Beneficial effects of an online mindfulness-based intervention on sleep quality in a sample of Italian poor-sleepers during the COVID-19 pandemic: a randomized trial

Running title: Beneficial effect of Mindfulness in poor-sleepers

Abstract

OBJECTIVES: Sleep of inadequate quantity and quality is increasing in the 24-hour society with negative impact on physical and mental health. Mindfulness-based interventions (MBIs) generate a state of calm behavior that could reduce hyperactivity and improve sleep. We hypothesized that our specific MBI, administered online, may improve sleep quality and foster emotion regulation and mindfulness.

METHODS: This is a two-group pre-post experimental study. Pittsburgh Sleep Quality Index (PSQI), Sleep Condition Indicator (SCI), Arousal Predisposition Scale (APS), Ford Insomnia Response to Stress Test (FIRST), Sleep Hygiene Index (SHI) and Insomnia Severity Index (ISI) were taken as outcome measures of sleep quality and stability. Emotion regulation and mindfulness were measured via Emotion Regulation Questionnaire (ERQ) and Five Facet Mindfulness Questionnaire (FFMQ). The intervention included 12 Integral Meditation (IM) classes given twice a week, a recorded IM training programme for individual practice, and dietary advice designed to promote sleep regulation. Participation was voluntary and 56 Italian subjects with poor sleep quality as measured by PSQI>5 were included in the study and randomly allocated to treated (n=28) and control (n=28) group. Linear mixed models were used to estimate the effectiveness of the intervention on the investigated outcomes measured before and after the intervention.

RESULTS: Statistically significant results were observed in FFMQ sub-domain *non-reactivity to inner experience* (β=0.29[0.06;-0.52],p=0.01), PSQI global score (β=-1.93[-3.43;-0.43],p=0.01), SCI (β=3.39[0.66; 6.13], p=0.02) and ISI (β=-3.50[-5.86;-1.14],p=0.004). No effect was observed in the remaining scales and subscales.

CONCLUSIONS: These results confirm our hypothesis regarding the beneficial effects of our intervention on sleep quality.

Keywords: COVID-19; emotion regulation; mindfulness; sleep quality; sleep stability; wellbeing

Word count:3928

Introduction

Sleep disorders have a relatively high incidence among the general population. Terzano et al[1] reported a prevalence of insomnia among the Italian population of about 64%, and 44% of those interviewed complained of diurnal disturbances as a consequence of their nocturnal disorder. A study carried out on 3,970 Italians aged 15 years or older found that insomnia symptoms affected 27.6% of the sample, whilst sleep dissatisfaction affected 10.1%, and 7% had a diagnosis of insomnia disorder[2]. A more recent study on 3,120 Italian adults, revealed similar percentages[3]. More specifically, sleep dissatisfaction was reported by 14.2% and insufficient sleep duration by 29.5% of the adults. In this scenario, the current COVID-19 pandemic emergency has profoundly changed the lifestyle of people, in many cases exacerbating sleep problems[4,5].

Pharmacological treatments for sleep disorders may come with considerable side effects, so that 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) being a safe treatment with long-lasting beneficial effects, albeit not widely accessible, is considered as the first option to treat insomnia, recommended by the international guidelines of insomnia therapy[6].

Recently, meditation techniques have also begun to emerge as alternative treatment for sleep ameliorating sleep quality[7,8]. Meditation allows you to have greater mastery of the activities of the mind. Its beneficial effects on emotional, psychological and physical level in both clinical and non-clinical populations are supported by an ever-increasing number of scientific publications[9–11]. 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), that focus on breathing and directed attention, e.g., 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[12]. These results supporting mindfulness as an alternative or additional treatment to the classic pharmacological and/or cognitive behavioral therapies.

The rationale is that 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[13]. 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 thereby 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[14].

Furthermore, healthy eating habits or specific diets can improve the quality and quantity of sleep[15]. For these reasons, it is conceivable that providing instructions for a healthy diet can act synergistically 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.

