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Determining the influence of a sleep improvement intervention on medical students' sleep and fatigue: protocol of the PROMESS-Sleep clinical trial

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Abstract

Background Medical students face a demanding workload, stressful situations, and irregular sleep patterns, which can lead to elevated sleep disturbances and high fatigue levels. These difficulties may be further associated with a major decline in well-being, quality of life, performance, and health. Thus, these struggles must be addressed to reduce these students' sleep disturbances and fatigue during their curriculum.

Methods The PROMESS-Sleep clinical trial aims to support future healthcare professionals by enhancing their abilities to manage their sleep. The support will be provided through a three-session sleep management program. Each session will include an individual meeting between a PROMESS-Sleep expert and a medical student, during which self-care education, advice, and personalized goals will be established. The present protocol is designed to assess the influence of this program on 45 undergraduate medical students (fourth- and fifth-year) of the Lyon-Est Faculty of Medicine (Claude Bernard University Lyon 1, France). Assessments of sleep and fatigue will be conducted before and during the intervention using self-reported questionnaires and actigraphy. At the end of the third session, the student's satisfaction levels regarding the program will be assessed.

The primary outcome will be changes in scores on the Pittsburgh Sleep Quality Index (PSQI) during the program. Secondary outcomes will provide a detailed characterization of changes in various aspects of sleep disturbances, fatigue, sleep habits, and sleep-wake rhythms. Exploratory outcomes will provide information regarding the students' satisfaction levels and will determine the moderators of the program's efficacy.

Data will be analyzed according to the intention-to-treat principle and presented in accordance with the CONSORT Guidelines. Ethical approval has been obtained by the Institutional Review Board (IRB: 2023-07-04-03), and all procedures will be performed in adherence to the Helsinki Declaration. The results from this study will be presented at scientific conferences and in peer-reviewed scientific journals.

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Discussion The results will provide valuable insights into the program's efficacy in reducing sleep disturbances and fatigue. If its efficacy is proven, PROMESS-Sleep could become an integral and sustainable part of medical education due to fostering a healthier and more resilient future for healthcare professionals.

This manuscript follows the SPIRIT guidelines (Additional files 1 & 8).

Trial registration ClinicalTrials.gov: NCT06297330; retrospectively registered.

Keywords Actigraphy, Curriculum, Disturbance, Fatigue, Health intervention, Pedagogy, Peer coaching, Prevention, PSQI, Physiology, Remediation, Sleep

Background

Medical students face numerous difficult situations, such as intense academic workloads, hyper-competitive examinations, stressful situations, peer pressure, irregular schedules, and night shifts [1–4]. Confronting these situations may cause these students significant difficulties in taking care of their sleep and managing fatigue. Medical students experience numerous sleep disturbances, such as sleep deprivation, poor sleep quality, altered sleep-wake cycles, excessive sleepiness, and critical fatigue levels [3, 5–7]. Previous studies have reported that sleep disturbances are associated with lower well-being [8], altered quality of life [1], and the critical deterioration of mental health (i.e., increased levels of anxiety and depression symptoms [3]). While the influence of sleep disturbances on medical students' physical health remains unexplored, deterioration is expected. It has been widely reported that short sleep duration is associated with many diseases (e.g., diabetes, hypertension, cardiovascular and coronary heart diseases, and obesity [9]). In addition, sleep disturbances are associated with altered emotional regulation, decreased cognitive impairment, reduced academic success, and deteriorated patient safety [3, 6, 10–12].

Given that medical students often face challenging situations that can cause sleep disturbances during their studies and professional activities, it is crucial to introduce programs early in their curriculum to help mitigate these disturbances and their consequences. In university students, many interventions for sleep improvement have been validated, including sleep hygiene education, cognitive behavioral therapy for insomnia, relaxation and mindfulness, and technology-based interventions like sleep tracking apps [13, 14].

However, despite the urgent need to help medical students improve their sleep, the influence of sleep interventions on these students remains poorly explored. To our knowledge, only five sleep interventions have been explored in medical students (i.e., sunrise alarm clock and electronic device removal at bedtime, dormitory environment advice, sleep education and sleep trackers, and health habits feedback) [15–19]. While these interventions have offered interesting results in terms of improving sleep, comprehensive sleep management programs considering the specific needs and constraints of medical students are still required.

In response, sleep interventions can be collaboratively developed with medical students and faculty members to address these specific needs through co-construction workshops [4]. To date, the literature has revealed that efficient sleep interventions require changes in habits, such as maintaining a regular sleep schedule and avoiding using screens [20, 21]. Thus, programs should include planning these changes, setting goals, and receiving encouragement and personalized advice to increase intention to change [22]. As an initial step in this direction, our team involved medical students and faculty members in developing a sleep improvement program entitled Preventive Remediation for Optimal MEdical StudentS (PROMESS)-Sleep [4]. PROMESS-Sleep is a preventive program that aims to provide solutions to medical students to reduce sleep disturbances during their curriculum. It includes multiple one-on-one sessions, during which an expert will provide self-care educational content and personalized assessments related to sleep. These sessions will also provide a platform for students to discuss their personal challenges related to sleep and fatigue while identifying their needs. Personalized advice and goal-setting will stem from these discussions.

Aims

This clinical trial will aim to determine the influence of the PROMESS-Sleep program on medical students' sleep disturbance and fatigue levels. The primary outcome will be changes in scores on sleep disturbances assessed using the PSQI during the program [23]. Secondary outcomes will provide a detailed characterization of changes in various aspects of fatigue, sleep habits, and sleep-wake rhythms. This study defines fatigue as a multidimensional concept with four key dimensions that evaluate its impact across various aspects of an individual's life. These dimensions, highlight both physical and psychological components (i.e., general fatigue, mental fatigue, motivation, reduced activities; Multidimensional Fatigue Inventory [24, 25]). Exploratory outcomes will provide information regarding the students' levels of satisfaction and will determine the moderators of the program's

