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Research Methods, Protocols, Procedures

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Protocol for a pilot hybrid type I effectiveness-implementation study to improve help-seeking for sleep disorders in the future healthcare workforce: The Sleep Check Before Shift Work trial

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Abstract

Sleep disorders are prevalent in shift workers but are commonly undiagnosed and unmanaged. This poses considerable safety, productivity, and health risks. There is limited education or early intervention to encourage awareness of, and treatment for, sleep disorders in young adults who will transition into careers requiring shift work. This study aims to investigate (a) the *clinical effectiveness* of simulated shift work exposure and cognitive performance feedback for prompting help-seeking for sleep problems, and (b) the feasibility and acceptability of *implementing* this intervention for future healthcare workers. A hybrid type I effectiveness-implementation trial will be conducted from June 2024 to December 2025 with prospective healthcare workers currently enrolled in a medicine, paramedicine, or nursing degree. Ninety adults (18–39 years) who self-report sleep disturbances will be recruited and complete a combination of structured clinical interviews, screening questionnaires, remote monitoring technology, and overnight polysomnography (PSG). Participants will be randomized across three conditions, with varying exposure to a simulated transition to night shift without sleep, and cognitive performance feedback. All individuals will attend a diagnostic appointment with a sleep psychologist or sleep physician and discuss help-seeking pathways for their sleep. The primary outcomes will be help-seeking from a health professional for sleep (yes/no), time to help-seeking (days), and road safety-related events over 12 months. Process evaluation will explore the feasibility and acceptability of this approach from the participants' perspective.

Key words: shift work; performance; sleep disorder; implementation; translation; healthcare; occupational health; safety

Statement of Significance

Young adults with sleep disorders are poorly screened and managed. This is particularly problematic in the context of further disruption to their sleep opportunities due to shift work requirements. This effectiveness-implementation trial is the first to consider supported care pathways for help-seeking to improve sleep before making the transition to regular shift work in the healthcare industry, with a focus on improving road safety and mental health outcomes.

Shift work is a common working arrangement in Australia, broadly defined as schedules which fall outside the traditional 0800–1800 hours. This can include fixed schedules (morning, afternoon, or night shift), casual or variable rosters, and rotating rosters [1]. Extended periods of wakefulness, and working at times of day when the body is biologically primed for sleep, are both

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synonymous with shift work. Consequently, shift workers are vulnerable to workplace and road safety incidents. This vulnerability can be a function of extended wake periods and insufficient sleep, both of which are common for shift workers. This is particularly concerning for workers who need to drive at night either as part of their job or to commute to and from the workplace.

Shift workers are also vulnerable to common sleep disorders. Prevalence rates for common sleep disorders (obstructive sleep apnea [OSA], insomnia, restless legs syndrome) severe enough to warrant clinical investigation and management range from 20% in early adulthood [2] through to 43% by middle age [3] in the broader population. These rates are thought to be similar [4] or higher [5, 6] in shift workers. Both sleep disorders and shift work conditions are independently associated with performance decrements, including neurocognitive impairment [7–9], impaired driving performance [10–13], and higher rates of near misses and actual road safety events [14–16]. Studies on the combined effects of both shift work and sleep disorders suggest a cumulative negative effect of night shift work and a sleep disorder for mental health [4], and prospective associations with falling asleep at the wheel [17].

High rates of both shift work conditions and sleep disorders in emerging adults mean shift work and sleep disorders commonly co-occur; yet population estimates suggest that >80% of young adults with sleep disorders are undiagnosed [4], likely indicative of low help-seeking rates. Even when provided with cost-free specialist treatment options, active help-seeking for a sleep disorder is limited in emerging and early adulthood [18]. This aligns with broader evidence that shift workers with sleep disorder symptoms do not actively seek help for their sleep complaints [19, 20], often attributing their symptoms to shift work schedules alone. Consequently, shift workers can report long times to seek help, and pathways to diagnosis that are not straightforward [19]. Collectively, these issues represent a significant barrier to timely and effective care, exposing shift workers to additional health and safety risks associated with unmanaged sleep disorders.

With ~25% of employed emerging adults identifying as shift workers, 20% of whom meet the criteria for a sleep disorder in Australia [4], there is a demonstrable need for intervention strategies that promote early and rapid help-seeking for sleep disorders. This should be a priority for improving road safety [21, 22], productivity [23], and mental health [4] outcomes observed in emerging and early adulthood. This manuscript outlines the protocol for a hybrid type I effectiveness-implementation randomized controlled trial (RCT). The trial will assess both the clinical effectiveness and implementation of a multi-component night shift simulation intervention aimed at increasing help-seeking behavior for sleep disorders in emerging and early adulthood, specifically in those who are training to enter healthcare professions with shift work requirements.

