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Improving sleep health in paramedics through an app-based intervention: a randomised waitlist control pilot trial

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Abstract

Background Due to work commitments, shiftworkers often obtain inadequate sleep, consequently experiencing negative health, wellbeing, and safety outcomes. Given shiftworkers may have limited control over their work commitments, lifestyle and environmental factors within their control may present an intervention opportunity. However, such interventions require tailoring to ensure applicability for this sleep-vulnerable population.

Methods A randomised waitlist control pilot trial investigated the effectiveness of mobile health application *Sleepfit*, which delivered a tailored sleep health intervention aimed at improving sleep health and sleep hygiene outcomes amongst paramedic shiftworkers. Outcome measures of self-reported sleep health (sleep need, duration, and quality, fatigue, Insomnia Severity Index, Fatigue Severity Scale, and Epworth Sleepiness Scale scores) and sleep hygiene (Sleep Hygiene Index score) were collected at baseline, post-intervention, and 3-month follow-up.

Results Fifty-eight paramedics (aged 33.4±8.0 years; 50% male) were recruited, and trialed *Sleepfit* for a 14-day intervention period between August 2021–January 2022. For all participants, there was a significant reduction in Insomnia Severity Index and Sleep Hygiene index scores after intervention engagement. Regression models demonstrated no significant intervention effect on sleep health or sleep hygiene outcomes (intervention versus waitlist control group). A high study drop-out rate (91.4%) prevented assessment of outcomes at 3-month follow-up.

Conclusions Pilot trial findings demonstrate that *Sleepfit* may elicit improvements in sleep health and sleep hygiene outcomes amongst paramedic shiftworkers. However, low enrolment and retention means that findings should be interpreted with caution, further highlighting potential engagement challenges, especially among paramedics who are particularly in need of support for improved sleep.

Trial registration Prospectively registered with the Australian New Zealand Clinical Trial Registry 24/01/2020 (reference no. ACTRN12620000059965).

Keywords Sleep hygiene, mHealth, Shiftwork

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Background

Shiftwork, requiring individuals to work beyond conventional office hours of 0800-1800, disrupts natural human circadian rhythms [1]. This disruption results from irregular sleep and wake times, shortened sleep periods, and misaligned light exposure and food intake, among other factors [2]. This can lead to circadian misalignment, which may negatively impact shiftworkers' health, wellbeing, productivity, and safety [3, 4], increasing risk of cognitive impairment [5], mood disturbances [6], cardiovascular disease [7], metabolic syndromes [8], and workplace errors and injuries [3, 4]. Despite these consequences, shiftwork has significant economic and societal benefits, as it allows many critical services to operate across extended hours, if not continuously [9]. Paramedicine - the delivery of pre-hospital emergency healthcare - is one such service.

Paramedics operate across a variety of contexts, including within ambulance settings, as well as hospitals and community-based clinics [10]. As part of their role, paramedics are required to work in 'unscheduled, unpredictable or dynamic' environments [10], in which it may be difficult to control the factors contributing to the negative impacts of their work schedules. For example, paramedics are rarely able to control external stimuli (e.g., light exposure) or consistently engage in beneficial behaviours (e.g., strategic napping) to limit the damaging effects of shiftwork [11]. Therefore, interventions designed for the general population may not be appropriate for this cohort, with such challenging shift-working environments prompting a considered approach to the tailoring of interventions aimed at improving shiftworker sleep.

A number of interventions aiming to improve sleep health are available to shiftworkers. Such interventions may incorporate pharmacological elements (i.e., sleep-inducing medications; [12]), cognitive elements (e.g., cognitive behavioural therapy for insomnia; [13]), or behavioural elements (e.g., improving sleep hygiene; [14]). However, given the variation in shiftwork arrangements (shift timing and length, roster configurations, variable work environments etc.), and the interindividual differences (age, gender, comorbidities etc.), there is no universally accepted approach to implementing these interventions. Instead, a stepped care model should be employed, with the most cost-effective and non-invasive strategies trialed first [15]. This often involves providing shiftworkers with education about sleep health through sleep hygiene advice [16].

Sleep hygiene refers to lifestyle and environmental factors which can be adapted to optimise sleep quality and quantity [17], and was originally developed to improve sleep outcomes for adults with insomnia [18]. However, sleep hygiene advice has since been found to have limited efficacy as a stand-alone treatment for this sleep disorder, and is now a tool for improving sleep health in the general population [16], with demonstrated efficacy in children and adolescents [19, 20], adults [21, 22], older adults [23], and athletes [24, 25]. Sleep hygiene advice is founded on a diurnal sleep pattern, and therefore assumes that individuals implementing this advice have the ability to optimise their lifestyle and environmental factors around 'normal' sleep/wake patterns (e.g., going to bed and waking at the same time each day, avoiding bright light during nighttime hours) [17]. Shiftworkers, by virtue of their work commitments and non-traditional sleep/wake patterns, will likely experience significant difficulty in implementing such advice [17]. Further, some elements of sleep hygiene advice contradict evidencebased fatigue management strategies (e.g., avoidance of daytime sleep, limitation of caffeine intake), further contributing to the challenges shiftworkers experience in implementing sleep hygiene [17]. Perhaps as a result, sleep hygiene advice has not been widely investigated as a strategy to improve shiftworker sleep [17]. Given this limited research attention, further investigations exploring the tailoring of sleep hygiene advice for shiftworkers, and subsequent impacts on their sleep health, may be of benefit.

Identifying opportunities for interventions that may improve shiftworker sleep health is only one part of the solution. Methods to deliver such interventions effectively and on a large scale are another essential consideration. Given their dynamic work environment, paramedics lack a consistent context or schedule in which they could be reliably targeted with sleep interventions. For example, they may begin and end their shifts at a base or station but spend their working hours across a range of locations (e.g., ambulance, community, hospitals etc.). As such, positioning interventions within a single location may not be practical or efficacious. Additionally, many elements of sleep hygiene advice for shiftworkers would include lifestyle and environmental factors which require action during non-work hours or in non-work environments, which further suggests that a portable, non-work-based intervention may be of benefit. As such, tailored sleep hygiene advice could be delivered in a format which is accessible at any time and in any place - personalised digital interventions offer this important flexibility [26].

In conjunction with the growth in health and wellbeing self-management [27], personalised digital interventions (i.e., wearable technologies, mobile health applications) aimed at improving sleep health are rapidly gaining popularity [28]. Mobile health applications (apps) in particular are increasingly being trialed in occupational contexts [29, 30], including with shiftworkers [31, 32], and have demonstrated improvement in sleep hygiene in the general population [33]. However, sleep hygiene advice tailored for shiftworkers is yet to be implemented through such a platform. Therefore, this study aims to trial a sleep health-based mobile health intervention, incorporating sleep hygiene advice tailored for shiftworkers, to explore the following research questions:

- 1. Can a sleep health intervention, incorporating tailored sleep hygiene advice, delivered via a mobile health application improve sleep health outcomes in shiftworkers?
- 2. Can a sleep health intervention, incorporating tailored sleep hygiene advice, delivered via a mobile health application improve sleep hygiene outcomes in shiftworkers?
- 3. How do shiftworkers engage with a mobile health application delivering tailored sleep hygiene advice?