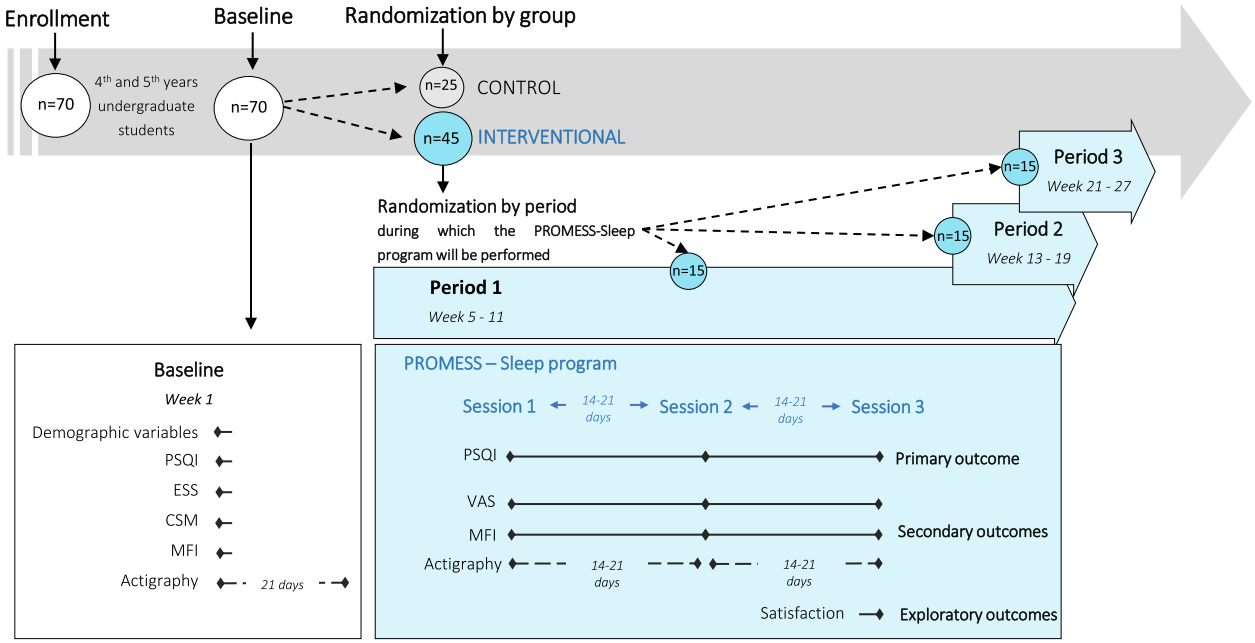

Fig. 1 Study Design. Seventy undergraduate medical students will be enrolled. First, students will perform baseline measurements. Then, they will be randomized into a control or an interventional group stratified by gender and study years (fourth or fifth). This clinical trial (PROMESS-Sleep) will specifically focus on the interventional group ($n = 45$). Each student in this group will be simply randomly assigned to one of the three periods to follow a sleep improvement program (i.e., PROMESS-Sleep). This program will consist of three sessions spaced 14 to 21 days apart. The primary outcome will be the PSQI scores during sessions 1, 2, and 3. Secondary outcomes will comprise VAS scores, MFI scores, and sleep variables assessed through a survey and/or actigraphy. Exploratory outcomes will include the student's level of satisfaction regarding the program and will determine the moderators of the program's efficacy. Abbreviations: CSM, Composite Scale of Morningness; ESS, Epworth Sleepiness Scale; MFI, Multidimensional Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index; VAS, Visual Analog Scale

efficacy. It is supposed that the level of sleep disturbances and fatigue will decrease during the program. In addition, as the intervention has been co-designed by local health professionals and medical students [4], the students are expected to be highly satisfied with the program.

Methods/design

Design and setting

This study is part of a larger randomized controlled trial assessing the effects of a multimodal health intervention called the PROMESS project [26]. The project will be presented to all fourth- and fifth-year undergraduate students of the Lyon-Est Faculty of Medicine (Claude Bernard University Lyon 1, France) through a lecture. An informative email will be sent to their university addresses. Volunteer students can register for the project by replying to the email. The first 70 volunteers will be recruited. No exclusion criteria will be applied. For the entire PROMESS project, the 70 students recruited will be randomized into two groups (1:2 ratio): a control group ($n = 25$) and an interventional group ($n = 45$; stratified by gender and years of study). The present clinical trial (PROMESS-Sleep) will specifically focus on the interventional group, in which 45 students will undergo a preventive program focused on sleep improvement (Fig. 1).

Ethic statement

The research project was discussed and approved by the dean of the faculty (GR), the Lyon University Health Department, and a sample of local medical students. All procedures will be performed in adherence to the Helsinki Declaration [27]. Ethical approval from the Institutional Review Board of the Claude Bernard University Lyon 1 (CUMG, France) was obtained (IRB 2023-07-04-03), and the study was registered in ClinicalTrials.gov (NCT06297330). Modifications to the protocol that may impact the conduct of the study will require a formal amendment. The participants' anonymity and confidentiality will be ensured and maintained according to laws and regulations. The principal investigator (SS) will provide oral and written information and participants will provide a written consent before enrollment in the study following sufficient reflection time (Additional file 2).

Characterization of the population at baseline

Before the intervention, participating students will complete a brief demographic survey, providing information

regarding their year of study, age, gender, height, weight, level of physical activity and sport practice, smoking status, and any medication use. Their levels of sleep disturbances, fatigue, sleep habits, and sleep-wake rhythms will be assessed through questionnaires and actigraphy to establish baseline scores.

Sleep disturbances, fatigue and sleep habits

A set of the following questionnaires will be answered at baseline:

Pittsburgh Sleep Quality Index The PSQI is composed of 19 items that assess the quality of sleep and sleep disturbances during the last month [23]. The questionnaire evaluates seven dimensions: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleep medication use, and daytime dysfunction. Each dimension is scored from 0 (no difficulty) to 3 (severe difficulty), and the sum of the seven dimensions creates a global score ranging from 0 to 21. The highest global score indicates the highest sleep disturbances, while a global score of 5 or higher indicates sleep disturbances. The French-validated version will be used, which has good internal consistency (Cronbach's alpha 0.88) [28].

Epworth Sleepiness Scale The ESS is an 8-item questionnaire that assesses daytime sleepiness in recent times [29]. Sleepiness is defined as an increased propensity to doze off or fall asleep [30]. For each item that corresponds to a specific situation, subjects must evaluate their risk of dozing, from 0 (no chance of dozing) to 3 (high chance of dozing). The global score ranges from 0 to 24. The highest ESS score indicates the highest daytime sleepiness. A score of 11 or above indicates excessive daytime sleepiness. The French-validated version will be used, which has good internal consistency (Cronbach's alpha 0.88) [31].