Aims and objectives

In a cohort of healthcare students with a high likelihood of future shift work requirements, the Sleep Check before Shift Work trial aims to:

(1) assess the effectiveness of a brief sleep disorder education module combined with an in-laboratory sleep study and shift work simulation experience (+/– personalized performance feedback) for improving help-seeking behavior for sleep problems,
(2) determine whether engaging with diagnosis and treatment for sleep disorders improves self-reported road safety events, and
(3) conduct a process evaluation to understand the feasibility and acceptability of the intervention, including facilitators and barriers to implementation from the participant's perspective.

Methods

This protocol was designed and reported in accordance with The Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement [24] (Supplementary Table 1). Ethical approval was granted for this protocol (Version 1.0) by Flinders University's Human Research Ethics Committee (6548) in January 2024 and the trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12624000339550). Translation of findings will be through funder-supported fora, scientific meetings, tertiary education (guest lectures, University events), peer-reviewed publications, and broader healthcare industry events.

Study design

Sleep check before shift work is a hybrid type-I effectiveness-implementation study [25], comprising a three-arm, RCT. The study protocol is visualized in Figure 1. Participants will be randomized into one of three groups: a control group undergoing only diagnostic polysomnography (PSG; Arm 1); a group undergoing PSG and a simulated night shift (Arm 2); and a third group undergoing PSG, simulated night shift and additional personalized cognitive feedback (Arm 3). The aim of the study is to identify the most effective strategy for encouraging help-seeking behavior for sleep disorders in future healthcare workers. An integrated process evaluation using the Health Belief Model will be conducted; both qualitative interviews and quantitative measures of acceptability, appropriateness, and feasibility are included to understand barriers and facilitators to implementation. Ethical approval was obtained from the Human Research Ethics Committee at Flinders University (project number: 6548) in January 2024. Modifications to the protocol will be communicated to the research team at monthly reporting, immediately updated with local ethics committees, amended in the trial registration documents, and communicated to impacted parties (e.g. participants, journals) as appropriate. No formal data monitoring committee was established for this trial due to its short duration and known minimal risks. Data quality checks will be performed at the conclusion of every laboratory visit. As a single-site implementation trial, a formal auditing procedure is not provided.

The health belief model

This trial design, and the process evaluation, are informed by the Health Belief Model [26]. The Health Belief Model proposes that engagement in health behaviors is influenced by individual perceptions about the severity of a health condition (or disease), their own susceptibility, and any perceived benefits or barriers to engaging in health behavior to address the health condition (or disease) [26]. In the context of this study, for an individual to engage in health behavior (*help-seeking*) related to a health condition (*sleep problems*), the perceived threat of the sleep problem and potential benefits of help-seeking would need to be greater than the perceived and/or actual barriers to help-seeking (including

