ISRCTN39530091 https://doi.org/10.1186/ISRCTN39530091

Effect of a mindfulness-based intervention on sleep quality

Submission date	Recruitment status	[ ] Prospectively registered
22/07/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/09/2022	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/12/2024	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Sleep disorders have a relatively high incidence among the general population. The COVID-19 pandemic has profoundly changed the lifestyle of people, in many cases exacerbating sleep problems.

Pharmacological (drug) treatments for sleep disorders may come with considerable side effects, so non-pharmacological interventions are now considered as potential alternatives. Most effective treatments have been addressed, namely psychological and behavioral interventions that incorporate many treatment components including stimulus control, sleep restriction, relaxation, and cognitive therapy. Cognitive behavioral therapy (CBT) is a safe treatment with long-lasting beneficial effects, albeit not widely accessible, and is considered as the first option to treat insomnia, recommended by the international guidelines of insomnia therapy.

Recently, meditation techniques have also begun to emerge as alternative treatments for sleep ameliorating sleep quality. Meditation allows you to have greater mastery of the activities of the mind. Its beneficial effects on an emotional, psychological and physical level in both clinical and non-clinical populations are supported by an ever-increasing number of scientific publications. Beneficial effects of meditation on sleep were also reported and most of the research in this area has been carried out on mindfulness-based interventions (MBIs), which focus on breathing and directed attention, such as mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR), demonstrating improvement in sleep quality and insomnia symptoms both immediately after MBIs and in the follow-up, thus suggesting a crucial long-term effect. These results supporting mindfulness as an alternative or additional treatment to the classic pharmacological and/or cognitive behavioral therapies.

Sleep includes a state of calm behavior and an active search for the regulation of biological systems. Sleep disturbances commonly occur when there is a dysregulation in these systems accompanied by an activation of the sympathetic nervous system that generates a state of hyperactivity. Mindfulness is also a state of calm behavior that includes active regulation. For this reason, it could be effective in acting on the state of hyperactivity and in improving self-regulation and attentional control, providing practitioners with a strategy to improve their sleep. More specifically, mindfulness can be used to raise awareness of the physical and mental states that are present when experiencing symptoms of insomnia. This would allow practitioners to change their mental processes in response to these symptoms by promoting an adaptive and conscious attitude characterized by a more balanced assessment, by cognitive flexibility and

equanimity. Maintaining a conscious attitude allows the sleep-related arousal state to decrease and normal sleep patterns to re-emerge.
Furthermore, healthy eating habits or specific diets can improve the quality and quantity of sleep. For these reasons, it is conceivable that providing instructions for a healthy diet can act together with other treatments to improve sleep quality.
However, although when investigating MBIs promising results have been obtained, preliminary and additional well-planned studies are still needed, especially for the lack of study on the estimation of the dose-response effect.
The aim of this study is to assess on a sample of Italians poor-sleepers the effect of a short online MBI on sleep pattern and quality. Specifically, MBI comprises: online integral meditation (IM), a mindfulness-based technique here tested for the first time on poor-sleepers, classes given twice a week; a recorded IM class for individual practice; and dietary advice to specifically promote sleep regulation.

Who can participate?
Adults volunteers with impaired sleep quality

What does the study involve?
Eligible participants are randomly assigned to the intervention or control group. Participants in the passive control group are assigned to a waiting list and, for ethical reasons will be offered the same intervention as the treatment group once the study is completed.
The intervention consists of 12 mindfulness-based Integral Meditation (IM) classes given twice a week from October to December 2020. Each class lasts about 60 minutes and is delivered on the Zoom video conferencing platform. Briefly, IM training, the core element of the intervention, involves developing awareness of the body and mind in terms of improving the ability to generate relaxation and mental peace; stabilizing the mind to stop ruminations and perennial inner chatter; refining the ability to hear and recognize the dynamics between emotions and thought; enhancing the balance between openness to others and attention to oneself that in turn promotes well-being in general. IM simultaneously uses breathing, focusing attention, the release of physical tensions, thoughts and sensations through internal senses and imagery. This enables rapid relaxation and a deep physical, energetic, and spiritual well-being.
Participants also receive a 25-minute audio recording for practising IM daily before going to sleep, to release physical and emotional tension through focused breathing and body-parts relaxation. In addition, they receive general dietary non-mandatory advice and recommendations from a nutritionist aimed at promoting healthy sleep. In particular, eating tryptophan-containing food (e.g., legumes, dairy products, whole grain, etc) is recommended. Participants with high levels of inflammation are also recommended to reduce the consumption of histamine-rich food (e.g, tomatoes, spinach, eggplant, parmesan, blue cheese, and red wine).

What are the possible benefits and risks of participating?
Possible benefits include improvement of quality of life. There are no possible known risks.