Composite Scale of Morningness The CSM is a 13-item questionnaire assessing the chronotype [32]. For each item, subjects must choose the assertions closest to their situations. Ten items range from 1 to 4 and three from 1 to 5. The total score ranges from 13 to 55. A score of 22 or lower indicates an evening chronotype, a score of 44 and above indicates a morning chronotype, and a score between 22 and 44 indicates an intermediate chronotype. The French-validated version will be used, which has good internal consistency (Cronbach's alpha 0.85) [33].

Multidimensional Fatigue Inventory The MFI is a 20-item questionnaire that assesses the perceived fatigue level during the last month [24]. For each item, subjects must evaluate each statement on a 5-point Likert scale ranging from 1 (yes, that is true) to 5 (no, that is not true). The French version assess four dimensions: general fatigue ranging from 9 to 45 (i.e., general sensation of being tired), mental fatigue ranging from 6 to 30 (i.e., cognitive aspect : difficulties with concentration, memory, or mental tasks due to tiredness), motivation ranging from 2 to 10 (i.e., a difficulty, or not, of imagining enjoying a pleasant activity), and reduced activities ranging from 3 to 15 (i.e., capacity to physically do, or not to do something; a decrease in activity levels, often due to feelings of fatigue) [25]. The highest score indicates the highest level of fatigue. The French-validated version will be used, which has good internal consistency (Cronbach's alpha 0.92, 0.84, 0.68, 0.73 for general fatigue, mental fatigue, reduced activities and motivation, respectively [25].

Sleep-wake rhythms

The baseline sleep-wake rhythms of medical students will be recorded by actigraphy for 21 consecutive days through a wrist accelerometer worn on the non-dominant hand (GENEActiv, Activinsights, Unit 11, Harvard Industrial Estate, Kimbolton, Cambridgeshire, PE28 0NJ, United Kingdom) [34]. This wrist device also contains a light sensor [35]. In addition, each morning, the students will be asked to report their bedtime (when they were in bed ready to fall asleep), their wake-up time (when they were awake but not necessarily out of bed), and whether they took a nap the previous day on an electronic survey (i.e., an online sleep diary). Following the 21 days, the accelerometer will be collected by an investigator.

The recordings (i.e., actograms) will be analyzed using Philips Actiware Sleep Software 6.3.0 (Philips Respironics, Murrysville, PA, USA) in 60-second sampling epochs [36]. Periods with an activity count equal to or below the threshold value, set at 40 counts (medium sensitivity), will be scored as sleep, whereas periods exceeding this threshold will be scored as waking. All actograms will be visually reviewed by individuals trained in actigraphy monitoring. Bedtimes and get-up times will be checked according to data from the online sleep diary and/or the light sensor [35, 37]. Individuals' records will be included in the subsequent analyses if they contain data for at least seven nights [38].

Automatic analyses will be run to extract the following sleep markers (Fig. 2) according to the Actiware sleep algorithm (Software Philips Actiware 6.3.0). Bedtime (hours:min) reflects the time when students attempt to fall asleep, Sleep Onset Latency (minutes) represents the amount of time elapsing from bedtime to the first period of sleep (Sleep Onset Time), Wake After Sleep

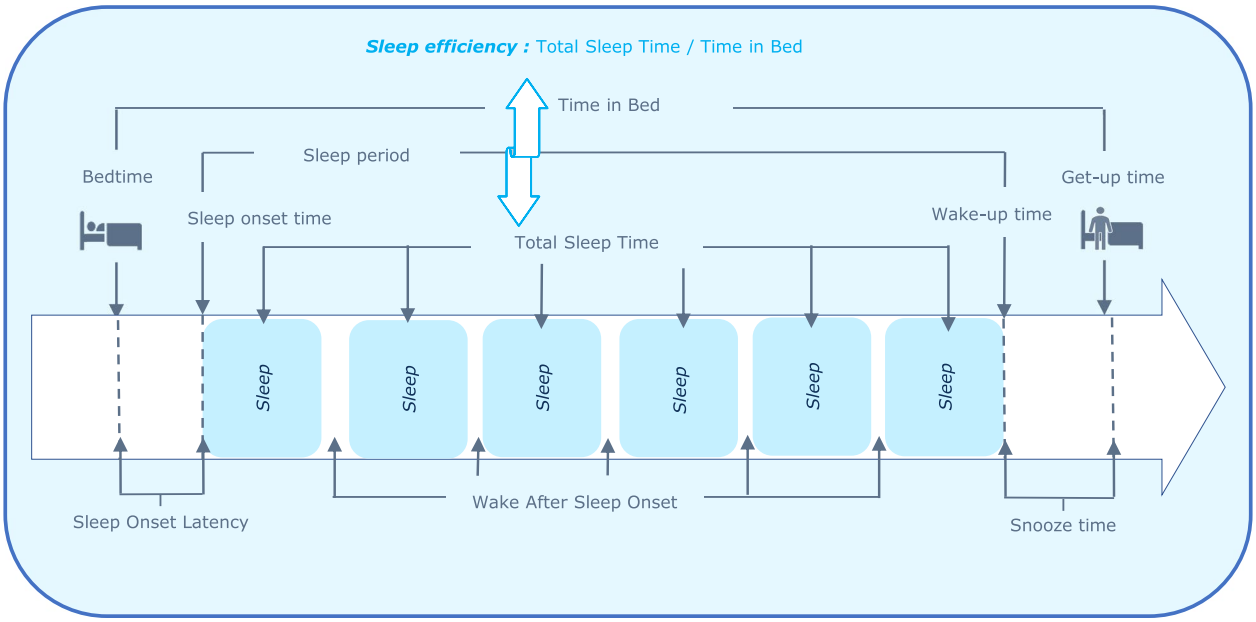

Fig. 2 Sleep-wake rhythms variables

Onset (minutes) reflects the time spent awake during the sleep period, Total Sleep Time (hours:min) estimates the amount of time scored as sleep, Wake-up time (hours:min) reflects the clock time when students wake-up, Time In Bed (hours:min) estimates the opportunity of time spent as sleep, Sleep Efficiency (percentage; Total Sleep Time/Time In Bed x 100), and Snooze time represents the time (minutes) between waking up and getting out of bed (Get-up Time). In addition, a Sleep Regularity Index will be calculated to assess the consistency of sleep-wake patterns [39]. A low index indicates irregular sleep patterns, which are often associated with poor sleep hygiene, sleep disturbances, and deceased health outcomes [40, 41].