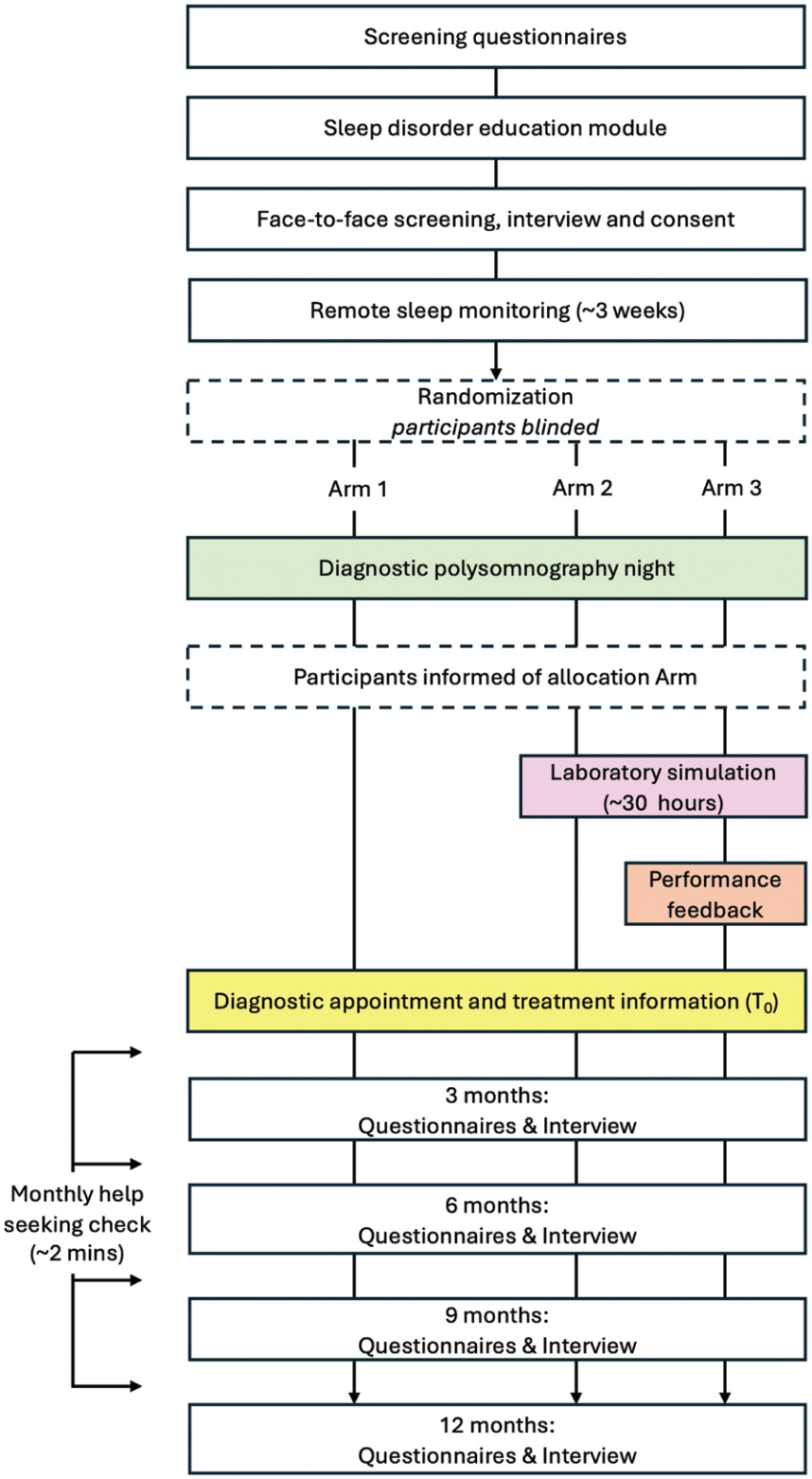

Figure 1. Flow diagram showing participant screening, recruitment, randomization, and intervention arms.

known cost, time demands, and challenges with health system navigation from pilot work) [18]. The trial is designed to provide personalized information to increase awareness of susceptibility and severity, by providing diagnostic information and varying degrees of exposure and feedback on performance related to sleep (see *Intervention* below). Cues to action are supported through a personalized sleep feedback appointment, coupled with information for the participant and their general practitioner (should they choose to share with their GP), about the primary sleep complaint and findings from the trial. Participants are also provided with the option of gap-free treatment for 12 months post-intervention if they choose, to address previous barriers identified with regards

to cost and access [18]. This is not compulsory for participation in the trial, and it is at the participants' discretion if they choose to access care with their own provider, or through a gap-free option at the AISH Sleep Health Clinic. This trial proposes that addressing aspects of the Health Belief Model can increase the likelihood of help-seeking behavior in a cohort of future healthcare workers. Targeting facets of the Health Belief Model have contributed to successful behavior change across a diverse range of health conditions including colorectal cancer [27], osteoporosis [28], vaccination uptake [29], and increasing levels of physical activity in healthy adults [30].

Setting

The diagnostic sleep studies and simulated night shift will be undertaken at the Nick Antic Sleep Laboratory (Flinders Health and Medical Research Institute: Sleep Health [FHMRI:Sleep Health]), a six-bedroom human sleep laboratory located at Flinders University in Adelaide, South Australia. The trial will be overseen by a qualified sleep physician, as well as registered and provisional psychologists within the co-located AISH Sleep Health Clinics. Adherence to the in-laboratory intervention will be ensured with continuous research team monitoring for the duration of a participant's stay in the sleep laboratory.

Participants

We will recruit 90 emerging and early adults aged 18–39 years with undergraduate healthcare degrees. These degree qualifications are selected due to their high likelihood of future shift work requirements (medicine, paramedicine, and nursing). Emerging (18–25 years) [31] and early (~25–40 years) adulthood is the target participant group. Participants will be recruited via electronic communications (email and course home pages), or by advertisements posted on websites and media outlets. Potential participants will initially view a brief (~15 minutes) educational video about sleep disorders in early adulthood, delivered by an early career health professional in their relevant field and a video tailored to their degree sequence. This video was designed in response to feedback from early career healthcare workers that there is insufficient education about sleep disorders for future shift workers during tertiary education, and that education needs to be provided with input from peers and professionals [32]. The videos were designed specifically for this project, with content delivered by an Australian Health Practitioner Regulation Agency registered paramedic, nurse and sleep physician, and paired with lived experience content. Potential participants will have the opportunity to express interest in the trial upon completion of the educational video.

Inclusion and exclusion criteria are summarized in Table 1.

Procedure

Screening

A series of validated sleep questionnaires will be used initially to identify risk for a sleep disorder, and are summarized in Table 2.