Here we assessed on a sample of Italians poor-sleepers the effect of a short, delivered online, MBI on sleep pattern and quality. Specifically, our MBI comprised: i) 12 online Integral Meditation (IM), a mindfulness-based technique here tested for the first time on poor-sleepers, classes given twice a week; ii) a recorded IM class for individual practice; and iii) dietary advice to specifically promote sleep regulation. Our research hypothesis was that this intervention has a beneficial effect on the mental life of individuals which in turn improves sleep patterns and therefore ameliorates the symptoms of insomnia. To this aim we estimated the effectiveness of the proposed intervention on six outcomes related to sleep patterns and quality assessed via six self-reported questionnaires, i.e., Pittsburgh Sleep Quality Index (PSQI), Sleep Condition Indicator (SCI), Arousal Predisposition Scale (APS), Ford Insomnia

Response to Stress Test (FIRST), Sleep Hygiene Index (SHI) and Insomnia Severity Index (ISI). Furthermore, we hypothesized that our intervention fosters emotion regulation and mindfulness as measured by Emotion Regulation Questionnaire (ERQ) and Five Facet Mindfulness Questionnaire (FFMQ) respectively. In addition, we also tried to investigate a possible dose-response effect.

Materials and methods

2.1 Participants

In September 2020, via social media posts and emailing, a recruitment call was opened for investigating the efficacy of a MBI in poor-sleepers. All those showing interest in participating in the study were asked to complete the PSQI to select participants with low sleep quality (target population). More specifically, the inclusion criteria were: i) having a PSQI score >5 indicating impaired sleep quality, and ii) 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. This second criterion was checked by directly asking the participant about their condition. All the subjects signed the informed consent and the privacy policy.

Eligible participants were randomly assigned to the intervention or control group. Participants in the passive control group were assigned to a waiting list and, for ethical reasons, were offered the same intervention as the treatment group once the study was completed.

The study was registered in the ISRCTN registry (ISRCTN39530091).

2.2 Intervention

The intervention consisted of 12 mindfulness-based IM classes given twice a week from October to December 2020. Each class lasted approximately 60 minutes and was delivered on the Zoom video conferencing platform[16]. 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[17–19]. Here for the first time, we tested its efficacy on poor-sleepers, for this reason the IM protocol was slightly adjusted to meet the needs of the target population placing a particular emphasis on self-body and emotional listening, and thoughts awareness in order to differentiate positive and negative thoughts.

Participants also received 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 received 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.) was recommended[20]. 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[21]. 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 were 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[22]; so that H1 receptor antagonist are often used for the treatment of insomnia even if with potential side effects.

2.3 Psychological and sleep metrics

Each participant in both groups at two different time points, t0 (before the start of the study) and t1 (at the end of the study), filled in eight self-report questionnaires; two measuring psychological factors (ERQ and FFMQ) and six measuring parameters of sleep quantity, global quality and continuity (PSQI, APS, SCI, FIRST, ISI, SHI). Sociodemographic information was also collected from each participant through a background questionnaire administered at t0 only.

As for the sleep-related outcomes:

The PSQI questionnaire comprises 19 questions exploring seven different components of sleep quality over a month: sleep duration, sleep disturbance, sleep latency, daytime dysfunction due to sleepiness, sleep efficiency, overall sleep quality, and sleep medication used, plus five questions rated by the bed partner or roommate (if one is available). Each item is rated from 0 to 3. PSQI scores > 5 and ≤ 5 indicated poor and good sleep quality, respectively. Sleep disorders are determined when PSQI>7[23]. PSQI was also used to identify eligible participants (see section 2.1).

The SCI is an eight-item rating scale that was developed to screen for insomnia disorder based on the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria. The SCI comprises two items on sleep continuity (item 1: getting to sleep; item 2: remaining asleep), two items on sleep satisfaction/dissatisfaction (item 4: sleep quality; item 7: troubled or not), two items on severity (item 3: nights per week; item 8: duration of problem), two items on attributed daytime consequences of poor sleep (item 5: effects on mood, energy or relationships (personal functioning); item 6: effects on concentration, productivity, or ability to stay awake (daytime performance)[24].

The ISI is a seven-item questionnaire assessing the nature, severity, and impact of insomnia. The usual recall period is the “last month” and the dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A five-point Likert scale is used to rate each item (0=no problem; 4=very severe problem) and total scores range from 0 to 28. Between 22 and 28 points indicate a possible clinical insomnia problem[25].

The SHI is a 13-item index developed to assess the presence of sleep hygiene behaviors. Participants are asked to show how frequently they engaged in specific behaviors (always, frequently, sometimes, rarely, never). Each item is rated on a five-point Likert scale (ranging from 0=never to 4=always). The total scores ranged from 0 to 52, with higher scores revealing more maladaptive sleep hygiene status[26].