Methods

Study design

This study was conducted as a two-group randomised waitlist controlled pilot trial amongst paramedic shiftworkers in Queensland, Australia, between August 2021 and January 2022 (5 months). Participants were randomised in a 1:1 ratio to either intervention (Sleepfit use for 14 days) or waitlist control (14-day waitlist period, followed by *Sleepfit* use for 14 days) groups. Outcomes were assessed at baseline, post-intervention, and followup (3 months after intervention completion) through data collected in online questionnaires and the *Sleepfit* app. Prior to recruitment, ethics approval was obtained from the Human Research Ethics Committee at Central Queensland University, Australia (reference no. 0000021715), and the study was registered with the Australian New Zealand Clinical Trials Registry (reference no. ACTRN12620000059965). Organisational approval was also obtained from Queensland Ambulance Service. All participants provided informed consent to participate in the study and could withdraw participation at any time for any reason, with their associated data omitted from analysis. No changes to the methodology were made after trial commencement. The results of this study are reported in adherence with CONSORT guidelines [34].

Population

Participants were shiftwork employees of Queensland Ambulance Service (QAS), in Queensland, Australia. QAS is divided into regions that approximately align with the Hospital and Health Services Areas operated by Queensland Health, through which public healthcare is provided [35]. Participants were sought from the Metro North Region, which provides emergency pre-hospital healthcare and non-urgent transport to a population of approximately 900,000 people [36]. Staff in this region Page 3 of 17

(n=1830) were invited to participate via email, in which they were provided with study information and a link to register their interest. Participants were informed that they would not receive any specific incentives or remuneration for participating, beyond free use of the app and potential benefits to their sleep health and sleep hygiene. In order to register, participants were required to confirm they met the inclusion criteria of being currently employed as a shiftworker by QAS. This included 'onroad' staff in clinical (e.g., paramedics, patient transport officers) and non-clinical (e.g., managerial staff) roles. This cohort of paramedic shiftworkers were employed across a variety of roster types, however, the most common structure involved working 4-5 shifts in a row, with shifts lasting 10-12 h each, and a minimum of 10 h break between shifts. The vast majority of rosters are forward rotating, and may include day (e.g., 7:00am-7:00pm), afternoon (e.g., 11:00am-9:00pm), evening (2:00pm-2:00am), and night (e.g., 6:00pm-6:00am) shifts, followed by 3-5 days off.

As this is a pilot trial, the data obtained will inform sample size calculations for future, larger-scale investigations. In line with best practice recommendations, a minimum of 30 participants (i.e., 15 participants per group) were recruited to estimate effect sizes [32, 37].

Intervention development

This study utilised mobile app *Sleepfit* as a base platform. Sleepfit offers evidence-based assessment of user sleep health, reports for sharing with healthcare professionals, as well as sleep education and tailored behavioural solutions for the user. Sleepfit Solutions, which operates Sleepfit, has a collaborative relationship with the authors and their broader research organisation (Appleton Institute, CQU), spanning several years. The relationship has facilitated non-funded trialing and evaluation of a number of products, with related publications forthcoming. At commencement of the project, the existing content within *Sleepfit* was designed for people who were able to maintain traditional sleep/wake patterns (i.e., non-shiftworkers), and required tailoring by the research team, where appropriate, to incorporate information that was relevant for shiftworkers.

All existing *Sleepfit* content was assessed by members of the research team (AES, GEV, SAF, GR) against the current evidence base on sleep in shiftworkers, including fatigue management guidelines [38] and the outcomes of previous research [39]. In reviewing existing *Sleepfit* content, the research team assessed whether the advice aligned with best-practice advice and maintained relevance for shiftworkers. In the event that the existing *Sleepfit* content was incongruent with this evidence, the research team members with content expertise in sleep and shiftwork (AES, GEV, SAF, GR) convened to tailor the content to ensure applicability to shiftworkers. This involved a consensus approach, in that the research team developed tailored advice as a group, which was only finalised for inclusion in *Sleepfit* when all members of the research team were in agreement that the tailored advice (i.e., content, language) accurately reflected the bestpractice advice for shiftworkers. As an example of this process, existing sleep hygiene advice, including that used in Sleepfit, often recommends the avoidance of daytime napping, or limitation of caffeine intake [16], however, both of these are well-established fatigue management practices for shiftworkers [38]. As such, this advice was tailored to reflect the relevant fatigue management advice (i.e., using daytime naps to reduce sleep debt, and using caffeine before and during shift to minimise fatigue). There were no instances in which consensus agreement on such amendments and/or inclusions was unable to be reached.

Intervention content was organised across ten modules by theme and delivered through 52 activities in *Sleepfit* (e.g., short articles, educational quizzes, guided meditation). Figure 1 provides an overview of the *Sleepfit* user interface, while Table 1 contains further information regarding the activities within each module. Additional features were included to track engagement with content and implementation of advice, including a sleep diary, goal setting, and daily check-ins via a chatbot. All elements of *Sleepfit* (i.e., opening the app, engaging with the content, sleep diary entries, etc.) were optional throughout the intervention period, in that participants were able to use *Sleepfit* as frequently as they chose. Participants could elect to receive prompts (i.e., mobile phone