Enrollment and consent

Potential participants will be screened for eligibility using an online questionnaire administered via the secure online Research Electronic Data Capture (REDCap) database. Consent for the online screening will be provided electronically. Individuals with an indication of a possible sleep disorder according to screening

Table 1. Trial Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria

- Aged 18 and 39 years (inclusive)
- Currently enrolled in tertiary-level study in medicine, paramedicine, or nursing.
- Meet threshold criteria for one or more validated sleep disorder screening questionnaires:
  - Insomnia Severity Index (ISI) score ≥8
  - Epworth Sleepiness Scale (ESS) score >10
  - Screen as highly likely to have obstructive sleep apnea (OSA) on the Berlin questionnaire, and/or
  - Screen as highly likely to have restless legs syndrome (RLS) according to IRLSSG criteria
- Report a sleep difficulty in a structured clinical interview with a sleep physician or psychologist, consistent with an ICSD-3-TR or DSM-V-TR sleep disorder
	- Use of any illicit drugs or cannabis in the previous 4 weeks, or having drug dependencies that would mean they could not abstain for the duration of the extended wakefulness protocol.
	- Unmanaged current suicidal ideation or intent.
	- A history of traumatic brain injury, stroke, or neurodegenerative disorders (e.g. Parkinson's disease, Dementia).
	- Smoking dependence (non-casual smoking) which would prevent them from remaining in the laboratory to complete the study.
	- Pregnant, lactating, or caring for a newborn (under 12 months of age).
	- Undertaking shift work between the hours of midnight and 05:00 am in the three days prior to their scheduled laboratory stay.

ICSD-3-TR, International Classification of Sleep Disorders Third Edition, text revision; DSM-V-TR, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, text revision; IRLSSG, International Restless Legs Syndrome Study Group.

Table 2. Validated Sleep Questionnaires Used in Sleep Check Before Shift Work

Questionnaire	Screening purpose
Epworth Sleepiness Scale [33]	• Identifying excessive sleepiness (score > 10)
Berlin Questionnaire [34]	• Identify the risk of possible sleep apnea
Insomnia Severity Index [35]	• Determine the presence, and severity, of insomnia symptoms (score ≥8)
Pittsburgh Sleep Quality Index [36]	• Self-reported poor sleep quality (score ≥5) • Self-reported habitual bed and wake time • Self-reported habitual sleep duration
IRLSSG* restless legs symptoms criteria [37]	• Identify the risk of restless legs syndrome

IRLSSG, International Restless Legs Syndrome Study Group.

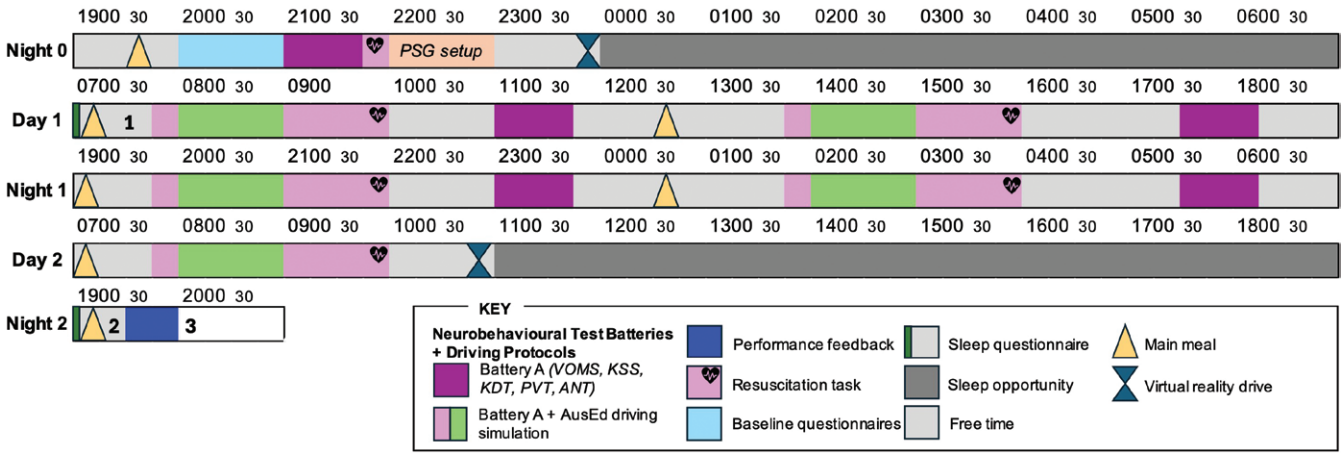

Figure 2. Conceptual example of the simulated transition to shift work protocol for a participant with 00:00 hours habitual bedtime, and 07:00 hours wake time. Protocol timing will be individualized to the participant's habitual bed and wake time to reflect the transition to the night shift relative to habitual sleep time. Numbers (1,2,3) correspond to the point at which participants conclude the protocol according to study Arm. Clock times reflect 12-hour spans across the days and nights studied. PSG, polysomnography; VOMS, vestibular-ocular motor reflexes; KSS, Karolinska sleepiness scale; KDT, Karolinska drowsiness test; PVT, psychomotor vigilance task; ANT, attention network test.

questionnaires (Table 2) will be invited to an in-person laboratory appointment, where trained research personnel will conduct a 2-hour screening and eligibility appointment.