Intervention

The PROMESS-Sleep program was developed with input from medical students and health professionals to prioritize participants' well-being and security (i.e., previous co-construction workshop; Additional file 3) [4]. It was agreed that all students would receive printed and oral information about local health resources (e.g., medical doctors, psychiatrists, psychologists, and sleep physicians), accompanied by a reassuring discussion aimed at destigmatizing health issues. In cases where medical issues are identified during the program, students will be promptly referred to a qualified professional. Additionally, PROMESS-Sleep experts may consult the Director of the University Health Service (AH) for advice on managing specific difficult situations.

The PROMESS-Sleep program will consist of three sessions spaced 14 to 21 days apart. These sessions will be conducted in three distinct periods, with 15 medical students randomly undergoing three sessions during one of the periods (Fig. 1). Each session will involve an individual meeting between a PROMESS-Sleep expert and a student.

Expert training

According to the findings of a previous co-construction workshop [4], meetings will be conducted by graduate medical students who are considered experienced peers regarding their advancement in the medical curriculum (Additional file 3). Before these meetings, these experienced peers will undergo thorough training to become experts. This training will involve several key steps, including reading a set of articles outlined in Additional file 4, observing each session at least once to obtain practical insights, and conducting each session at least once, guided by an individual (SS) with previous experience in sleep coaching for health professionals (https://topsurgeons.univ-lyon1.fr/en/team/). The observation and guidance steps will be repeated if necessary. This comprehensive training process is designed to ensure that peers will be adequately prepared and proficient to effectively deliver the PROMESS-Sleep program.

Overall organization of the sessions

Each session will consist of an individual meeting between a PROMESS-Sleep expert and an undergraduate

medical student. To improve the reproducibility of the program, the experts will follow a detailed step-by-step descriptive procedure for each session (available from the corresponding author upon request).

All sessions will follow a consistent structure. Each session will start with a short introduction talk, during which the experts will briefly explain the main steps of the session. Next, the students will be asked to complete questionnaires. The experts will then provide self-care pedagogical content about sleep and sleep hygiene. During the meeting, the experts and students will discuss the source of sleep disturbances to identify specific needs regarding sleep and fatigue. Detailed advice and goals will be set partly based on a predefined list created for medical students in a prior co-construction workshop (Additional file 5) [4]. Personalized assessments related to sleep and fatigue and self-monitoring tools will be provided to increase habit awareness, help students eliminate unhealthy habits, and reinforce or develop healthier ones. PROMESS-sleep is a pedagogical preventive program; no specific questions will be asked about snoring, insomnia, OSA, RLS, parasomnias, night terrors, narcolepsy, or hypersomnia.

Providing feedback to students

During the meeting, the experts will take written notes and provide numerous feedback points on the students' measures to encourage reflective discussion and foster a truly personalized experience. Some feedback will concern self-reported measures, while others will address more objective measures (e.g., actigraphy data). These feedback points will be provided along with explanations of the limitations of each measurement tool. The baseline and session 1 will be spaced at least 3 weeks apart, and each subsequent session will be spaced at least 2 weeks apart. This scheduling ensures sufficient time for treatment and scoring of the self-reported and actigraphy data.

Questionnaires

At the beginning of each session, the student will answer several 100-mm Visual Analog Scales (VAS) and complete the PSQI and MFI questionnaires. Each VAS will prompt the student to move the cursors to indicate responses. The cursors will start at the 0 position for each question.

VAS – sleep quantity The students' sleep quantity will be assessed on a VAS asking, "In the past 2 weeks, how would you characterize your sleep quantity?" Answers will range from 0 (largely insufficient) to 100 (largely sufficient).

VAS – sleep quality The students' sleep quality will be assessed on a VAS asking, "In the past 2 weeks, how would you characterize your sleep quality?" Answers will range from 0 (the worst quality) to 100 (the best quality).

VAS – fatigue The students' fatigue will be assessed on a VAS asking, "Over the past 2 weeks, how would you characterize your physical and mental fatigue level?" Answers will range from 0 (extreme fatigue) to 100 (no fatigue at all).

Session description

Session 1 (S1). The first session will last approximately 60 minutes (Fig. 3). This session will begin with a brief presentation of the expert's background and an explanation regarding the confidentiality of the exchanges. Then, the following points will be addressed:

Assessment of sleep disturbances and fatigue The student will answer the questionnaires described above (i.e., the VAS, PSQI, and MFI).

Pedagogical content This content, composed of three main sections, will be supported by printed materials.

The first provides information on a sleep cycle containing personalized data (Fig. 4). It is composed of 3 parts: (i) the "day" part with scores of daytime sleepiness (ESS baseline score) and fatigue encountered by the student at baseline (MFI baseline scores); (ii) the "evening" part that allows for discussing the importance of daily sleep hygiene (e.g., light exposure and regular meals [17, 42, 43]) and (iii) the "night" part with students' sleep disturbances levels, sleep habits, and chronotypes (i.e., PSQI, CSM, and baseline scores). Providing quantified information to student will allow for discussing these scores and, more importantly, identifying the origin of their sleep disturbances and needs.

The second part provides information on sleep physiology and architecture [44]. The experts will explain the different stages of sleep and the predominance of deepest non-REM sleep in the first part of the night [44, 45]. The experts will stress the importance of having at least 7 hours of sleep per 24 hours with a regular sleep schedule to improve sleep quality and reduce fatigue [20, 44]. Finally, many medical students experience high levels of stress and have reported stress as a major cause of sleep disturbance [8, 46]. The relationship is bidirectional, as poor sleep quality is also associated with depression, anxiety, and stress [47]. Thus, to help to improve both issues, the experts will introduce stress management interventions, such as