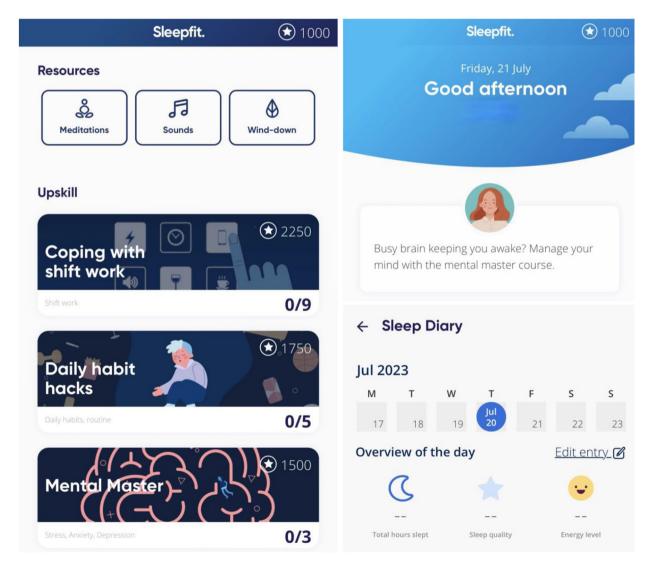


 Table 1
 Content included in each Sleepfit module

| Module | Activities | | | | |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Sleep Disorders and Concerns | Insomnia Sleep apnoea Shift work disorder Jetlag Sleep medication Parasomnias | REM sleep disorder Dreams & nightmares Restless legs syndrome Narcolepsy Bruxism Delayed sleep phase disorder | | | |
| Sleep Science | Neurological activity Ageing & sleep needs | Dreaming Role of genetics | | | |
| Sleep and Physical Health | Disease risk Weight loss & sleep | Pain & sleepPregnancy & sleep | | | |
| Sleep and Mental Health | Stress, anxiety & depression Thoughts impact sleep | Thinking patterns & insomnia | | | |
| Sleep Health | Long-term outcomesDaily habits | Bedroom impacts | | | |
| Coping with Shift Work | Circadian rhythm education Fatigue management strategies Napping Sleep inertia Caffeine | Physical activity Daytime sleeping Scheduling health behaviours Nutrition | | | |
| Daily Habit Hacks | Sleep drivers Cognitive processes Lifestyle factors | Daily habits Sleep problems | | | |
| Mental Master | Stress Unhelpful thoughts | Anxiety & worry | | | |
| Bedroom Makeover | Technology use Noise, temperature & light | Mattress & bedding Bedroom atmosphere | | | |
| Relaxation Relay | Guided meditationProgressive muscle relaxationAutogenic training | Visualisation activity Sleep sounds | | | |

notifications) at a time of their choosing each day, which would remind them to open and engage with *Sleepfit*.

A brief diagnostic tool administered upon opening the app for the first time remained functional in *Sleepfit* during participant use. This tool is used to assess risk of common sleep disorders (e.g., insomnia, obstructive sleep apnoea), and recommend user action (e.g., generating a letter that could be provided to a general practitioner). While functional during the intervention period, the data collected by this tool was not obtained or analysed by the research team for the purposes of this study.

Procedure

Following expression of interest, all participants were asked to complete an online pre-intervention (baseline) questionnaire which collected data on sleep health and sleep hygiene outcomes, as well as demographic information (age, gender, relationship status, number of dependents) and work characteristics (usual shift pattern, hours worked per week, years in service). Income and socioeconomic data was not collected, given the homogenous nature of participants in terms of industry and occupation. Following completion of the baseline questionnaire, participants were assigned via 1:1 simple randomisation [40] to either the intervention group or waitlist control group. Those participants allocated to the intervention group were then provided with access to Sleepfit, including email instructions on downloading and using the app for the following 14-day intervention period. This timeframe was selected to enable participants to complete a full rotation of shifts and rostered days off during the intervention period, whilst encompassing the various roster types commonly used by QAS. Additionally, a 14-day intervention period is frequently selected as the minimum amount of time required to trial app-based interventions focusing on sleep [41]. During the intervention period, participants were presented with the same content within *Sleepfit* (i.e., all participants saw the same modules and activities), however, could selfselect which content they engaged with, and could do so as much or as little as they chose. During this period, those in the waitlist control group were advised to continue their usual work and non-work routines, including sleep patterns.

Following the 14-day intervention period, participants in the intervention group completed a post-intervention questionnaire, assessing sleep health and sleep hygiene outcomes. At this point, waitlist control participants completed a post-waitlist questionnaire, which collected the same information as the baseline questionnaire. Following this, waitlist control participants were provided with access to *Sleepfit*, and completed the 14-day intervention protocol. At the end of the intervention period, waitlist control participants also completed the post-intervention questionnaire. At the conclusion of each group's intervention period, engagement data (number of diary entries and activities completed) were collated for each participant from *Sleepfit* backend data. All participants were asked to complete a follow-up questionnaire 3-months after completion of their intervention period to assess sleep health and sleep hygiene outcomes. Figure 2 provides a graphical representation of the study protocol timeline.

Measures

To determine the impact of *Sleepfit* on sleep health and sleep hygiene, self-report data were collected by shift type and on rostered days off for sleep duration (in hours), quality of sleep (on 5-point Likert scale from $1 - 'extremely \ badly'$ to $5 - 'extremely \ well'$), and frequency of feeling fatigued (on 5-point Likert scale from $1 - 'almost \ never'$ to $5 - 'almost \ always'$), as well as overall sleep dissatisfaction (on 5-point Likert scale from $0 - 'very \ satisfied'$ to $4 - 'very \ dissatisfied'$ as isolated from the Insomnia Severity Index). Participants also self-reported their perceived sleep need (in hours) regardless of shift type, and completed the following measures: Insomnia Severity Index (ISI), Fatigue Severity Scale (FSS), Epworth Sleepiness Scale (ESS), and Sleep

Invitation to

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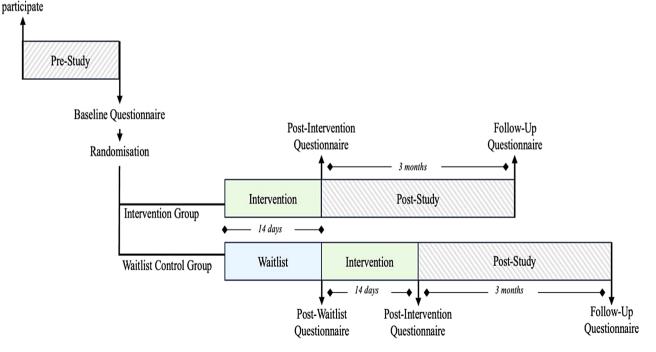
Hygiene Index (SHI). To investigate outcomes in relation to engagement with *Sleepfit*, the number of activities (out of a possible 52) and the number of diary entries (maximum of one diary entry each day for 14 days) completed were downloaded from backend data, as provided to the research team by *Sleepfit*, at the end of the intervention period. Supplementary Table 1 describes the timepoints at which each measure was collected.

Insomnia severity index

The ISI is a 7-item measure assessing sleep and waketime impacts of insomnia, with questions answered on a 5-point Likert scale. The ISI has a maximum score of 28, with scores over 14 suggestive of moderate-severe insomnia [42]. The ISI has demonstrated internal consistency and reliability in measuring perceived sleep difficulties, including amongst shiftworkers [43, 44].

Fatigue severity scale

The FSS is a 9-item instrument that assesses the effects of fatigue on daily life, with questions answered on a 7-point Likert scale. The FSS provides a maximum score of 63, with higher scores indicative of greater fatigue severity and impact [45]. There is some evidence that scores greater than 45 are indicative of abnormal levels of fatigue [46, 47]. The FSS has demonstrated validity and reliability in measuring clinically relevant fatigue [48, 49].



Epworth sleepiness scale

The ESS is an 8-item measure that assesses waketime sleepiness, with questions answered on a 4-point Likert scale. The ESS reports a maximum score of 24, with scores greater than 11 indicative of excessive sleepiness during wake hours [50]. The ESS has demonstrated validity and reliability in measuring waketime sleepiness, including amongst shiftworkers [44, 51].

Sleep hygiene index

The SHI is a 13-item measure of frequency of engagement in problematic sleep hygiene practices, with questions answered on a 5-point Likert scale. A maximum score of 52 is possible, with higher scores indicative of poorer sleep hygiene [52], with demonstrated validity and reliability for measuring sleep hygiene engagement [53].

