monitor for potential adverse effects at each treatment session or workshop.

Adverse events reported spontaneously or in response to open-ended questions asked routinely at each visit (by the study coordinator, psychiatrist or nurse) will be recorded with a medical evaluation of severity and causality and coded using the Medical Dictionary for Regulatory Activities (MEDDRA), Preferred Terms will be reported.

Serious Adverse Event Reporting

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that results in the following: death, is life-threatening (that is, imminent risk of death), requires medical inpatient hospitalisation or prolongation of existing hospitalisation, persistent or significant disability/incapacity, condition requiring unnecessary medical or surgical intervention. An SAE can also be a significant hazard as determined by the trial investigators. Serious adverse events occurring after a participant has left the study will not be reported unless the investigators feels that the event may have been caused by sleep consolidation therapy or a protocol procedure. Investigators will determine relatedness of an event based on a temporal relationship to the treatment, as well as whether the event is unexpected or unexplained given the participant's clinical course, previous medical conditions, and any concomitant medications

An SAE also includes adverse event that might have led to death or a serious deterioration in health had suitable action or intervention not taken place:

1) A malfunction of device such that it has to be modified or temporarily/permanently taken out of service
2) A factor found on examination of the device (a deterioration in characteristics or performance)

De-identified Serious Adverse Event Reports will be completed as required throughout the study period and sent the ethic committee.

Early Termination

Possible circumstances for early termination of the study include:

1. Early termination initiated by patient due to side-effects, change-of-mind, intolerability, or the perception that their sleep have improved sufficiently such that they no longer require participation in the program.
2. Loss of capacity to consent due to deterioration or variation in mental state
3. Loss of ability to participate due to deterioration or variation in mental tate
4. Medical admission of patient due to an acute medical illness whilst inpatient at PMBC
5. Transfer of patient to a different facility.

The study coordinator will be responsible for correspondence with HREC.
Investigators involved in implementing the Sleep Program clinically, can receive formal notification of termination from the participant by verbal or written form. They may receive notice of termination through a delegate (such as the participant's nurse or medical officer responsible). The investigator will need to formally inform the Study Coordinator in written form.

The Study Coordinator will then be required to document termination in digital study data for this participant – whose data will be separated from overall data pool. Early termination data will be kept for discussion purposes but will be excluded in results and statistical analyses.

The Study Coordinator will be responsible for informing the

> *(who is responsible for what aspect in the process of terminating the study (informing participants, correspondence to HREC, compiling a final study report, unbinding if applicable).*

BLINDING AND UNBLINDING

a) Blinding (Masking): This trial is an open-label with no attempt at masking
b) Emergency unblinding: not applicable

STATISTICAL CONSIDERATIONS

Sample Size or Power Calculation

The pilot study will determine the sample size. Power calculation will be the minimum number of samples required to provide adequate power for the primary outcome. (Actigraphic changes in sleep duration)

Statistical Analysis Plan

Given the pilot study nature we will describe the sample, and the outcomes using but only use analytical techniques to estimate potential effects using difference of means within person measures in SPSS. The pilot study is unlikely to generate sufficient data points for bivariate or multivariate regression modelling.

Data Safety and Storage

There are two forms of data collected in pilot study: digital data, and physical data handwritten on paper forms.

Digital Data

Patient name, MRN and date of birth are linked to a Participant ID number. This is kept on an Excel spreadsheet, which is password protected on a single desktop issued by the Sydney Local Health District. The computer will be kept on-site only, in the secured, staff-only section of PMBC, which is accessible via swipe card only. The patient data spreadsheet can only be accessible within a Sydney LHD premises which has access to the SLHD intranet. Back-up copy of this spreadsheet is kept within the Sydney LHD ICT infrastructure.

De-identified digital data includes all data that are entered digitally, and are only identifiable through Participant ID. This includes any digitised data from physical forms, actigraphy data, aggregate length-of-stay data, and so on. Computers with access to these files that are password-protected and individualised for the investigator.

For security, a complete back-up of the data will be kept on a separate, secure Sydney LHD laptop, and is performed on a daily basis. Periodic data analysis files will also be backed-up and kept. Primary access to the Sydney LHD computing facilities will be through physical access onsite and through the intranet. Security will be enforced through restricted, swipe-card physical access, passwords and different levels will be assigned to groups and individuals.

Physical Data

Physical data includes the following; patient-completed self-assessment forms (PSQI, sleep diary, Visual scales), equipment check-in and check-out equipment logs. These are identifiable to patient with *only* the Participant ID.