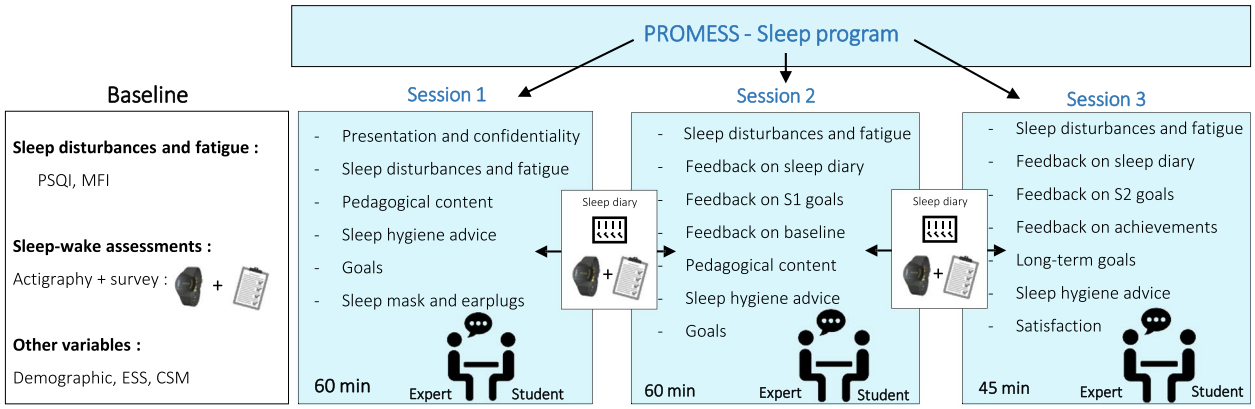

Fig. 3 The PROMESS-Sleep program. Before the intervention, the levels of sleep disturbances and fatigue, sleep habits, and sleep-wake rhythms of the students will be assessed through questionnaires and actigraphy to establish baseline scores. The PROMESS-Sleep program will comprise three sessions spaced 14 to 21 days apart. Each session will involve an individual meeting between a PROMESS-Sleep expert and a student. These sessions aim to identify students' needs regarding sleep and fatigue, set individual goals, and reduce sleep trouble and fatigue. Between each session, students will wear accelerometers and fill out online sleep diaries to determine sleep-wake rhythms. Abbreviations: CSM, Composite Scale of Morningness; ESS, Epworth Sleepiness Scale; MFI, Multidimensional Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index; S1, Session 1; S2, Session 2

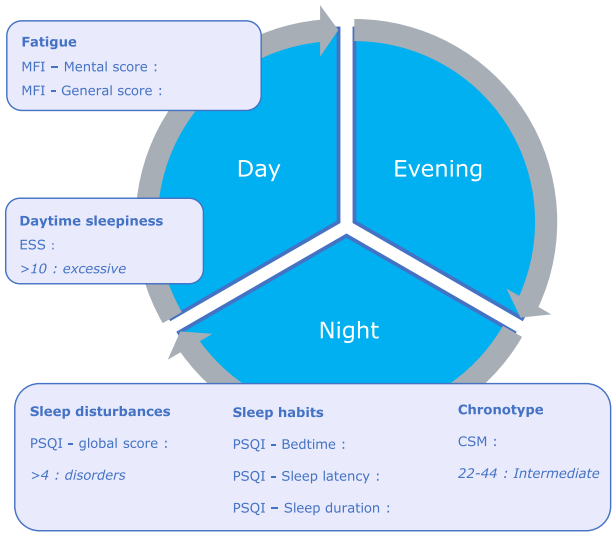

Fig. 4 Example of the pedagogical content of the PROMESS-Sleep program. During the sessions, students will receive pedagogical content on sleep and sleep hygiene and individual feedback related to their sleep and fatigue. This figure illustrates an example of the PROMESS-Sleep support given during session 1. A 3-part sleep-cycle will be provided: the "day" part with scores of daytime sleepiness and fatigue encountered at baseline; the "evening" part; and the "night" part with sleep disturbances levels, sleep habits, and chronotype. Providing quantified information will allow the experts and the students to discuss these scores and identify the students' needs. Abbreviations: CSM, Composite Scale of Morningness; ESS, Epworth Sleepiness Scale; MFI, Multidimensional Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index

mindfulness and slow-paced breathing, that may help students improve their sleep [48–51].

The third part provides further information on the influence of actions undertaken during daytime (e.g., energy drink/coffee consumption, meal regularity, sunlight exposure), in the evening (e.g., exposure to screen light), and at night (e.g., silent environment, obscurity) on sleep quality [17, 44].

Sleep diary A sleep diary will be given to the students to enable a self-monitoring process, increase habit awareness, and assess and reflect on their behaviors (Additional file 6). The students will be instructed to fill it out before the next session, including bedtime, sleep onset time, sleep latency, wake-up and get-up times, and any awakenings during daytime and nighttime sleep. The students will report the intensity of daily fatigue on a scale ranging from 1 (no fatigue at all) to 5 (extreme fatigue). In addition, the students will indicate whether they have engaged in mindfulness, slow-paced breathing, physical activity, and other specific behaviors. The experts and the students will fill the present day of the diary together to provide an example.

Sleep mask and earplugs Each students will receive a night mask and earplugs.

Advice and goals During the session, sleep hygiene advice for improving sleep and reducing fatigue will be provided. At the end of the session, the experts will answer all questions that may arise and settle the students' goals for the next session. Advice and goals will be based on the predefined list of specific guidance created

for medical students (Additional file 5). The students and the experts will write the goals and sign an agreement to promote the students' commitment and motivation [4]. If a fixed bedtime is set as a goal, the time will be marked in the students' sleep diaries.

Finally, the students must wear an accelerometer and answer the daily survey between S1 and S2 (Fig. 3).

Following the meeting, immediately after the students leave, the experts will report the following information:

Likert – Expert comfort The experts will report their comfort level regarding the relationship with the students during the session on a 5-point Likert scale (1: not comfortable at all, 2: slightly comfortable, 3: fairly comfortable, 4: comfortable, 5: very comfortable).

Likert – Expert satisfaction The experts will report their satisfaction level regarding the animation of the session on a 5-point Likert scale (1: not satisfied at all, 2: slightly satisfied, 3: fairly satisfied, 4: satisfied, 5: very satisfied).

Likert – Advice given Concerning predefined advice (Additional file 5), the experts will report on a 5-point Likert scale if 1) it was not mentioned, 2) it was mentioned but not directly advised, 3) it was mentioned and recommended, 4) it was set as a goal, and 5) if a positive reinforcement was performed. The experts will also report advice given that was missing from the predefined list.

Session 2 (S2). The second session will last approximately 60 minutes (Fig. 3), and the following points will be addressed:

Assessment of sleep disturbances and fatigue The assessment will use the above-mentioned procedure.