Participants will complete a modified Structured Clinical Interview for Sleep Disorders (SCISD-R) [38] with a psychologist (registered and/or provisional), to confirm eligibility prior to randomization. This semi-structured interview covers key DSM-V-TR sleep disorders including chronic insomnia disorder, hypersomnolence disorder, circadian rhythm sleep–wake disorders, OSA, hypopnea disorder, restless legs syndrome, nightmare disorder, non-rapid eye movement (REM) sleep arousal disorders, REM sleep behavior disorder, and narcolepsy. Additional consideration of ICSD-3-TR sleep disorders according to screeners and clinical interview findings are included in the interview to screen for possible behaviorally induced insufficient sleep syndrome and sleep paralysis which are not explicitly recognized in the SCISD-R.

The SCISD-R results will be reviewed by the overseeing sleep medicine physician and/or sleep psychologist as appropriate to symptom presentation during the interview, with participants eligible if there is a high index of suspicion for a sleep disorder, subject to polysomnography or confirmation with clinical staff (according to individual sleep disorder diagnostic criteria). Participants will be provided with a tour of the sleep laboratory facilities and given the opportunity to trial tasks they would undertake on the simulated night shift protocol.

Formal informed written consent to participate in the trial will be obtained, after which participants will be randomized. Participants will be booked in for their overnight sleep study (+ simulated night shift) allowing for ~2 to 3-week sleep tracking period. They will be provided with a Withings Sleep Analyzer [39] for pre-study monitoring of habitual bed and wake times at home, and risk for OSA based on the apnea–hypopnea index. This technology has been used previously to explore sleep–wake timings [40], sleep duration [41], and variability in OSA severity over time [42].

Participants will be randomized to a trial arm once their attendance is confirmed, using 1:1:1 block randomization [43], stratified by sex and healthcare degree sequence. The randomization sequence will be generated by an independent academic (KL) who is not directly involved in either recruitment or data collection, and allocation will be blinded to participant-facing personnel and potential participants prior to consent. The randomization will occur within an embedded module in REDCap, and data will be collected and stored securely in the platform for the intervention and follow-up period. Participants will be blinded to their condition prior to attendance at the sleep laboratory for their overnight study, with the instruction to participants being to plan for attendance for the duration of the laboratory protocol. Unblinding will only be permissible if there are circumstances related to inclusion criteria and attendance, and only under the instruction of the chief investigator.

Intervention

Up to six participants will be booked at a time for the laboratory protocol. All participants will be made aware that there are multiple arms to the trial, and that length of stay in the laboratory will differ by arm allocation. Consequently, participants will be asked to plan for admission to the laboratory for the full duration of the study. Allocation to the condition will not be revealed to participants until after the diagnostic night. Participants will be admitted to the laboratory in the evening ~5 hours prior to their habitual bedtime according to their pre-laboratory sleep diaries and under-mattress sleep data, with a subsequent sleep opportunity aligned to their habitual timing. A conceptual summary of the laboratory protocol for an individual with an 0000 hours habitual bedtime and sleep opportunity of seven hours is provided in Figure 2.

All participants will undergo diagnostic PSG on night one, to measure sleep timing and architecture as well as breathing, respiratory, and muscle activity metrics critical to the diagnosis of certain sleep disorders. Electroencephalography will be measured in the frontal (F3, F4, Fz), parietal (C3, C4, Cz), and occipital (O1, O2, and Oz) areas of the brain according to the international 10–20 electrode placement system [44, 45]. Standard electromyography (EMG), electrocardiography (ECG), and electro-oculography (EOG) will be assessed, as well as respiratory (abdominal and thoracic effort), airflow, snoring, and pulse oximetry [46]. Studies will then be independently scored according to the American Academy of Sleep Medicine 2017 guidelines [47]. While not a requirement for all sleep disorder diagnoses in the trial, this approach is included

to standardize the experience for all participants and ensure diagnoses of OSA are accurate, particularly as common screening instruments are insufficiently sensitive and specific to rule out OSA [48]. Events (i.e. nausea from simulator tasks, health outcomes, headaches, and fatigue) will be recorded in individual minute-by-minute protocols for the laboratory stay, and recorded in the secure REDCap database.

Arm 1 (diagnostic polysomnography only)

Participants randomized to Arm 1 will be invited to complete overnight polysomnography and will be advised the following morning that they are able to leave the laboratory after completing a morning sleep questionnaire about their overnight sleep opportunity and eating breakfast.

Arm 2 (diagnostic polysomnography + simulated transition to shift)

Participants randomized to Arms 2 and 3 will complete overnight PSG, as per Arm 1, and additionally experience a simulated transition to the night shift immediately thereafter (Figure 2). This will comprise ~28 hours of sustained wakefulness on performance tests (and a total of ~30 hours including final meals and PSG set-up), intentionally designed to simulate transitioning from day to night shift without an opportunity to nap.