Any original study forms will be entered onto the computer as de-identified patient data. The original forms are then kept on file at the Professor Marie Bashir Centre. Participant files will be stored in numerical order and in a secure cabinet within an office in the staff-only section (swipe-card access) of the PMBC. All participant files will be maintained for 15 years after the completion of the study.

Dissemination of the outcomes of the project

Sleep Actigraphy data will be identifiable only by Participant ID and will be given directly to the patient and not to any third party. This is part of the feed-back and discussion process in the Sleep Program.

The overall outcomes of the project will be disseminated in a confidential envelope with generalised outcomes (that are not identifiable to any original participant) and sent to the patient or given to the patient (if they are still inpatient in a lower acuity ward).

Findings of this pilot study will likely be submitted for publication in relevant scientific journals.

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APPENDICES

Patient Information Sheet

You are invited to take part in a clinical treatment research study for people with poor sleep. In this study, we aim to see whether a series of non-pharmacological measures, such as controlled light exposure and relaxation techniques improve sleep quality.

The study is being conducted within this institution by the following researchers:
Principal Investigator: Professor Nicholas Glozier

Study Coordinator:

Dr Peter Xie; Phone: 9351 6111 Email: peter.xie@health.nsw.gov.au

Please contact the study coordinator for day-to-day enquiries.

This project is funded by Sydney Local Health District. The LHD will provide funding for equipment for the study. The investigators will make all decisions about how the overall results of the study will be communicated to participants and clinicians. **'What are the aims of this study?'**

The main aim of this study is to explore the use of Behavioural Therapy to improve sleep. This means you will participate in a number of daytime activities that are aimed increase your exposure to light during daylight hours. We want to find out whether these measures will help your body to adjust to a correct sleep cycle, providing better sleep quality, use fewer as-needed ('PRN') sleep medication, and having shorter hospital stays.

'Why have I been invited to participate in this study?'

This study may be suitable for you because you are an inpatient who has disturbed sleep, and who can participate in our day program.

'Is participation in this study voluntary?'

Participation in this study is entirely voluntary and not renumerated. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. It may be best to discuss the study with friends or family prior to consent. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you. If you decide to terminate your participation in this study please notify your nurse, or contact Dr Peter Xie on 9351 6111 (Telephone) or at peter.xie@health.nsw.gov.au

'What does this study involve?'

Participation will comprise of 4 sessions of 30-45 minutes each:

1. Monday cooking group

2. Wednesday outdoor feedback session with psychiatry registrars and learning about sleep hygiene
3. Friday outdoor BBQ breakfasts aimed to give you more exposure to natural light
4. A "wind-down" session with relaxation, music, and beanbags aimed to reduce stress on Friday evenings

You will be required to:

- Participate in the activity groups above
- Wear a watch that measures how much sleep you get
- Wear the Retimer: a google that emits green light towards your eyes and face to simulate exposure to daylight. This is optional if you find it uncomfortable
- Maintaining a sleep diary to rate your sleep after every night (to the best of your abilities)
- Practicing all the things you have learned in the activity groups about improving your sleep.
- Complete two 10-minute surveys regarding the quality of your sleep at the beginning and end of the program

'How much time will the study take?' How much time do I have to consent?

The program is ongoing. Once you consent to be in the program, you can continue to participate in the groups until you are discharged from HDU. You may opt out of the program at any time.

You can consent to participate the study any time from now till the two weeks before you are expected to be discharged.

'How many other participants are there in the study?'

It is anticipated that no more than 4-56 participants will be enrolled into this study at the same time. However, there is no upper limit to how many participants we recruit in total, as this is a pilot study and we will be continuously collect data and run sessions for a period of three months.

'What are the study procedures?'

If you agree to participate, you will be asked to sign a Consent Form. If suitable, you will then be asked to undergo a screening evaluation by a research clinician and, if the study is deemed to be suitable for you, you will be invited to continue in the study.

A description of what each procedure or test involves is shown below.

Study Procedures

- Sleep Questionnaire (PSQI) – a self-rated questionnaire that we collect at the beginning and end of your time in the trial regarding the general state of your sleep. Your study clinicians will help you with this.

- Actigraphy Watches – which records the duration of your sleep and a real-time record of your exposure to light.