Feedback on sleep diary The sleep diary filled out between S1 and S2 will be discussed. The experts will question the students regarding the sleep issues encountered. Bedtime and sleep latency will be discussed. A latency of less than 5 minutes (indicating excessive sleep pressure and fatigue) or more than 30 minutes (indicating difficulties falling asleep) will be considered problematic [49, 50]. In addition, the experts will attempt to identify if specific practice or behaviors reported in the diary may have influenced the students' sleep.

Feedback on S1 goals The experts and the students will work together to identify the facilitators and obstacles to achieving each previously established goal.

Feedback on baseline The experts will give feedback on baseline measures supported by printed or digitalized materials. This presentation will give students deeper insights into their sleep and detect the putative confrontation between perceived and objective sleep variables. More specifically, the PSQI baseline scores (i.e., bedtime, wake-up time, and sleep duration) and the actigraphy baseline scores (i.e., Sleep Onset Time, Wake-up time, Time In Bed, Total Sleep Time, Wake After Sleep Onset) will be discussed. Information regarding Sleep Efficiency and Sleep Onset Latency will be given; it will be acknowledged that self-reported measures may be more precise, so these actigraphy scores should be interpreted cautiously. The experts will discuss the students' Sleep Efficiency regarding the threshold of 80% [51]; a score under 80% will be considered pathological and may need to be addressed by a physician [49].

Pedagogical content This pedagogical content, composed of three main sections, will be supported by printed or digitalized materials.

First, the experts will briefly remind the students about the sleep cycle using Fig. 4 and the different stages of sleep.

Second, the experts will help the students to better understand sleep using Fig. 2 and will stress the importance of considering sleep regularity [39, 52, 53].

Third, the experts will explain the benefit of napping as a countermeasure against fatigue. Naps can be an additional solution to achieve the minimum recommendation of 7 hours of sleep per 24 hours [54, 55]. Naps will be advised according to individuals' needs: short naps (10 to 20 minutes) are known to increase alertness and performance [56], while longer naps (90 minutes) are known to help reduce sleep debt. The experts will raise awareness that naps less than 10 minutes long may be too short to show positive effects, whereas naps longer than 20 minutes may induce sleep inertia. In addition, the experts will warn that longer naps should be avoided before main sleep to avoid increased sleep onset latency [57]. Ideally, nap should take place in a quiet, dark, and cool environment for the best sleep quality. The experts will explain favorable conditions for napping according to shift schedules and individual chronotypes. Studies have shown that evening chronotypes nap more frequently than morning chronotypes during weekdays [58, 59].

Fourth, the experts will address the challenges associated with night shifts and recommend best practices to adopt before, during, and after these shifts (e.g., naps before, during, and between shifts may be beneficial) [57]. The experts will address how sleep deprivation affects metabolism and

hormonal balance by decreasing leptin and increasing ghrelin, which potentially leads to weight gain [44, 60]. The experts will also advise limiting food intake during night shifts and choosing lighter meals before bed [57].

As performed in S1, sleep hygiene advice will be provided throughout the session. The experts will address all questions, and individual goals will be established and signed. The students will receive a new sleep diary to complete, wear an accelerometer, and answer the daily surveys until the next session (Fig. 3).

Immediately following the meeting, the experts will report their comfort and satisfaction levels and the advice and goals established during this session, as described above. In addition, the experts will estimate whether the students achieved the goals previously set (S1 goals) on a 4-point Likert scale (i.e., 0: not achieved at all, 1: slightly achieved, 2: fairly well achieved, 3: well achieved).

Session 3 (S3). The third session will last approximately 45 minutes (Fig. 3); the following points will be addressed:

Assessment of sleep disturbances and fatigue The assessment will use the above-mentioned procedure.

Feedback on sleep diary The sleep diary filled out between S2 and S3 will be discussed as described above.

Feedback on S2 goals Feedback on S2 goals will be provided as described above.

Feedback on achievements To offer a comprehensive overview of student achievements across the program, the experts will provide individualized printed or digitalized visual summaries that comprise 1) the evolution of sleep time assessed through the PSQI (sleep duration at baseline, S1, S2, S3) and actigraphy (Total Sleep Time at baseline and between S1 and S2), 2) the evolution of sleep disturbances (PSQI global score at baseline, S1, S2, S3), 3) the evolution of the general, mental, and physical fatigue (MFI scores at baseline, S1, S2, S3), and 4) goals set during the program (S1, S2, S3). Progression will be discussed based on the goals to help the students identify what was effective. In addition, at the end of the session, the students will be encouraged to proactively determine and report their long-term goals independently to enhance their autonomy, short- and long-term commitment, and motivation.

As performed in sessions 1 and 2, sleep hygiene advice will be provided throughout the session, and the experts will address all questions. Then, a comprehensive list of advice will be distributed to help the students adopt long-term changes and provide opportunities to find advice that matches future needs (Additional file 7).

Before ending the session, the level of student satisfaction regarding the PROMESS-Sleep program will be assessed using several 100-mm VASs. Each VAS will prompt the students to move a cursor to indicate a response. The cursor will start at the 0 position for each question.

Composite score – Student's satisfaction The composite score will be the mean of two sub-scores: 1) the specific score (i.e., sleep and fatigue) as the mean of the score obtained from the VAS, "Do you think the intervention has helped you to improve your sleep?" and the score obtained from the VAS, "Do you think the intervention allowed you to decrease your fatigue?"; 2) the general score (i.e., relevance and sustainability) as the mean of the score obtained from the VAS, "Do you think the proposed goals were suitable for your daily life?" and the score obtained at the VAS, "Do you think you can sustain the performed changes in habits?". The answer for the four VASs will range from 0 (absolutely not) to 100 (completely).

For these scores of student's satisfaction, a score lower than 30 will be considered highly negative, from 30 to 45 negative, from 45 to 55 neutral, from 55 to 70 positive, and equal or above 70 highly positive.

Immediately following the meeting, the experts will report their comfort and satisfaction levels and the advice and goals established during this session, and estimate whether the students achieved the goals settled in S2, as described above. In addition, the experts will report the overall satisfaction level regarding student progress during the PROMESS-Sleep program: "Are you satisfied with the student's progress throughout the intervention?" Answers will range on a Likert scale from 1 (not satisfied at all) to 5 (very satisfied).

Availability of the PROMESS-Sleep material

All materials necessary to perform the PROMESS-Sleep program are available from the authors upon reasonable request (SS, AM, promess_sante@univ-lyon1.fr and/or personal mail).