The simulated shift will comprise repetitive testing including the 10 minutes visual psychomotor vigilance task (PVT) as an indicator of sustained attention [49], the attention network test as a measure of conflict resolution, spatial orienting, and alerting [50], vestibular-ocular motor screening as an indicator of alertness [51, 52], and the AusEd driving task (Woolcock Institute for Medical Research, Sydney, Australia) to assess simulated indicators of drowsy driving in accordance with previous protocols [53]. The NASA Task Load Index (NASA-TLX) [54] and Karolinska Sleepiness Scale [55] will be measured throughout test batteries to assess perceived workload and situational sleepiness, given their established utility in a sleep deprivation context.

Participants will also be asked to undertake a ~5-minute basic life support resuscitation exercise using a Laerdal Resusci Anne QCPR (Cardiopulmonary Resuscitation) torso manikin to assess practical resuscitation abilities during the transition to the night shift. Performance on objectively recorded CPR sessions will be recorded for each exercise. Arm 2 will be provided a recovery sleep opportunity (up to 8 hours), before leaving the laboratory.

Arm 3 (Arm 2 + personalized cognitive performance feedback)

Arm 3 will experience the same simulated transition to the night shift. Upon completion of the recovery sleep opportunity, participants in Arm 3 will meet with a member of the research team prior to departure to review a standardized performance report showing their performance on PVT, driving simulation, and resuscitation tasks both when rested (first test battery after waking from diagnostic sleep), and after the final test battery in the simulated transition to night shift (sleepy). Comparison of their results to published performance after alcohol, and after longer sleep deprivation, will be shown for PVT performance, and comparison to participants with healthy sleep opportunities who experienced the same driving and wakefulness protocol in our sleep laboratory will be shown for driving performance. The simulated night shift can induce fatigue and sleepiness, and individuals respond differently. Being unable to maintain wakefulness, and needing to cease the protocol, reflects the impact of the transition for an individual. Consequently, for both Arms 2 and 3, a participant can remain in the trial once they have started the simulation, even if they need to cease the protocol early and sleep. For participants in Arm 3 who cease the protocol early, their performance data to the point of cessation will be compared to their baseline during feedback. Any adverse events related to the protocol will be recorded in minute-by-minute protocols, and in the central REDCap system.

Clinical follow-up appointment

In the week following the completion of their laboratory visit, all participants will attend a ~30-minute sleep physician and/or sleep psychologist appointment either at the AISH Clinic (located at Flinders University), or via telehealth, subject to participant preference. During the appointments, participants' sleep difficulties and symptoms will be discussed and clinicians will explain gold standard, evidence-based options for treatment of any identified sleep disorder(s), including written information about relevant sleep disorder(s) from the Australian Sleep Health Foundation webpage. Participants will be provided with the choice of cost-free treatment for their sleep disorder via referral to the AISH Sleep Health Clinic at Flinders University as part of the trial, or a letter explaining any trial findings related to their sleep for their General Practitioner if external treatment is preferred. It will be at the patient's discretion which treatment option/s (if any) they choose to engage with following this appointment, and participation in the trial is not contingent on help-seeking through the AISH Sleep Health Clinic.

Follow-up contact

After completion of the in-person component, participants will receive a monthly REDCap link via a short message service to complete brief questions (~2 minutes) about their help-seeking behavior for sleep for 12 months. Participants will have the option to request contact for sleep treatment at these monthly check-ins should they choose. Participants will also be asked to complete comprehensive follow-up online questionnaires at 3, 6, 9, and 12 months electronically through the REDCap online questionnaire system, per Table 3 and Supplementary Table 2. Follow-up contacts will occur via short message service, phone calls, and email for data capture to adequately track time to help-seeking. At 3 months, interviews will consider the motivation for participation, explore help-seeking (or non-help-seeking) behavior according to the Health Belief Model, and ask participants in Arms 2 and 3 to reflect on whether the simulation and performance feedback informed their help-seeking behavior. At 6, 9, and 12 months, check-ins will also consider any new or sustained behavior related to sleep. All interviews will contribute to a Process Evaluation, in order to assess the effectiveness, acceptability, appropriateness, and feasibility of the interventions. This will be conducted by a member of the research team with qualitative methods experience either via phone call, online (Microsoft Teams), or in-person subject to participant preference. Interviews will be recorded and transcribed.