There were no changes to outcome measures after trial commencement.

Statistical analysis

SPSS v29 [54] was used for statistical analyses. Due to the high drop-out rate at 3-month follow-up (91.4%), inferential analyses were performed only for the comparison of baseline to post-intervention (14-days of *Sleepfit* use) data (i.e., baseline measurement, followed by postintervention measurement for the intervention group compared to post-waitlist measurement for the waitlist control group). Given both groups received the same intervention, post-intervention measurement was then collapsed down for all participants to further understand intervention effect. To test for change in measures across the study, paired sample t-tests were conducted, with Bonferroni multiple comparison corrections of statistical significance applied. Pearson correlations were used to determine the relationship between intervention engagement and outcomes. Effects of Sleepfit on sleep health and sleep hygiene outcomes were tested using multiple linear regression models, with outcomes regressed onto intervention group, adjusted for the covariates of age, gender, and years in service. Prior to models being tested, univariate and multivariate assumption testing was conducted, with no assumptions unmet. Although statistical significance is reported for all tests, the aim of the pilot is informing anticipated effect sizes for larger scale trials and therefore the focus of the results interpretations is on effect sizes. Given this exploratory, pilot trial approach, a power analysis was not conducted [37, 55, 56], with Cohen's d of 0.3 or greater considered to be a moderate effect size, and Cohen's *d* above 0.8 a large effect size [57].

Results

Participants

The flow of participants through the study is illustrated in Fig. 3. Following invitation, 71 paramedics expressed interest in participating (3.9% of those invited), with 58 (81.7%) of these completing the baseline questionnaire and randomised to either the intervention (n=29) or waitlist control (n=29) group.

Sample demographic and work characteristics

Participant demographic and work characteristics are presented in Table 2. The mean age of participants was 33.4 years (\pm 8.0), with 50.0% (n=29) identifying as male. The majority of participants (77.6%) were married or in a de facto relationship, with half (51.7%) living with dependents under the age of 18 years.

Participants worked, on average, a total of 46.2 h per week (± 6.8) across 3.9 shifts (± 0.8). Most participants worked day (91.4%), night (70.7%) and afternoon (56.9%) shifts as part of their regular roster and had worked in the service for an average 8.7 years (± 5.6).

Changes in sleep health outcomes

Changes in sleep health outcomes, including those measured by shift type, at post-waitlist measurement are presented in Supplementary Table 2. At this timepoint, sleep duration had increased for afternoon shifts, but decreased for night shifts, amongst the intervention group, with moderate-large effect sizes. Sleep quality had also mostly declined amongst the intervention group across most shift types, with the exception of rostered days off, again with moderate-large effect sizes. Finally, at this timepoint, fatigue on evening shifts amongst intervention group participants had reduced with a moderate effect size.

Following collapse of all participants post-intervention, descriptive statistics of sleep health outcomes measured at baseline and post-intervention are presented in full in Supplementary Table 3, with Fig. 4 illustrating significant findings. Sleep dissatisfaction and insomnia severity decreased from baseline to post-intervention, both with a moderate effect size. Sleep duration when rostered on day shift and sleep quality when rostered on evening shift increased, while sleep duration when rostered on evening shift decreased, both with a moderate effect size. For clarity, measures of sleep duration and sleep quality refer to sleep obtained in relation to rostered shift types, and not sleep obtained during the actual shift. Fatigue during day shifts decreased, however, fatigue during afternoon and evening shifts increased, again, all with a moderate effect size.

The results of the regression models used to test the effects of intervention group on sleep health outcomes, adjusting for age, gender, and years in service are presented in Supplementary Table 4, with Fig. 5 illustrating significant findings. There was no statistically significant effect of group on sleep health outcomes. Participants who were older and served more years in the service

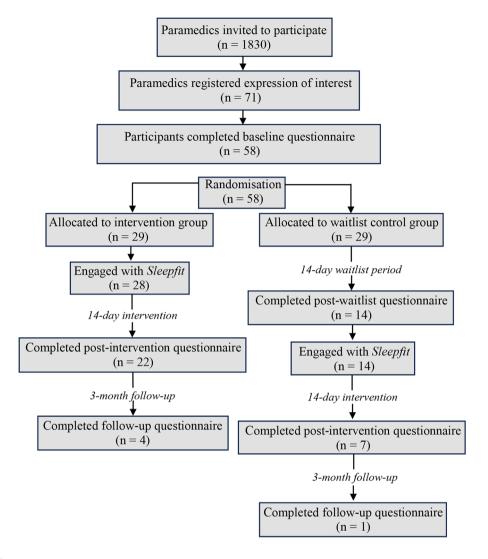


Fig. 3 Participant flow through study

tended to have a lower sleep need, regardless of shift type. A similar relationship was observed with participant age and average sleep duration, with older participants demonstrating lower sleep duration.

Changes in sleep hygiene outcomes

Changes in sleep hygiene outcomes at post-waitlist measurement, including the overall SHI score, as well individual item scores, are presented in Supplementary Table 4. One item score (Q8 – going to bed stressed, angry or upset) demonstrated a statistically significant reduction for the intervention group at this timepoint, with a large effect size. Several other item scores (Q4, Q7, Q11, Q12, Q13) also reduced with moderate-large effect sizes, but did not reach significance, while some item scores (Q2, Q6, Q10) increased amongst the intervention group at this timepoint, also with moderate-large effect sizes. Following collapse of all participants post-intervention, as presented in Table 3, overall SHI score reduced with a moderate effect size, as did the frequency of waking at different times each day (Q3), staying in bed longer than required (Q5), doing something wakeful before bed (Q7), and going to bed stressed, angry, or upset (Q8). However, the frequency of sleeping on an uncomfortable bed (Q10) increased, also with a moderate effect size.

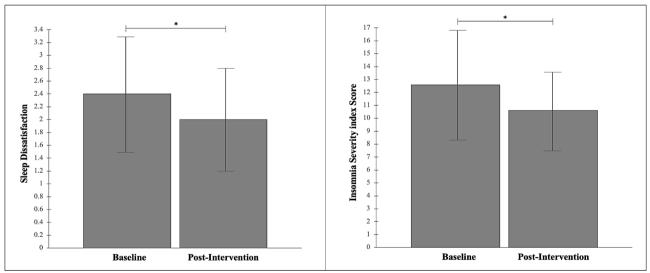
The results of the regression models used to test the effects of intervention group on sleep hygiene outcomes, adjusting for age, gender, and years in service, are presented in Table 4. Frequency of going to bed stressed, angry, or upset (Q8) was the only sleep hygiene outcome affected by group, with those in the intervention group reporting less frequent engagement. Participant age was associated with several sleep hygiene outcomes, with older participants reporting lower overall sleep hygiene score, as well as going to bed (Q2) and waking up (Q3) at