Data management and monitoring

The principal investigator (SS) will ensure that the protocol, ethical data collection, and analysis guidelines will be followed. She will be responsible for maintaining the anonymity of the included students (participants will be assigned a unique identification code). In addition, the students will receive a letter with information that clarifies how their

data will be used regarding the General Data Protection Regulation, including the contact details of the university's data protection officer and the contact information of the principal investigator. Students will be informed that if they wish to withdraw their data, they must contact the principal investigator, who will conduct a dropout analysis. All source documents, including informed written consent, data, and printed materials, will be stored in a secure locker at the RESHAPE Laboratory (INSERM U1290, Université Claude Bernard Lyon 1, Lyon, France) for 5 years after the last publication of the results. Raw data, processed data, and analysis scripts will be stored on a password-protected computer at the RESHAPE Laboratory, accessible only to registered investigators (SS, AM). The database preparation and statistical analysis will be conducted anonymously. Since the study involves minimal risk to participants, a Data Monitoring Committee (DMC) was deemed unnecessary. Moreover, the project received positive feedback from an ethical committee that affirmed adequate monitoring. No spontaneously reported adverse events and other are expected.

Data analysis

Data analysis will occur once all data will be collected. No interim analyses or stopping guidelines to terminate the study are planned.

Data analyzed

Variables will be expressed as means with standard deviations and ranges, medians with interquartile ranges, or counts and percentages. Data will be analyzed according to the intention-to-treat principle and presented following international consolidated standards of reporting trial guidelines. A p-value < 0.05 will be considered statistically significant, while $p < 0.10$ will be a trend. The normality of data distribution will be assessed using normality tests, histograms, and quantile-quantile plots. In the case of non-normality, data will be transformed or non-parametric tests will be used. All models' assumptions will be checked. β coefficients at a 95% confidence interval and R^2 will be provided for linear regressions. All statistical analysis will be performed using the most recent version of the R software [61].

Outcomes

The primary outcome will be the global PSQI score (scores obtained during S1, S2, S3). The seven dimensions of the PSQI will also be described. The secondary outcomes will be the change of other variables assessing various aspects of sleep disturbances, fatigue, sleep habits, and sleep-wake rhythms (scores obtained during S1, S2, S3; Table 1). The outcomes will be assessed by the PROMESS-Sleep experts.

Table 1 A priori hierarchical ordering of secondary outcomes. Abbreviations: MFI, Multidimensional Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index; VAS, Visual Analog Scale. S1, Session 1; S2, Session 2; S3, Session 3. S1–S2; recording from session 1 to session 2. S2–S3; recording from session 2 to session 3

Outcomes	Evolution
Mental fatigue (MFI)	Score changes (S1, S2, S3)
Bedtime (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Sleep regularity index (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Sleep quality (VAS)	Score changes (S1, S2, S3)
Sleep quantity (VAS)	Score changes (S1, S2, S3)
Sleep fatigue (VAS)	Score changes (S1, S2, S3)
General Fatigue (MFI)	Score changes (S1, S2, S3)
Reduced activity (MFI)	Score changes (S1, S2, S3)
Motivation (MFI)	Score changes (S1, S2, S3)
Physical Fatigue (MFI)	Score changes (S1, S2, S3)
Time in Bed (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Total Sleep Time (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Sleep Onset Time (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Sleep Onset Latency (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Snooze time (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Wake After Sleep Onset (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Wake-up time (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Get-up time (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)
Sleep Efficiency (actigraphy)	Score changes (Baseline, S1–S2, S2–S3)

Hierarchical ordering

An a priori hierarchical ordering of secondary outcomes has been performed (Table 1). The ordering was defined by the PROMESS-Sleep experts according to the existing literature, their expectations regarding the program, and the results of a pilot study [4]. This hierarchical ordering will allow us to conclude the program's impact until the *p*-value becomes non-significant. In such cases, the following secondary outcomes will be assessed as exploratory descriptive outcomes [60].

A priori-sample size

The sample size was a priori calculated for the primary outcome (evolution of the global PSQI score during S1, S2, S3). Based on an expected medium effect size for

repeated measures (i.e., $f = 0.20$, $\alpha = 5\%$, power = 0.80, and three measurements), the calculation resulted in a total sample size of 42 participants (G*Power v3.1.9.6). To ensure robustness against potential attrition or data loss, we will recruit an additional 10% of volunteers to result in a total sample size of 45 students.

Statistical analysis plan

Primary and secondary outcomes Linear mixed models (with a random effect for students and experts, and a fixed effect for time) will be performed to explore the impact of the PROMESS-Sleep program on the primary and secondary outcomes following the hierarchical ordering.

Exploratory outcomes

Moderators of efficacy The program's efficacy will be determined by a delta score on the global PSQI (score S3 – score S1). A negative delta score will indicate reduced sleep disturbances, a neutral score no change, and a positive score an increase in sleep disturbances during the program. As such, a lower delta score will represent higher efficacy. The model will explore whether the delta score was influenced by the students' characteristics at inclusion, such as gender, age, study year and baseline levels of sleep disturbances (i.e., global PSQI baseline score). This model will also explore the influence of the periods (periods 1, 2, and 3) and the experts on the delta score.

Composite score – Student's satisfaction The mean composite satisfaction score should be equal to or greater than 70 to conclude that the students will be highly satisfied (using a one-sample *t*-test or Wilcoxon signed-rank test). Similarly, the four scores of satisfactions will be independently explored, and compared to 70, in order to have a greater insight into the program's acceptability.

Moderators of satisfaction The model will explore the influence of student characteristics at inclusion, such as gender, age, study year and baseline levels of sleep disturbances, on the composite satisfaction score. This model will also explore the potential influence of the periods and the experts on the composite satisfaction score.

Dissemination and open science strategies

The results of this study will be presented at international and national scientific conferences, in peer-reviewed scientific journals, in medical theses and dissertations, and in local and national educational committees. We will organize a one-day local congress to present the results of this study to university and hospital leaders, teachers, and medical students, aiming to promote advances in medical education.

Preliminary survey on students' interest

To determine medical students' interest in the PROMESS program, we administered a survey in June 2023 to all 535 fourth-year undergraduate medical students of the Lyon-Est Faculty of Medicine (Claude Bernard University Lyon 1, France). Students answered several questions, including, "How interested are you in following an intervention aimed at improving your sleep: Very interested, interested, moderately interested, not interested, or highly uninterested?". We found that 13% were very interested, 27% were interested, 29% were moderately interested (16% and 15% were not interested and highly uninterested, respectively). These preliminary results reinforced the pertinence of the PROMESS-Sleep project.