Where is the study run from?
University of Pavia (Italy)

When is the study starting and how long is expected to run for?
July 2020 to March 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Teresa Fazia, PhD, teresa.fazia01@universitadipavia.it

Contact information

Type(s)
Scientific

Contact name
Dr Teresa Fazia

Contact details
Via Bassi 21
Pavia
Italy
27100
+39 (0)3408336268
teresa.fazia01@universitadipavia.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1

Study information

Scientific Title
Beneficial effects of an online minDfulness-based inteRvention on sleEp quAlity in a sample of Italian poor-sleepers during the COVID-19 pandeMic (DREAM)

Acronym
DREAM

Study objectives
The proposed mindfulness-based intervention improves sleep quality and sleep-related behaviors, and fosters emotion regulation and mindfulness.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 15/10/2020, Ethical Committee of the Department of Brain and Behavioral Sciences of the University of Pavia (Comitato Etico - sezione di Psicologia - Dipartimento di Scienze del SIstema Nervoso e del Comportamento, Piazza Botta, 11, 27100 Pavia, Italy; +39 (0)382 986455; sara.longo@unipv.it), ref: 63/2020

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Impaired sleep quality

Interventions
Eligible participants are randomly assigned to the intervention or control group. Method of randomization: simple randomization procedure with a 1:1 allocation ratio, by using the R package "randomize". Participants in the passive control group are assigned to a waiting list and, for ethical reasons, will be offered the same intervention as the treatment group once the study is completed.

The intervention consists of 12 mindfulness-based Integral Meditation (IM) classes given twice a week from October to December 2020. Each class lasts approximately 60 minutes and is delivered on the Zoom video conferencing platform. Briefly, our IM training, that represents the core element of our intervention, involves: i) developing awareness of the body and mind in terms of improving the ability to generate relaxation and mental peace; ii) stabilizing the mind to stop ruminations and perennial inner chatter; iii) refining the ability to hear and recognize the dynamics between emotions and thought; iv) enhancing the balance between openness to others and attention to oneself that in turn promotes psycho-physical well-being in general. IM simultaneously uses breathing, focusing attention, the release of physical tensions, thoughts and sensations through internal senses and imagery. This enables rapid relaxation and a deep physical, energetic, and spiritual well-being. IM has a demonstrated efficacy in the non-clinical general population as reported in previous studies.

Participants also receive a 25-minute audio recording for practising IM daily before going to sleep, to release physical and emotional tension through focused breathing and body-parts relaxation. In addition, they receive general dietary non-mandatory advice and recommendations from a nutritionist aimed at promoting healthy sleep. In particular, the assumption of tryptophan-containing food (e.g., legumes, dairy products, whole grain, etc.) is recommended. The capacity of tryptophan in improving sleep resides in its conversion into serotine, and this largely depends on its ability to cross the blood-brain barrier, which in turn seems to be favored by the consumption of high-carbohydrates meals. In fact, the increase of plasma glucose leads to insulin secretion thus removing circulating large neutral amino acids in favour of tryptophan that in this way can cross the blood-brain barrier and can be converted into serotonin. Subjects characterized by self-reported high levels of inflammations are also recommended to reduce the assumption of histamine-rich food (e.g, tomatoes, spinach, eggplant, parmesan, blue cheese, red wine, etc.). Furthermore, scientific evidence suggests

histamine in the central nervous system as player in the regulation of sleep-wakefulness through its receptors especially H1 and H3; so that H1 receptor antagonist are often used for the treatment of insomnia even if with potential side effects.

Intervention Type
Behavioural

Primary outcome(s)
Different aspects of sleep quality and quantity measured by six self-reported questionnaires:
1. Seven different components of sleep quality (i.e., sleep duration, disturbance, latency, daytime dysfunction due to sleepiness, sleep efficiency, overall sleep quality, and sleep medication used) measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and after the intervention
2. Insomnia disorder measured using the Sleep Condition Indicator (SCI) questionnaire at baseline and after the intervention
3. The nature, severity, and impact of insomnia measured using the Insomnia Severity Index (ISI) questionnaire at baseline and after the intervention
4. Presence of sleep hygiene behaviors assessed using the Sleep Hygiene Index (SHI) questionnaire at baseline and after the intervention
5. An individual's likelihood of experiencing sleep difficulties in response to common stressful situations assessed using the Ford Insomnia Response to Stress Test (FIRST) questionnaire at baseline and after the intervention
6. Arousability measured using the APS questionnaire at baseline and after the intervention

Key secondary outcome(s))
Emotion regulation and level of mindfulness measured by two self-reported questionnaires:
1. Two different emotion regulation strategies, cognitive reappraisal and expressive suppression, measured using the Emotion Regulation Questionnaire (ERQ) at baseline and after the intervention
2. Level of mindfulness measured using the Five Facet Mindfulness Questionnaire (FFMQ) before and after the intervention

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Pittsburgh Sleep Quality Index (PSQI) score >5 indicating impaired sleep quality
2. Not suffering at the time of recruitment from severe anxiety or depression, severe mental illness (e.g., hypomania or psychotic episode), or any other diagnosed mental or physical health condition

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
78

Key exclusion criteria
1. PSQI score <5
2. Suffering at the time of recruitment from severe anxiety or depression, severe mental illness (e.g., hypomania or psychotic episode), or any other diagnosed mental or physical health condition

Date of first enrolment
01/09/2020

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
Italy

Study participating centre
University of Pavia
Via Bassi 21
Pavia
Italy
27100

Sponsor information

Organisation
University of Pavia

ROR
https://ror.org/00s6t1f81

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be shared as supplementary material in the published paper

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/02/2023	03/12/2024	Yes	No
Basic results			03/10/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results			03/10/2022	No	No