Table 2 Participant demographics and work characteristics

| | All (<i>n</i> = 58) | Intervention Group (n=29) | Waitlist Control Group (n=29) | <i>p</i> -value |
|-----------------------|-------------------------|------------------------------|----------------------------------|-----------------|
| | n (%) | n (%) | n (%) | |
| Gender | 29 (50.9%) | 11 (39.3%) | 18 (62.1%) | 0.05 |
| Male | 28 (49.1%) | 17 (60.7%) | 11 (37.9%) | |
| Female | < 5 | < 5 | < 5 | |
| Non-Binary | | | | |
| Relationship Status | 45 (83.3%) | 21 (77.8%) | 24 (100%) | 1.00 |
| Married/De Facto | <5 | <5 | < 5 | |
| Separated/Divorced | 9 (16.7%) | 6 (22.2%) | <5 | |
| Single | | | | |
| Dependents < 18 years | 30 (51.7%) | 13 (44.8%) | 17 (58.6%) | 0.08 |
| Routine Roster* | 53 (91.4%) | 28 (96.6%) | 25 (86.2%) | 0.72 |
| Day Shifts | 33 (56.9%) | 21 (72.4%) | 12 (41.4%) | 1.00 |
| Afternoon Shifts | 11 (19.0%) | <5 | 8 (27.6%) | 0.12 |
| Evening Shifts | 41 (70.7%) | 21 (72.4%) | 20 (69.0%) | 0.33 |
| Night Shifts | | | | |
| | M (SD) | M (SD) | M (SD) | |
| Age | 33.4 (8.0) | 32.7 (7.5) | 34.2 (8.6) | 0.06 |
| Rostered Hours/Week | 41.3 (6.1) | 41.4 (7.0) | 41.3 (5.2) | 0.97 |
| Overtime Hours/Week | 4.9 (2.9) | 5.1 (3.1) | 4.6 (2.7) | 0.52 |
| Total Hours/Week | 46.2 (6.8) | 46.5 (7.6) | 45.9 (5.9) | 0.87 |
| No. Shifts in a Row | 3.9 (0.7) | 3.8 (0.9) | 3.9 (0.6) | 0.69 |
| Years in Service | 8.7 (5.6) | 8.3 (5.3) | 9.0 (6.0) | 0.38 |

NB: Statistical significance set at p < 0.025 via Bonferroni correction for multiple test comparisons. Where there were less than 5 participants in a category, < 5 is shown in the table to avoid potential identification of individuals. For these variables, percentages were calculated excluding these participants from the denominator. This applies to the following variables: gender (non-binary category); relationship status (separated/divorced; and single categories)

* Shift types were not mutually exclusive, in that participants may have more than one shift type as part of their regular roster. Examples of shift timing: day shift (e.g., 7am-7pm), afternoon shift (e.g., 11am-9pm), evening shift (e.g., 2pm-12pm), night shift (e.g., 6pm-6am)



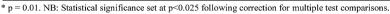


Fig. 4 Significant changes to sleep outcomes at baseline and post-intervention

different times, staying in bed longer than required (Q5), doing something wakeful before bed (Q7), and thinking, planning, and worrying in bed (Q13), less frequently than younger participants. Years in service was also associated with several sleep hygiene measures. Participants with more years in service reported going to bed at different times (Q2), staying in bed longer than required (Q5), doing something wakeful before bed (Q7), and thinking, planning, and worrying in bed (Q13) less frequently than participants with fewer years in service. Finally, relationships between participant gender and individual item scores were also noted. Participants identifying as female



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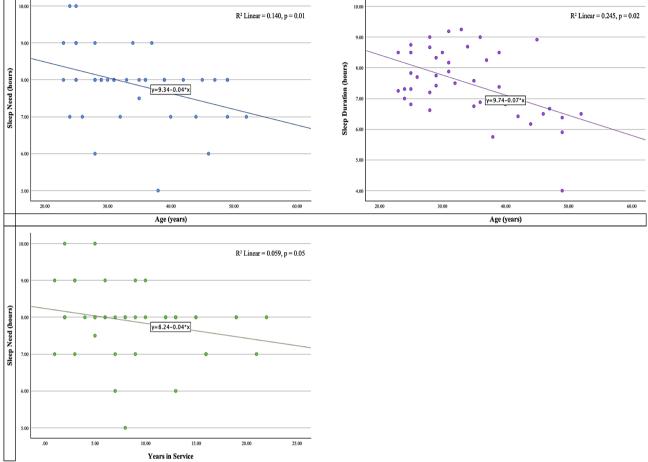


Fig. 5 Significant effects of intervention (Group), age, gender, and years of service on sleep outcomes

| | Baseline | Post-Intervention | Effect Size |
|------------------------------------------|------------------|-------------------|-----------------------|
| | (<i>n</i> = 58) | (<i>n</i> =29) | |
| | M (SD) | M (SD) | d (p-value) |
| Overall SHI score | 20.41 (4.60) | 18.76 (4.76) | -0.50 (0.01) |
| SHI Q1 Daytime naps | 0.62 (0.90) | 0.45 (0.63) | -0.23 (0.23) |
| SHI Q2 Different bedtimes | 2.66 (1.01) | 2.62 (0.86) | -0.04 (0.82) |
| SHI Q3 Different waketimes | 2.66 (0.90) | 2.45 (0.95) | -0.31 (0.11) |
| SHI Q4 Exercise before bed | 0.72 (0.80) | 0.62 (0.73) | -0.17 (0.38) |
| SHI Q5 Staying in bed | 1.62 (1.08) | 1.34 (1.14) | -0.33 (0.09) |
| SHI Q6 Substances before bed | 1.10 (1.01) | 1.14 (0.99) | 0.03 (0.87) |
| SHI Q7 Wakeful activity before bed | 2.62 (0.78) | 2.34 (0.94) | -0.33 (0.09) |
| SHI Q8 Stressed, angry, upset at bedtime | 1.72 (0.65) | 1.17 (0.47) | -0.75 (0.01) |
| SHI Q9 Wakeful activities in bed | 1.69 (1.23) | 1.45 (1.24) | -0.25 (0.18) |
| SHI Q10 Uncomfortable bed | 0.38 (0.62) | 0.66 (0.81) | 0.47 (0.02) |
| SHI Q11 Uncomfortable bedroom | 0.93 (1.03) | 1.10 (0.86) | 0.16 (0.39) |
| SHI Q12 Important work before bed | 1.48 (0.83) | 1.31 (0.71) | -0.21 (0.26) |
| SHI Q13 Think, plan, worry in bed | 2.21 (0.82) | 2.10 (0.67) | -0.13 (0.48) |

NB: Statistical significance set at p < 0.025 following correction for multiple test comparisons. SHI=Sleep Hygiene Index