The FIRST is a nine-item scale used to assess an individual's likelihood of experiencing sleep difficulties in response to common stressful situations. Each item is self-rated on a four-point Likert scale and summed to yield a score between 9 and 36, higher scores indicate higher levels of sleep reactivity[27].

The APS is a 12-item scale that measures arousability. Each item is in the format of a self-description (e.g., “I get excited easily”). Subjects can select one of five responses: “never”, “seldom”, “occasionally”, “frequently” or “always”. Six specific indexes frequently associated with insomnia are assessed: (1) delayed sleep onset latency, (2) frequent night awakenings, (3) frequent nightmares, (4) dormital restlessness, (5) early morning awakenings, and (6) subjective feelings of tiredness upon arising[28].

As for the psychological outcomes:

The ERQ is a 10-item questionnaire that consists of two scales corresponding to two different emotion regulation strategies: cognitive reappraisal (six items) and expressive suppression (four items). The 10 items are rated on a seven-point Likert scale from strongly disagree to strongly agree[29].

The FFMQ is a 39-item multidimensional assessment tool designed to measure a person’s level of mindfulness. In particular, it is aimed to measure five interrelated components of mindfulness, which are: (1) observing (three items), (2) describing (three items), (3) acting with awareness (three items), (4) non-judging of inner experiences (three items), (5) non-reactivity to inner experience (three items). A higher score in the FFMQ full-scale as well as in its subscales reflects a higher level of mindfulness[30]. The questionnaire has shown good psychometric properties both in the English and Italian versions, which show a similar factorial structure to the original. A higher score after an intervention reflects an improved level of mindfulness.

For all the above listed questionnaires we used the validated Italian versions.

At the end of the study, participants in the treatment group were also asked to evaluate their adherence to the dietary advice on a scale from 1 (“I haven’t followed the dietary advice”) to 10 (“I followed the dietary advice at every meal”).

Participants completed all the above-described questionnaires online via Google Forms following the instructions sent by email.

2.4 Statistical analysis

This was a two-groups pre-post experimental design, in which participants were randomly assigned to the intervention or the control group (allocation ratio 1:1). For each group, outcome variables were collected at two time points (t0 and t1) and subjects who did not fill in all the proposed questionnaires at both time points were excluded from the analysis. Questionnaires were scored following the provided guidelines, and, for each questionnaire, internal consistency was assessed via Cronbach's α coefficient[31].

Differences between groups at baseline characteristics, collected through the background questionnaire, were investigated in each continuous variable by using t-test or Wilcoxon test and in each categorical variables by using chi-squared or Fisher's exact test.

Linear Mixed Effect (LME) models[32] were applied to evaluate the pre-post treatment changes on each outcome. A random intercept for subjects in the form of 1|subject was used to adjust the models for intra-subject variability produced by the two repeated measurements at t0 and t1 carried out on the same subject.

To test our research hypotheses regarding the beneficial effect of our intervention on ameliorating sleep problems and on fostering emotion regulation and mindfulness, we investigated the six sleep-related outcomes and the two psychological indicators. For each outcome we estimated the coefficient of the interaction between time and treatment indicating how much more the intervention group improved over time with respect to the investigated endpoints, compared to the control group over the same period.

All models were adjusted for sex, age, previous meditation experience and consumption of drugs for sleep disturbance. A p-value<0.05 on a two-sided test was considered as statistically significant. For each model, normality of residuals was assessed graphically through Q-Q plots and via the Shapiro-Wilk test. In the case of non-normality of residuals, empirical bootstrap with 5,000 bootstrapped replicates was applied to estimate non-parametric 95% C.I.s and p-values based on distribution's quantiles[33].

A linear model of the number of IM classes attended by each participant on each post-pre difference in questionnaires score (Δ) was also fitted for testing the possible dose-response effect using the number of meditation sessions attended (in days) as explanatory variable, controlling for sex, age, previous meditation experience and consumption of drugs for sleep disturbances treatment.

Descriptive statistics are reported as the mean ± standard deviation (SD). All analysis were done using R 3.5.1 software[34].