- Sleep Diary - a self-rated daily grid that you fill out about your sleep duration and quality, which is completed daily. It involves rating your sleep and noting the length of sleep. You will have access to a visual scale to help you rate your sleep

- A behavioural therapy program – three Activity Group sessions facilitated by allied health, doctors, and nurses designed togive you better routines, improve your exposure to daylight and to teach you about sleep and to improve the quality of your sleep:

Session	Day and time	Content	Measurement tools	
			Sleep diary	Actigraphy
1	Monday 11:30am – 12pm	• Cooking group • Preliminary psychoeducation • Program information and obtaining consent • Providing actigraph watch and diary for participant	X	X
	Tuesday	Nil active intervention for Day 2 participants complete diary +/- nurse Day 8 participants - maintain stimulus control and am light goggles	X	X
2	Wednesday (Pre-session)	• Collecting watches + analysing actigraphy	X	X
	Wednesday 11:30am – 12pm	• Outdoor session with snacks • Psychoeducation about • Stimulus Control Therapy, Sleep Hygiene • Present sleep results • Administer PSQI and one-item Sleep Quality measure (start and terminating session only)		
	Thursday		X	X
3	Friday AM	• Outdoors session with bacon and eggs	X	X
	Friday PM 9 - 9:30pm	• Booster session • Wind down with beanbags • Headphones provided for relaxing music • Reinforcing stimulus control therapy		

- Light Therapy using goggles
- Relaxation
- A series of ward improvement to help your process – catered especially for the participants:

	Ward environmental initiatives
Stimulus Control Therapy	• Consistent wake time at 7am encouraged by ward staff • Beanbags: an alternate place to sit other than the bed
Sleep Psycho-education	• Visual cues regarding specific sleep hygiene strategies around patient room and ward area. • Reinforcement, encouragement and further psychoeducation provided by nursing staff
Increased light exposure (regulating circadian rhythm)	• Using available open spaces wherever possible enhanced with early morning Retimer™ blue-green light goggles for those with sleep-phase delay
Relaxation	• Calming music during wind down • Quiet space with dim lights and beanbags

- Questionnaire Follow-up

Please also see the following Table 1 on the next page for an overview of the study timeline.

TABLE 1: PARTICIPANT TIMELINE

Time Frame for Activity	Screen	Program cycle		
		At recruitment	Weekly	At discharge
Initial screening in handovers by clinical staff	X			
Initial medical assessment for appropriateness	X			
Self-report measures		X	x	X
Sleep Diary			X	
Ward initiatives		X	X	
Retimer™ Light goggles			X	
Actigraphy data		X	X	
Sleep Program groups		x	X	
Psychoeducation about sleep hygiene		X	X	
Program usage		X	X	X
Qualitative evaluation Questionnaire				X

'What are my responsibilities as a participant in this study?'

If you decide to participate in this research study, you will be expected to follow the guidelines contained in this Information for Participants, and those provided by the study clinicians and hospital staff. You will also be expected to:

- Attend the sessions and wear the watches/light exposure as guided.
- Contact the study coordinator if you decide to discontinue your participation in the study: Dr Peter Xie; Phone: 9351 6111 Email: peter.xie@health.nsw.gov.au

You must also tell your study clinicians about any other medications that you are already taking, e.g. over-the-counter medicines, herbal preparations, vitamins. It is important that you talk with the study Sleep Clinician before starting or stopping any prescription medications during this study.

In addition, if you were granted leave from the High Dependency Unit, or if you are discharged from the High Dependency Unit, you must return the watch, google and other equipment to the study clinicians. You may keep the information, worksheets and handouts from the program, if you wish.

'Are there any side-effects and/or risks associated with this study?'

There are a number of uncommon and mild side-effects to do with the study.

- If you are on a medication which increases your sensitivity to light (such as Chlorpromazine), the increased sunlight and artificial light exposure during the workshops may cause sunburn.
- The increased light exposure and activity during the day might not improve your sleep. If you have what is known as Phase Advance (that is, if you sleep early in the evening and wake up very early in the morning), the activities may worsen your sleep pattern.
- The exposure of green light towards your face and eyes may cause some discomfort and in extreme cases, mild headaches
- The goggles are single-sized and it is not possible to adjust the length and width. Because of this, there is a small possibility of discomfort or skin irritation to the bridge of your nose, your temples, and the skin around your ears.

As this is a very new trial and there is little pre-existing similar studies, it is difficult to quantify a more precise probability of risk.

In addition to the risks and discomforts listed above, there may be other known and unknown risks that are not disclosed here; talk to your study clinicians if you would like more information.