Table 4 Effects of intervention (Group), age, gender, and years of service on Sleep Hygiene outcomes

| | Variable | β | SE | p | | Variable | β | SE | р |
|---------------------|------------------|---------|------|-------|-----------------------------------|------------------|---------|------|-------|
| SHI Score | Group | 0.15 | 1.62 | 0.39 | SHI Q7 | Group | 0.20 | 0.29 | 0.26 |
| | Age | -0.53 | 0.08 | 0.002 | Wakeful activity | Age | -0.64 | 0.01 | 0.001 |
| | Gender | 0.22 | 1.50 | 0.22 | before bed | Gender | 0.19 | 0.27 | 0.29 |
| | Years in service | -0.24 | 0.13 | 0.16 | | Years in service | -0.32 | 0.02 | 0.06 |
| SHI Q1 | Group | -0.16 | 0.69 | 0.48 | SHI Q8 | Group | -0.60 | 0.14 | 0.001 |
| Daytime naps | Age | -0.19 | 0.02 | 0.41 | Stressed, angry, | Age | -0.17 | 0.01 | 0.23 |
| | Gender | 0.00 | 0.25 | 1.00 | upset at bedtime | Gender | -0.06 | 0.13 | 0.68 |
| | Years in service | -0.01 | 0.03 | 0.97 | | Years in service | -0.24 | 0.01 | 0.09 |
| SHI Q2 | Group | 0.11 | 0.33 | 0.53 | SHI Q9 | Group | 0.23 | 1.19 | 0.30 |
| Different bedtimes | Age | -0.38 | 0.02 | 0.03 | Wakeful activities in bed | Age | 0.03 | 0.03 | 0.90 |
| | Gender | 0.30 | 0.30 | 0.09 | | Gender | -0.09 | 0.43 | 0.70 |
| | Years in service | -0.32 | 0.03 | 0.06 | | Years in service | 0.14 | 0.06 | 0.56 |
| SHI Q3 | Group | -0.02 | 0.29 | 0.89 | SHI Q10 Uncomfortable bed | Group | 0.15 | 0.27 | 0.39 |
| Different waketimes | Age | -0.42 | 0.02 | 0.02 | | Age | 0.19 | 0.01 | 0.29 |
| | Gender | 0.21 | 0.27 | 0.24 | | Gender | -0.09 | 0.25 | 0.64 |
| | Years in service | -0.23 | 0.02 | 0.18 | | Years in service | 0.28 | 0.02 | 0.10 |
| SHI Q4 | Group | 0.20 | 0.79 | 0.36 | SHI Q11 Uncomfortable bedroom | Group | 0.25 | 0.29 | 0.14 |
| Exercise before | Age | -0.28 | 0.02 | 0.23 | | Age | -0.28 | 0.02 | 0.10 |
| bed | Gender | 0.44 | 0.26 | 0.04 | | Gender | 0.26 | 0.27 | 0.14 |
| | Years in service | -0.28 | 0.04 | 0.25 | | Years in service | -0.05 | 0.02 | 0.78 |
| SHI Q5 | Group | 0.08 | 0.36 | 0.65 | SHI Q12 Important work before bed | Group | 0.08 | 0.72 | 0.71 |
| Staying in bed | Age | -0.58 | 0.02 | 0.001 | | Age | -0.10 | 0.02 | 0.67 |
| | Gender | 0.36 | 0.32 | 0.04 | | Gender | 0.08 | 0.26 | 0.71 |
| | Years in service | -0.44 | 0.03 | 0.01 | | Years in service | 0.13 | 0.03 | 0.60 |
| SHI Q6 | Group | -0.19 | 1.04 | 0.39 | SHI Q13 | Group | 0.03 | 0.24 | 0.87 |
| Substances before | Age | 0.03 | 0.03 | 0.89 | Think, plan, worry in bed | Age | -0.33 | 0.01 | 0.06 |
| bed | Gender | 0.07 | 0.38 | 0.75 | | Gender | 0.36 | 0.22 | 0.05 |
| | Years in service | 0.07 | 0.05 | 0.78 | | Years in service | -0.47 | 0.02 | 0.004 |

NB: SHI=Sleep Hygiene Index; β = standardised effect sizes

Table 5 Engagement with *Sleepfit* by Intervention Group

| | All (n=42) | Intervention Group (n=28) | Waitlist Control Group (n=14) |
|------------------------------------------------------------|---------------|---------------------------------|----------------------------------------|
| | M (SD) | M (SD) | M (SD) |
| Learning activities completed (out of 52 activities) | 7.3 (9.8) | 5.9 (7.7) | 10.1 (12.9) |
| Diary entries made (days, out of 14 days) | 9.3 (4.8) | 9.2 (4.7) | 9.4 (5.2) |

reported going to bed at different times (Q2), exercising before bed (Q4), staying in bed longer than required (Q5), and thinking, planning, and worrying in bed (Q13) more frequently.

Sleepfit engagement

Descriptive statistics of participant engagement with *Sleepfit*, as measured by the number of activities completed (out of a possible 52 activities) and number of days diary entries were made (out of a possible 14 days), are presented across Table 5 and Supplementary Table 5. On

average, participants engaged with seven of the available 52 activities, and completed sleep diary entries on nine of the 14 days during the intervention period. In regard to specific modules, Daily Habit Hacks and Coping with Shift Work were the most engaged with; activities within these modules were completed by, on average, 11 participants (26.2%). Within Daily Habit Hacks, an activity on relationships between habits and sleep problems was the most popular, being completed by 26 participants (61.9%), while in Coping with Shift Work, all activities were engaged with reasonably frequently, by 12-17 participants (28.6 - 40.5%). This was with the exception of one activity on sleep inertia, and one on physical activity, which were completed by no participants. Modules on general sleep and sleep health information (e.g., *Sleep* Science and Sleep and Physical Health) were the least popular modules; activities within these were completed, on average, by 1-2 participants (2.4 - 4.8%).

The results of the regression model testing associations of engagement with *Sleepfit* are presented in Table 6. Sleep need, ESS, and SHI scores all increased as the number of completed activities increased, all with a moderate

| | Number of activities | | | Number of o | Number of diary entries | | |
|----------------------------------|----------------------|------|------|-------------|-------------------------|------|--|
| | β | SE | p | β | SE | р | |
| Sleep need (regardless of shift) | 0.39 | 0.02 | 0.07 | -0.26 | 0.05 | 0.24 | |
| Sleep duration (average) | 0.21 | 0.03 | 0.35 | 0.09 | 0.06 | 0.70 | |
| Sleep quality (average) | -0.15 | 0.02 | 0.52 | 0.25 | 0.04 | 0.29 | |
| Sleep dissatisfaction | -0.03 | 0.02 | 0.89 | 0.09 | 0.05 | 0.73 | |
| Fatigue (average) | -0.01 | 0.01 | 0.99 | 0.02 | 0.03 | 0.95 | |
| Insomnia Severity Index score | -0.04 | 0.08 | 0.87 | -0.09 | 0.18 | 0.71 | |
| Fatigue Severity Scale score | 0.28 | 0.17 | 0.20 | -0.36 | 0.36 | 0.12 | |
| Epworth Sleepiness Scale score | 0.34 | 0.10 | 0.12 | -0.01 | 0.22 | 0.98 | |
| Sleep Hygiene Index score | 0.44 | 0.12 | 0.04 | -0.22 | 0.27 | 0.31 | |

Table 6 Association of Sleepfit Engagement with Sleep and Sleep Hygiene outcomes

 β = standardised effect sizes

effect size. Conversely, FSS score decreased as the number of diary entries increased, also with a moderate effect size.