Results

Ninety subjects showed interest in participating in the study and received the eligibility questionnaire: 78 filled in the questionnaire but only 59 fulfilled the inclusion criteria and were randomly allocated to the treated (n=30) or control (n=29) group. Of these 59 eligible subjects, two in the treated and one in the control group, did not fill in the endpoints questionnaires so were excluded from the analysis. This resulted in a final total sample of 56 subjects, 28 per group, 46 females and 10 males, with a mean age of 53.7 (SD= 11.6) (see **Figure 1**).

Baseline (t0) characteristics of participants for the two groups are shown separately in **Table 1**. No statistically significant differences were observed between the two groups at

baseline parameters. In **Table 2** mean, SD and internal consistency for each questionnaire and subscale in the two groups at both time points are reported.

It is worth noting that at t0, 39 subjects (19 controls and 20 treated) had a SCI questionnaire score<16, indicating an insomnia condition; all of them also reported a chronic insomnia condition (persisting for at least three months) as measured by the 8th item of the SCI questionnaire. After the intervention, 16 subjects (12 controls and only four treated) had an SCI questionnaire score<16. As regards PSQI, at t0 the whole sample had a score ≥ 5, indicating a poor sleep quality, while at t1, three subjects in the control group and seven subjects in the treatment group had a score<5, indicating that they no longer had a poor sleep quality. Moreover, before the intervention, a total of 13 subjects reported sleeping less than five hours a day (seven controls and six treated), while at t1 a total of eight subjects reported sleeping less than five hours a day (six controls and two treated), as measured by Component 3, i.e., sleep latency, of the PSQI.

The mean number of IM classes attended by the 38 participants was 8.9 over a total of 12 classes with 78% of the participants attending at least seven classes. This indicates good participation by our subjects in the intervention proposed. So, IM classes participation showed the applicability of our study to those who wanted to improve sleep quality.

As for the dietary advice in the intervention group, 15 subjects reported a low adherence, eight a medium adherence, and five a high adherence.

Data were analyzed following an Intention-To-Treat (ITT) approach and LME models were used to estimate the effectiveness of the intervention on the investigated outcomes. The results, as reported in **Table 3**, support the hypothesis of the beneficial effect of our intervention on the sub-domain of FFMQ, *non-reactivity to inner experience*, (β = 0.29 [0.06; −0.52], p=0.01), on PSQI global score (β = -1.93 [-3.43; −0.43], p=0.01), on SCI (β = 3.39 [0.66; 6.13],

p=0.02) and on ISI (β = -3.50 [-5.86; -1.14], p=0.004) while no beneficial effect was observed on the remaining scales.

Furthermore, as regard the dose-response effect of the number of attended IM sessions on the pre-post differences in the questionnaire scores, no statistically significant dose-response effect was observed. This result must be interpreted with caution as the amount of time the participants engaged in individual practice of meditation was not recorded. For this reason, it is difficult to estimate a dose-response effect based only on IM class attendance.

Discussion

Sleep disorders, as characterized by poor sleep quantity and/or quality, have a high prevalence in the general population and are associated with an increased risk of developing mental, metabolic, and cardiovascular diseases, thus representing a public health issue[35,36]. For this reason, there is an urgent need to find easily accessible, effective, safe alternative treatments.

In our study, we tested the beneficial effect of a short MBI on sleep quality, quantity, and continuity, and on emotion regulation and mindfulness. The effect of our intervention was tested using a sample of poor-sleepers Italian as assessed using the PSQI questionnaire. We detected beneficial effects of our intervention in the intervention group compared to the control group. In the intervention group we found improved sleep quality and decreased insomnia symptoms and severity as indicated by the statistically significant results obtained in the global score of PSQI global (β=-1.93[-3.43;−0.43],p=0.01), in SCI (β=3.39[0.66;6.13],p=0.02) and in ISI (β=-3.50[-5.86;-1.14],p=0.004). These results are in accordance with our hypothesis and indicate that our intervention, whose core element is the IM, represents an effective tool in promoting healthy sleep components in those samples with poor sleep quality. Our findings

support current literature which indicates how MBIs improve sleep quality in people with sleep disturbances as compared with inactive or nonspecific active controls[7,8].

It is important to emphasize that before the intervention, 68% of the participants in the control group and 71% of the participants in the intervention group reported an insomnia condition, this rate decreased to 57% and 14% respectively after the intervention. Furthermore, 10% of the participants in the control group and 25% of the participants in the treated group reported no longer having poor sleep quality.