In all cases, if you experience any discomforts or worsening sleep disturbance, please let your study clinicians know immediately.

Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study, you should contact the study coordinator as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital). You do not give up any legal rights to compensation by participating in this study.

In the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the Executive Officer of the Ethics Review Committee or electronically at https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

Benefits

It is hoped that by taking part in this research, you will be providing valuable information regarding the use of a specifically designed therapy program within the hospital setting (Stimulus Control Therapy and ward initiatives) to help quality and quantity of sleep. We also hope that you will benefit from the program by learning more about sleep, and leave the hospital with better quality sleep with less reliance on sedating medications. We hope that this program helps you to feel empowered and have more autonomy in your care; and that the program will help shorten your stay in HDU and reduce your symptoms.

Study costs and reimbursements

Participation in this study will not cost you anything. You will not be reimbursed for your time during this study. If you have any questions, please discuss this matter with the study team.

'Could my study participation be terminated?'/ 'Do I have to be in or finish the study?'

Your participation in this study is voluntary. If you decide to take part, you will be given this information to keep and be asked to sign the Consent Form. You may choose not to take part

in this study or, once in the study, you may decide to discontinue participation at any time. You must inform the study coordinator if you decide to do this. He/she will explain the best way for you to discontinue your participation in this research study. Your decision not to take part in the study or to stop participating in the study will not affect your current or future medical care, or any benefits to which you may otherwise be entitled.

Any study data that are collected before you discontinue from the study will be used in the analysis of the study results.

We would very much appreciate it if you could discuss any concerns with the study clinicians before you terminate, as we will strive to mitigate your concerns. We would also encourage you to provide us with feedback, regardless of your final decision.

Confidentiality and Disclosures of Information

All information obtained during this study, including hospital records, personal data and research data will be kept confidential. Any information taken from these records will be coded with a study number and your initials. By signing the Consent Form, you consent to these conditions and understand that any data published in scientific journals will not identify you.

Data from this study might also be used in future research – using only data that will not identify you. We will not use any data identifiable to you to in future research.

Further Information

When you have read this information, one of the study clinicians will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please firstly discuss with your boss, or contact Dr Peter Xie; Phone: 9351 6111 Email: peter.xie@health.nsw.gov.au.

The study Medical Principal Investigator is Professor Nicholas Glozier who is available to answer any inquiries or discuss conerns about the study procedures or the therapy described. Please feel free to contact him on (02) 9515 1596 (Telephone) or at nick.glozier@sydney.edu.au (email).

Ethics Approval and Complaints

The Ethics Review Committee (RPAH Zone) of the Sydney Local Health District has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated May 2015). This Statement has been developed to protect the interests of people who agree to participate in human research studies.

Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on _____and quote protocol number _____.

The conduct of this study has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the hospital and quote project number [xx/xxx].

This information sheet is for you to keep.

Patient Consent Form

PARTICIPANT CONSENT FORM

PMBC Sleep Study

I, ... [name]

Of .....[address]

have read and understood the Participant information sheet version 1.0 (April 2018) for the above named research study and have discussed the study with .....(insert name of study investigator).

- I freely agree to participate in this research project according to the conditions in the Participant Information Sheet which I confirm has been provided to me.
- I understand that my involvement in this study may not be of any direct benefit to me.
- I have been told that no information regarding my medical history will be divulged to unauthorised third parties and the results of any tests involving me will not be published so as to reveal my identity.
- I understand that access may be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.
- I declare that all my questions have been answered to my satisfaction.
- I have read, or have had read to me in a language in which I am fluent, and I understand the Participant Information Sheet, version 1.0, dated April 2018

I hereby agree to participate in all aspects of this research study YES • NO •

NAME: .....

SIGNATURE: .....

DATE: .....

NAME OF WITNESS: .....

SIGNATURE OF WITNESS: .....

Sydney Local Health District

MODIFIED PITTSBURGH SLEEP QUALITY INDEX (PSQI)

ID NUMBER: _____

Instructions: The following questions relate to your usual sleep habits during the Past week only.

During the past week,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. When have you usually gotten up in the morning? _____
4. How many hours of actual sleep do you get at night? _____

5. During the past week, how often have you had trouble sleeping because you…	Not during the past week (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):				
6. During the **past week**, how often have you taken medicine (or asked a nurse for tablet) to help you sleep?				
7. During the past week, how often have you had trouble staying awake while eating meals, or engaging in social activity?				
8. During the past week, how much of a problem has it been for you to keep up enthusiasm to get things done?				
	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)
9. During the past week, how would you rate your sleep quality overall?				