Discussion

This randomised waitlist control pilot trial investigated whether engagement with tailored sleep hygiene advice, as delivered through a sleep health-based intervention via mobile health app *Sleepfit*, could improve sleep health and sleep hygiene outcomes amongst paramedic shiftworkers. After collapsing post-intervention measures for both waitlist and intervention groups, significant reductions in ISI and SHI scores were observed following Sleepfit use, in addition to reduced sleep dissatisfaction and less frequent engagement with a range of poor sleep hygiene practices. These findings were observed relative to baseline measurement for all participants post-use of Sleepfit, resulting in no significant between-group differences. While potentially suggestive of intervention efficacy in improving sleep health and sleep hygiene outcomes, these outcomes were demonstrated in the context of notably higher participant engagement with shiftworkspecific content in the intervention.

In considering the impact of *Sleepfit* on sleep health outcomes, it is worth noting that this cohort reported better than expected sleep, at both baseline and postintervention measurements. Both self-reported sleep need, and actual sleep duration, when averaged across shift type and rostered days off, were between 7.5 and 8.0 h for most participants - well within the recommended sleep duration for healthy adults [58], and inconsistent with other literature that has demonstrated lower average sleep duration for shiftworkers [59–63]. However, sleep duration is not the only metric by which sleep is measured, and despite reporting 'normal' sleep need and duration, participants presented with insomnia severity scores indicative of mild or subthreshold insomnia. Positively, however, at post-intervention measurement, this score had reduced, on average, by two points (12.6 at baseline to 10.6 at post-intervention measurement) for all participants. This is promising, given the many factors (e.g., age, gender, roster type) that can contribute to sleep problems in shiftworkers [64]. The reduction in insomnia severity is complemented by reduced sleep dissatisfaction, with an almost half-point reduction at post-intervention measurement. These findings could therefore be interpreted as an improvement in sleep health amongst this cohort of shiftworkers following *Sleepfit* use.

In determining Sleepfit impact on sleep hygiene outcomes, a significant reduction in SHI score, after collapsing both intervention and waitlist measures, indicates participants were less frequently engaging in poor sleep hygiene after *Sleepfit* use. This was reinforced by decreases in several item level scores, illustrating that participants were waking up at different times each day, staying in bed longer than required, doing something wakeful before bed, and going to bed stressed, angry, or upset less frequently after using Sleepfit. Despite improvements in sleep hygiene, mean SHI scores at both baseline (20.4) and post-intervention (18.8) remained at a level that has previously been suggestive of poor sleep hygiene [65]. This indicates that, while positive changes were seen following the use of Sleepfit, this cohort of shiftworkers demonstrated engagement with sleep hygiene behaviours, both at baseline and post-intervention measurement, that may not be supportive of sleep health. This finding is consistent with previous research on such behaviours in this sleep-vulnerable population [39, 66, 67].

Findings from this pilot trial are indicative of positive outcomes following *Sleepfit* use regarding sleep health and sleep hygiene amongst paramedic shiftworkers, however, this is noted in the absence of between-group differences, and only observed after both waitlist and intervention group measures were collapsed. These findings are intriguing in the context of limited participant engagement with many of the activities offered in *Sleepfit*: most participants engaged with only seven of the 52 available activities. However, of note, shiftwork-specific activities appeared more popular than those focused on

generic sleep-related content. For example, one activity - a short educational article on daily strategies to improve sleep problems as a shiftworker - was by far the most popular, being read by two-thirds of participants. Activities addressing more general sleep topics (e.g., the relationship between physical health and sleep) were consistently less popular amongst participants. Another engagement theme emerged relating to content overlap. For topic areas that had more than one activity, participants rarely engaged with more than one activity on the same topic. In such instances, the activity that was more shiftwork-focused (e.g., scheduling physical activity around shiftwork versus the importance of physical activity) was engaged with more frequently. These findings are supported by the outcomes of previous investigations, which demonstrated that mobile health interventions demonstrate higher shiftworker engagement, particularly long-term, when the content is tailored, as opposed to that available to the general population [68]. Additional personalisation to an individual level (e.g., tailoring for their particular roster pattern) has been demonstrated to further enhance engagement, and is worth considering when conducting future trials on sleep hygiene or sleep health-based interventions for shiftworkers [68].

Some shiftworkers demonstrated greater intervention engagement than others, with those participants with a higher self-reported sleep need, and higher ESS and SHI scores demonstrating greater engagement with Sleepfit (i.e., engaged with more activities and completed more diary entries). This suggests that those participants with higher levels of waketime sleepiness and poorer sleep hygiene were more actively utilising Sleepfit. This is positive, as some research has previously suggested that shiftworkers may be less likely to seek information on, or assistance with, sleep problems [69]. The inconsistency of the current findings when compared to previous research may represent shiftworkers experiencing difficulty with locating or implementing sleep health advice that is relevant to their unique work and lifestyle commitments, and therefore strengthens the argument for shiftwork-specific sleep health information.

This study has demonstrated potential improvements in both insomnia severity and sleep hygiene engagement amongst shiftworkers following the provision of sleep health information, including tailored sleep hygiene advice. However, previous research has shown that, while education can elicit such outcomes, combining this with cognitive behavioural elements (i.e., cognitive behavioural therapy for insomnia, CBT-i) enhances improvements in sleep health and sleep hygiene [29]. While the present intervention did offer some CBT-i techniques (e.g., guided meditation, visualisation), these elements were presented in isolation, without wrap-around therapeutic and educational components. Further, and perhaps as a result of the aforementioned issue, participants demonstrated limited engagement with these elements of *Sleepfit* - the guided meditation component was the most popular, with only 14% of participants using this feature. In addition to the benefits of incorporating cognitive behavioural elements, previous research has highlighted specific considerations when trialling such interventions in an occupational context. Specifically, when developing and evaluating such interventions, engaging shiftworkers themselves to provide input and advice on relevant content (e.g., a co-design process) can improve future intervention outcomes [30, 31].

Strengths, limitations and future directions

The findings of this pilot trial provide tentatively promising evidence in regard to improvements in sleep health and sleep hygiene outcomes, however, several limitations should be considered. Outcomes were reliant on self-report measures, and it is therefore worth considering the benefit of including objective measures to enhance this data. For example, self-reported sleep need, regardless of shift type, may not be an accurate reflection of the amount of sleep that individuals actually need, particularly if long-term shiftwork has led to a degree of 'acclimatisation' to chronically poor sleep [1, 70]. Objective measurements of sleep health and sleep hygiene outcomes were not feasible in this communitybased pilot study, however, and as such, there could be potential response bias for those participants who completed through to post-intervention measurement, in that they may not have genuinely experienced changes to sleep health or sleep hygiene, but instead, had a greater understanding of these areas after intervention engagement (i.e., what high quality sleep or sleep hygiene is). Future studies would benefit from incorporating objective measures, particularly of sleep health (e.g., actigraphy, polysomnography) to better understand changes to this outcome following engagement with a sleep hygiene intervention. While evidence supports most shiftworkers accurately self-reporting performance and alertness [71], objective measures (e.g., psychomotor vigilance tasks) would provide further evidence for changes to waketime functioning, in addition to the self-report changes described by participants.