Discussion

It is crucial to support future healthcare professionals by enhancing their ability to manage their sleep and prevent cumulative fatigue. Since situations associated with sleep difficulties, such as heavy workloads and night shifts, may arise throughout their educational and professional courses, it is essential to implement programs that enhance medical students' abilities to care for their sleep early in the curriculum.

The PROMESS-Sleep program aims to provide solutions to medical students to reduce their sleep disturbances and fatigue. Therefore, the results of this upcoming study will provide valuable information on the efficacy of the PROMESS-Sleep program in this regard. Additionally, the study will offer a detailed characterization of the program's influence on numerous facets of sleep, such as sleep habits and sleep-wake rhythms, measured using questionnaires and actigraphy. Finally, the study will assess student satisfaction and identify the moderators of the program's efficacy. Therefore, the findings will collectively offer crucial insights to determine whether the PROMESS-Sleep program should be offered as a sustainable tool for medical students.

Research implications

This study may have several implications for students and faculty. The direct expectations for students are to reduce their sleep disturbances and fatigue. Since the intervention is primarily based on students' ability to change their behaviors, they are expected to maintain their ability to care for their sleep while maintaining a low level of fatigue. Furthermore, a sustained low level of sleep disturbances is anticipated to be associated with a long-term increase in well-being [8] and quality of life [3], with a

decreased risk of developing various mental (e.g., depression, anxiety, rumination, burnout [1, 62]), and physical health outcomes (e.g., diabetes mellitus, hypertension, cardiovascular and coronary heart diseases, obesity [3]).

The implications of the program may overcome the study's aim. First, reducing sleep disturbance may also help students improve their academic performance. A recent meta-analysis indicated that academic grades were positively correlated with sleep quality scores and negatively with diurnal sleepiness [6]. Second, the early exposure of medical students to sleep knowledge may improve their professionalization pathways. This improvement may take two paths: directly by acquiring the knowledge and skills required to handle situations that generate sleep disturbances (e.g., night shifts) encountered during their future careers as physicians and indirectly by enhancing their understanding of sleep, sleep disturbances, and sleep hygiene, which they can use to better support their future patients.

Recommendation for further implementation

The exploratory outcomes will provide important insights regarding the overall interpretation of the findings and the PROMESS-Sleep program's acceptability. It will be addressed by analyzing in detail the sub-scores of student's satisfactions, and exploring whether the program's efficacy and overall satisfaction are influenced by the characteristics of the students (e.g., gender, age, study year and baseline levels of sleep disturbances) and the implementation (expert, period). This will enable us to determine whether any of the explored variables affect the program's efficacy or student's satisfaction, and therefore suggest specific advice on how and for whom the program should be implemented.

Originality of this protocol

The current protocol represents an innovative and contemporary approach to the field of medical education. The American Medical Association (2022) recently advocated for an increased use of coaching as a key initiative to accelerate changes in medical education. The PROMESS-Sleep program can be characterized as a coaching program during which coaching recipients (i.e., students) define goals and formulate strategies to achieve them with the assistance of the coach (i.e., an expert) [63]. Since the experts will be more experienced medical students, this program may be considered a form of peer coaching (i.e., peer monitoring). This peer coaching offers numerous pedagogical and practical advantages [64, 65]. First, it addresses the desire of medical students to be coached by individuals who understand the specificities and difficulties of the medical curriculum [4]. Second, involving students to perform the sessions appears to be a cost-effective approach, which may be a key point for further large-scale program implementation [66].

Anticipated limitations and issues

This study has anticipated limitations. First, since only fourth- and fifth-year undergraduate medical students will be included, the generalization of our findings to other students experiencing sleep disturbances may be limited. Second, specific timing factors, such as proximity to exams, holidays, or hospital work with night shifts, may influence primary and secondary outcomes. This issue can be mitigated by implementing the PROMESS-Sleep program in three distinct periods. Third, PSQI and MFI scores assessed during sessions 2 and 3 may account for some of the same nights.

Conclusion

The PROMESS-Sleep program aims to provide solutions to medical students to reduce their sleep disturbances and fatigue during their curriculum. The results seek to provide valuable insights into the program's efficacy. If its efficacy is proven, PROMESS-Sleep may become an integral and sustainable part of medical education to foster a healthier and more resilient future for healthcare professionals.

Abbreviations

DMC	Data Monitoring Committee
CSM	Composite Scale of Morningness
ESS	Epworth Sleepiness Scale
MFI	Multidimensional Fatigue Inventory
PSQI	Pittsburgh Sleep Quality Index
S1; S2; S3	Session 1; Session 2; Session 3
VAS	Visual Analog Scales

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12909-024-06422-x.

Additional file 1.
Additional file 2.
Additional file 3.
Additional file 4.
Additional file 5.
Additional file 6.
Additional file 7.
Additional file 8.

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SPIRIT recommendations
This manuscript follows the SPIRIT recommendation (Additional file 8).

Authors' contributions
AR – Conceptualization; Investigation; Methodology; Resources; Writing - original draft; Writing - review & editing EN – Conceptualization; Investigation; Methodology; Resources; Writing - original draft; Writing - review & editing AM – Conceptualization; Investigation; Methodology; Resources; Project administration; Supervision; Writing - original draft; Writing - review & editing BV – Conceptualization; Methodology; Resources; Writing - review & editing AH – Conceptualization; Methodology; Resources; Project administration; Writing - review & editing AD – Methodology; Resources; Project administration; Writing - review & editing ML – Methodology; Resources; Project administration; Writing - review & editing GR – Conceptualization; Methodology; Resources; Project administration; Supervision; Writing - review & editing SS – Conceptualization; Investigation; Methodology; Resources; Project administration; Supervision; Writing - original draft; Writing - review & editing; Contact information for clinical trial

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Data availability
The data that support the findings of this study are available from the corresponding author (SS), upon reasonable request.

Declarations

Ethics approval and consent to participate
All participants will consent to participate in agreement with the ethical approval of the present study (Institutional Review Board IRB), and all the procedures will be performed in adherence to the Helsinki Declaration. Participants will receive oral and written information and provide written consent before enrollment in the study following sufficient reflection time.

Consent for publication
All authors gave their consent to publish the present article.

Competing interests
The authors declare no competing interests.

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