Sleep Diary

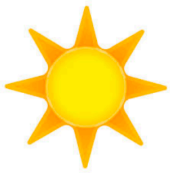
	LAST NIGHT I WENT TO BED AT	LAST NIGHT I FELL ASLEEP AT	OVERNIGHT MY SLEEP WAS DISTURBED BY	THIS MORNING I WOKE UP AT	THIS MORNING I GOT OUT OF BED AT	MY SLEEP QUALITY WAS	DID YOU HAVE A NAP DURING THE DAY	HOW LONG
DAY 1 ……						☐ Very Good ☐ Good ☐ Average ☐ Bad ☐ Very Bad	☐ Yes ☐ No	……hours ……minutes
DAY 2 ……						☐ Very Good ☐ Good ☐ Average ☐ Bad ☐ Very Bad	☐ Yes ☐ No	……hours ……minutes
DAY 3 ……						☐ Very Good ☐ Good ☐ Average ☐ Bad ☐ Very Bad	☐ Yes ☐ No	……hours ……minutes
DAY 4 ……						☐ Very Good ☐ Good ☐ Average ☐ Bad ☐ Very Bad	☐ Yes ☐ No	……hours ……minutes
DAY 5 ……						☐ Very Good ☐ Good ☐ Average ☐ Bad ☐ Very Bad	☐ Yes ☐ No	……hours ……minutes

Visual Analogue Scale : Sleep Quality

Ward Poster : A Good Night's Sleep

A GOOD NIGHT'S SLEEP

DURING THE DAY



ENJOY THE SUN!

EXERCISE!

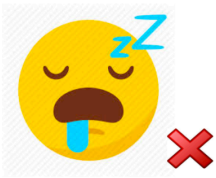
GET UP! DON'T STAY IN BED

KEEP UP THE ROUTINES

EAT RIGHT

Coffee is okay ☺

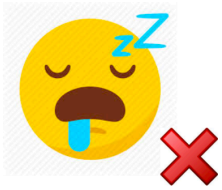
CHILL AND LISTEN TO MUSIC!



NO NAPPING!

A GOOD NIGHT 'S SLEEP

LATE AFTERNOONS & EVENINGS



NO NAPPING!

AVOID COFFEE!

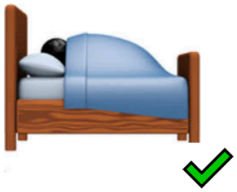
AVOID LATE-NIGHT TV

AVOID COKE

AVOID BIG MEALS

AVOID SMOKES & ALCOHOL

CHILL AND LISTEN TO MUSIC!



ONLY STAY IN BED IF YOU'RE READY TO SLEEP!

Patient Autonomy and Satisfaction Survey

PATIENT AUTONOMY AND SATISFACTION SURVEY

(Modified Healthcare Climate Questionnaire – HCCQ)

Participant ID:

Please answer the questions below regarding your relationship with your health care practitioners for the Sleep Program.

Practitioners have different styles in dealing with patients. Your responses will be kept confidential, so none of the practitioners will know your responses. Please be honest and candid.

Choose your answers using the scale below for each question by filling in the blank after each question with a number from 1 to 7.

	2	3	4	5	6	7
Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree

1. I feel that my health care practitioner has provided me choices and options about treating my sleep.	_____
2. I feel my health care practitioner understands how I see things with respect to my health.	_____
3. I am able to be open with my health care practitioner about my health.	_____
4. My health care practitioner conveys confidence in my ability to make changes regarding my health.	_____
5. I feel that my health care practitioner accepts me whether I follow their recommendations or not.	_____
6. My health care practitioner has made sure I really understand things that I do which might impact on my sleep, and the benefits of changing these behaviours without pressuring me to do so.	_____
7. My health care practitioner encourages me to ask questions.	_____
8. I feel a lot of trust in my health care practitioner.	_____
9. My health care practitioner answers my questions related to my sleep fully and carefully.	_____
10. My health care practitioner listens to how I would like to do things regarding my sleep.	_____
11. My health care practitioner handles my emotions very well.	_____
12. I feel that my health care practitioner cares about me as a person.	_____
13. I don't feel very good about the way my health care practitioner talks to me about my health.	_____
14. My health care practitioner tries to understand how I see my sleep habits before suggesting any changes.	_____
15. I feel able to share my feelings with my health care practitioner	_____