As a result of the sample size, sub-group analyses comparing the impact of the intervention in participants with varying levels of sleep quality and quantity (i.e., good vs. poor sleepers), and varying levels of sleep hygiene engagement, were precluded. As such, this is recommended as a focus of investigations into similar interventions in the future. Further, in regard to sleep hygiene outcomes, it must be noted that sleep hygiene is conceptualised through the lens of a diurnal sleep pattern. As such, the sleep hygiene practices that shift workers are being measured against (e.g., going to bed and waking up at the same time each day) are not always appropriate or relevant, given the non-traditional sleep and wake patterns that shiftworkers maintain. While the reduction in SHI score in this study is promising, it is difficult to truly understand how shiftworkers are engaging with sleep hygiene without a more appropriately constructed measure. Recently developed sleep hygiene (healthy sleep practice) guidelines for shiftworkers [67] may be a tool that could inform an adaptation of the SHI to ensure it can act as a more relevant benchmark by which to measure sleep hygiene in shiftworkers.

There was a low response rate in this study. This is not uncommon in studies utilising similar methods of recruitment amongst this particular group of healthcare workers (paramedics), but nonetheless, may indicate selection bias. There was also a high drop-out rate throughout the study, with more than 90% participants not completing the study to 3-month follow-up. While 22 of the 29 participants initially assigned to the intervention group engaged with Sleepfit, and completed the post-intervention measures, only 14 of the 29 participants assigned to the waitlist control group did the same. This is therefore a form of selection bias, and may explain the lack of observed, statistically significant intervention effect or between-group differences. It is also possible that the smaller number of waitlist control group participants that completed post-intervention measures contribute to the lack of observed, statistically significant intervention effect (i.e., type 2 error). Further, very few participants in both groups completed 3-month followup, therefore limiting investigation of ongoing changes to sleep health and sleep hygiene outcomes. Although a power analysis was not conducted due to the exploratory, pilot trial research design, the low response rate and high rate of attrition contributes to an underpowering of the analyses throughout. This should be taken into consideration when interpreting the current findings and their application.

The low response rate and drop-out rate may be explained by the period in which the study was conducted, during which the healthcare system, including QAS, was under increased operational demand due to COVID-19 [68], which may have resulted in paramedics being less inclined to participate in research. Also in relation to intervention engagement, it is worth noting that, for the purposes of this pilot study, app engagement metrics (number of activities completed, number of diary entries made) were the only objective measures. Future studies would benefit from incorporating additional objective measures, particularly in relation to intervention engagement, to develop a deeper understanding of participant engagement with such apps. The use of machine learning and/or artificial intelligence could be particularly beneficial in regard to iterative measurement of, and learning from, user patterns of engagement, both of which have demonstrated efficacy in measuring and responding to health behaviours [72, 73].

In light of the aforementioned limitations of the study, the findings may provide tentative evidence for the potential feasibility of an app-based sleep health intervention for improving sleep health and sleep hygiene outcomes in shiftworkers. For future studies investigating such interventions, consideration should be given to how engagement with these tools can be optimised for participants, and whether challenges with ongoing engagement is linked to shiftworkers having a limited understanding of sleep hygiene [39, 69], or a reluctance to seek help for sleep problems [66]. Other strategies that could improve engagement may involve embedding connectivity functionality with existing devices that are already being used by participants (e.g., smart watches, digital biometric devices such as weight scales), and consequent expansion of app interactivity (i.e., tracking sleep wake-time). This connectivity, particularly if involving wearable technologies, has demonstrated feasibility in monitoring sleep outcomes in community-based samples [74]. This would offer the added benefit of incorporating objective measures and could provide feedback to participants to demonstrate changes to such measures (e.g., improvements in sleep duration during intervention use). Further, future studies should consider trialling such interventions for longer periods. A 14-day period was selected for this pilot trial, as it was determined to be the minimum amount of time that such an intervention could be reasonably tested [41], whilst allowing participants to complete both rostered periods of work and non-work. It is worth noting that, specifically for female participants, hormonal fluctuations across a roughly 28-day cycle can impact sleep, and as such, extending the trial period and/or capturing menstrual cycle data would be helpful in mitigating this [75]. Finally, it is worth noting that future investigations building upon the promising findings of this pilot trial should consider expanding the tailoring of content beyond that conducted by the research team. This should involve incorporating a wider array of shiftwork industries (e.g., mining, transport, manufacturing) and schedules, as these different contexts have different impacts on sleep health and sleep hygiene engagement for shiftworkers. In such investigations, it would be important to capture variation in income and/or socioeconomic data, which wasn't measured in this study given the homogeneity of participants in terms of occupation and industry. These future investigations would also benefit from incorporating elements of co-design with specific cohorts of shiftworkers and/or subject matter experts to tailor the content for the unique needs of specific industries. Tailoring could also be strengthened through the

use of artificial intelligence or machine learning, which could monitor and adapt to user patterns of behaviour to develop tailored goals for improving sleep health and sleep hygiene outcomes, building on the provision of general advice. This further tailoring will allow for more rigorous testing and improved efficacy of such interventions for this diverse sleep-vulnerable population.

The results of this pilot study should be interpreted in the context of the above limitations, and potential sources or measurement and selection bias.

Conclusion

This study investigated engagement with a tailored sleep health-based intervention to improve sleep health and sleep hygiene amongst paramedic shiftworkers. In this pilot trial, results indicate that such an intervention may improve sleep, specifically by reducing insomnia severity and improving engagement with sleep hygiene, however, a low response and high attrition rate means results should be interpreted with caution. Given the well-documented impacts shiftwork has on health, wellbeing, and safety, and the significant contribution that shift-working industries make to society, interventions to improve shiftworker sleep require ongoing investigation.

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s12889-024-19823-w.

Supplementary Material 1

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Author contributions

AES: study conceptualisation and design, data collection, data analysis, reporting. GEV: study conceptualisation and design, reporting. SAF: study conceptualisation and design, reporting. AR: data analysis, reporting. TKA: reporting. GR: study conceptualisation and design, reporting. All authors read and approved the final manuscript for publication.

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Data availability

The de-identified data that supports the findings of this study is available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This study received ethics approval from the Central Queensland University Human Research Ethics Committee (reference no. 0000021715) and was prospectively registered with the Australia New Zealand Clinical Trials Registry (reference no. ACTRN1262000059965). Written informed consent was sought from all participants prior to enrolment in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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