Participant compensation

Participants will receive compensation in recognition of the time required to participate in the laboratory component of the trial, and subsequent follow-up. Across all arms, participants will receive $340 for participation in the in-laboratory study and clinical follow-up appointment. They will subsequently receive $20 gift cards for 3-, 6-, and 9-month follow-ups, and $100 for the final

Table 3. Primary Clinical Effectiveness and Implementation Outcomes for the Sleep Check Before Shift Work Trial

Outcome	Description and unit	Collection points across 12-month follow-up
Help-seeking for sleep disorders		
Sought help from a health care professional specifically for sleep	• Self-report of healthcare appointments *(categorized as yes/no over the 12-month follow-up, proportion)*	Monthly
Time to the appointment with a health professional specifically for sleep	• Self-report of appointments with a health professional to discuss sleep *(number of days post diagnostic appointment to first appointment)*	Monthly
Road safety events		
Self-reported driving events in the follow-up period	• Self-reported instances of falling asleep at the wheel, near-miss incidents due to sleepiness, or an incident or crash due to sleepiness in the past month (categorized as yes/no) • Self-reported indicators of sleepy or distracted driving [56] (total number endorsed per follow-up)	Quarterly
Implementation outcomes (process evaluation)		
Acceptability of intervention design	• Acceptability of intervention measure (AIM) score [57], continuous	Quarterly
Appropriateness of intervention design	• Intervention appropriateness measure (IAM) score [57], continuous	Quarterly
Feasibility of intervention design	• Feasibility of intervention measure (FIM) score [57], continuous	Quarterly
	• Semi-structured interviews with participants, qualitative	3, 6, 9, and 12 months

12-month follow-up, to compensate time required to participate in questionnaires and interviews.

Outcomes

Primary outcomes for clinical effectiveness and implementation of the trial are summarized in Table 3. Additional secondary outcomes will be collected over the course of the study relating to mental health, quality of life, and sleep symptoms, and are summarized in Supplementary Table 2. Quantitative and qualitative data collection approaches have been selected based on pilot feasibility work in a similar population to the proposed recruitment group, where high responsivity to mixed methods was observed in the population of interest [18]. As there are no RCTs to enhance help-seeking in young adults with sleep disorders to appropriately calculate sample size for RCTs, this work represents a critical step in piloting personalized feedback using a higher-cost in-laboratory design. This is essential to determine whether resource allocation to simulation and personalized reports is justified in larger trials, with a sample size sufficient to consider the breadth of sleep disorders across gender and healthcare degrees. This work will directly inform feasibility in larger samples and appropriate sample size targets for future large-scale RCTs in this population.

Data analysis

The primary software used to conduct statistical analyses will be R Studio (RStudio Team 2018, Boston, MA) with R version 4.3.2 (R Core Teams 2021, Vienna, Austria). Data transformations will be performed as appropriate for meeting statistical assumptions. If appropriate, and in accordance with published recommendations, multiple imputation will be used to manage missing data [58].

Using the intention to treat, binary logistic regression analysis will be used where the endpoint (help-seeking: yes/no) is compared by the trial arm. Time-to-event (survival) analysis will be conducted, with the event of interest being the number of days from the diagnostic interview (T_0) to a participant's self-reported appointment with a healthcare provider to discuss sleep management. Cox proportional hazards models [59] will be utilized with time (days) to help-seeking behavior and trial arm allocation (condition). This approach allows for the inclusion of cases lost to follow-up, as well as consideration of time-varying covariates [60]. We will include stratification factors for randomization (sex and degree sequence) as factors in analyses.

The acceptability, appropriateness, and feasibility of the intervention approach will be analyzed both quantitatively [57] and qualitatively. In accordance with developer instructions, scales will be created for each of the measures respectively by averaging responses and using linear mixed-effects models to consider differences between trial arms, and any changes in perceived acceptability, appropriateness, and feasibility over follow-up [57]. Qualitative analysis of feasibility and acceptability will be facilitated through semi-structured interviews, using both an inductive and deductive approach. Process evaluation will involve deductive coding to explore the participant's experience with the intervention across components of the Health Belief Model (perceived susceptibility and severity, perceived barriers or costs, perceived benefits, cues to action, and self-efficacy). We will explore similarities and differences between those who engage in help-seeking behavior, and consider these in the context of modifying factors including baseline demographic and psychological characteristics [61] to understand influences on implementation.

Subject to meeting assumptions for analysis, a combination of negative binomial logistic regression and mixed effects models will be used to examine the relationship between the intervention arm and driving events (categorized as Y/N), or indicators of fatigued driving (number and frequency of indicators endorsed) at quarterly follow-ups, allowing for within- and between-group comparisons of driving-related events. Appropriate adjustment for multiple comparisons will be incorporated in reporting, and exploratory analyses beyond the primary and secondary endpoints will be labeled accordingly.

Participant-level data will not be available for public access due to the confidential nature of clinical data and the potential for individual identification with less prevalent sleep disorder presentations. Access may be requested through the corresponding

author (ACR) and provided subject to consultation and consent from the local ethics office. Access to statistical code can be made available by the authorship teams with the publication, and the primary outcome paper will be publicly available through open-access publication.

Discussion

Undiagnosed sleep disorders pose a considerable risk to health and safety, and emerging evidence suggests that in shift workers, these can go undiagnosed for extended periods of time. Previous feasibility work suggests that supporting early and emerging adults to access cost-free sleep disorder management is not sufficient alone to prompt help-seeking. Time constraints, financial constraints, and pathways to access mental health care plans needed for accessing government rebatable sleep services are limiting factors [18]. Consequently, feasibility work in young adults suggests that managing a known sleep disorder is not a priority, despite presenting as symptomatic [18]. Yet, there are known productivity, health, and safety (road and workplace) consequences of unmanaged sleep disorders, in some cases with greater negative impacts for shift workers with sleep disorders [4, 17, 62]. This trial will inform the level of personal exposure and performance feedback future shift workers may require to encourage help-seeking for sleep problems and begin an important co-design process for determining implementation pathways should the trial be successful.

This trial should be considered in light of some strengths and limitations from the outset. A key strength is the inclusion of a gap-free treatment option on-site at the AISH Sleep Health Clinic, in response to feasibility work which suggests that this is an obstacle to care. This will be optional, and at the participant's discretion, and trial participation will not be dependent on a choice to engage with the clinic if they prefer to use their own primary care provider. The trial is potentially vulnerable, as with many clinical effectiveness trials, to self-selection bias, whereby participants who volunteer to participate may be more likely to have an interest or motivation to access care. This will be considered during semi-structured interviews in order to transparently reflect the motivations for participation and potential impacts for generalizability.

Sleep check before shift work addresses an unmet need by considering proactive education and introducing early intervention opportunities before the added burden of shift work is experienced by our healthcare workforce. This study is the first to implement a program designed to increase early help-seeking in the real-world setting for prospective shift workers and provide essential insight into implementation needs to support this vulnerable workforce. If effective, this intervention has the potential to improve health and safety outcomes for individuals and reduce the productivity burden in workplaces attributable to sleep disorders in young adults. Importantly, the hybrid implementation-effectiveness design will provide a strong foundation for advocating for policy change to improve access to sleep services which meet the needs of emerging and early adulthood. This has the potential for broader implications related to improving the well-being of the healthcare workforce and improving visibility and awareness of the benefits associated with managing sleep disorders.

Dissemination

Findings from the trial will be disseminated in peer-reviewed scientific manuscripts, through academic and industry conferences, and via broader public opportunities provided by the funder (Lifetime Support Authority). State and national healthcare providers will be approached to share information which can be integrated into local education for sleep management for healthcare providers through our existing networks. Upon completion of the trial, we will also share trial findings with participants, and broader industry networks impacted by shift work. Authorship of publications will be in accordance with CrediT (Contributor Roles Taxonomy) criteria, and subject to input for design, conduct, analysis, and reporting of findings.

Supplementary material

Supplementary material is available at *SLEEP Advances* online.

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Author Contribution

Claire Dunbar (Data curation [supporting], Project administration [equal], Writing - original draft [equal], Writing - review & editing [equal]), Kelly Sansom (Funding acquisition [supporting], Project administration [supporting], Writing - original draft [supporting], Writing - review & editing [supporting]), Nicole Lovato (Methodology [supporting], Project administration [supporting], Supervision [supporting], Writing - review & editing [supporting]), Andrew Vakulin (Data curation [supporting], Funding acquisition [supporting], Methodology [supporting], Resources [supporting], Software [supporting], Writing - review & editing [supporting]), Kelly Loffler (Formal analysis [supporting], Methodology [supporting], Project administration [supporting], Software [supporting], Writing - review & editing [supporting]), Katrina Nguyen (Data curation [supporting], Project administration [supporting], Writing - review & editing [supporting]), Josh Fitton (Data curation [supporting], Project administration [supporting], Writing - review & editing [supporting]), Tracey Sletten (Funding acquisition [supporting], Methodology [supporting], Resources [supporting], Writing - review & editing [supporting]), Shantha Rajaratnam (Funding acquisition [supporting], Methodology [supporting], Writing - review & editing [supporting]), Sian E Wanstall (Funding acquisition [supporting], Methodology [supporting], Resources [supporting], Writing - review & editing [supporting]), Brandon Brown (Funding acquisition [supporting], Methodology [Supporting], Resources [supporting], Writing - review & editing [supporting]), Gillian Harvey (Methodology [supporting], Resources [supporting], Supervision [supporting], Writing - review & editing [supporting]), Amy Reynolds (Conceptualization [lead], Data curation [lead], Formal analysis [lead], Funding acquisition [lead], Investigation [lead], Methodology [lead], Project administration [equal], Supervision [equal], Writing - original draft [equal], Writing - review & editing [equal]), Gorica Micic (Project administration [supporting], Supervision [supporting], Writing - review & editing [supporting]), Sally Ferguson (Funding acquisition

[supporting], Writing - review & editing [supporting]), and Robert Adams (Conceptualization [equal], Funding acquisition [supporting], Methodology [equal], Project administration [supporting], Supervision [equal], Writing - review & editing [equal])

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Data Availability

Access to trial data will be at the discretion of the chief investigator (ACR), subject to the granted ethical approvals for the trial. Model consent form and other related documentation given to participants can be requested from the corresponding author.

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