This study took place during a period when COVID-19 was still very widespread in Italy and as shown in a study conducted on 2,291 Italian, 57.1% experienced poor sleep quality, 32.1% high levels of generalized anxiety symptoms, and 41.8% psychological distress[37] and in another study was also found widespread pre-sleep arousal[38]; thus demonstrating how the participants' sleep quality was strongly affected by the COVID-19 situation in Italy.

We found no changes in predisposition to arousability (as measured by APS), nor in the trait sleep reactivity (as measured by FIRST). These results might be explained by the fact that these are probably too stable traits to change after such a short intervention. Interestingly, in our study 40 out of 56 subjects yielded a FIRST score≥18 at t0, indicating a high risk for insomnia[39].

As for sleep hygiene behaviors, measured by SHI, we found no changes either on the whole scale or on single items. We had expected that the change to a more mindful mindset would result in the improvement of some dysregulated behaviors. Since the participants showed only a small change or no change in their level of different mindfulness domains, we can assume that this shift in their mindset did not happen, and the benefits of the intervention led only to more immediate effects (i.e., stress relief, relaxation) that helped the participants to improve their sleep without affecting their mindset in a significant way. Another possible explanation

is the fairly high average age of participants. Spontaneous change in habitual rooted behavior is more difficult in older people. Although the dietary advice was a non-mandatory part of our intervention, we registered a low-medium adherence to the diet in most of the participants. As confirmed by SHI, the participants showed difficulty in actively regulating or changing their eating behaviours even when they knew it could improve their sleep quality.

Whilst we expected our intervention to produce noticeable changes in emotional regulation strategies and dispositional mindfulness, we did not find significant effects on them, except for on a sub-component of dispositional mindfulness, which is non-reactivity to inner experience. Probably because our intervention was only effective in helping the participants reach healthier sleep by providing them with a practical tool to auto-regulate their biological and psychological systems. This means that our intervention worked efficiently on the compelling evident needs of the participants without being able to produce a deeper shift in their emotional regulation strategies and their overall mindfulness level. Such a shift might require more consistent practice.

Conclusions and limitations

This study demonstrates the effectiveness of low-cost and easy-to-access online MBI in improving sleep quality and reducing insomnia symptoms and severity among poor-sleepers.

The study had the following limitations: i) given the nature of our intervention the obviously voluntary-based enrolment led to results that may be only applicable to people who are willing to meditate and interested in the theme of meditation; ii) the solely use of self-report measures; iiii) the absence of monitoring the individual practice of meditation with subsequent difficulties in the estimation of a dose-response effect.

Funding

This research did not receive any specific funding.

Data availability statement

All datasets presented in this study are included in the supplementary material.

Ethics statement

The study was approved by the Ethical Committee of the Department of Brain and Behavioral Sciences of the University of Pavia (Prot n. 63/2020) and was performed in accordance with the 1964 Helsinki declaration and its later amendments. The study was registered in the ISRCTN registry (ISRCTN39530091).

Tables

1. Baseline characteristics of the analysed sample (treated=28, controls=28).

Variables	**Mean (SD) controls**	**Mean (SD) treated**	**p-value[a]**
Age	53.96 (13.31)	53.46 (10.04)	0.87
	N (%) controls	**N (%) treated**	
Sex			
Male	5 (18%%)	5 (18%)	1
Female	23 (82%)	23 (82%)	
Nationality			
Italian	26 (93%)	28 (100%)	0.49
Non-Italian	2 (7%)	0 (0%)	
Marital status			
Cohabitant/married	11 (39%)	16 (57%)	0.36
Unmarried/single	8 (29%)	4 (14%)	
Separated/Divorced	8 (29%)	8 (29%)	
Wodowed	1 (4%)	0 (0%)	
Number of children			
0	10 (36%)	11 (39%)	0.43
1	6 (21%)	8 (28%)	
2	9 (32%)	9 (32%)	
≥3	3 (11%)	0 (0%)	
Dependent children/family members			
No	18 (64%)	18 (64%)	1
Yes	10 (36%)	10 (36%)	
Unpaid loans			
No	21 (75%)	22 (79%)	1
Yes	7 (25%)	6 (21%)	
Education			
Middle school	1 (4%)	1 (4%)	1
High school	11(39%)	10 (36%)	
Degree	13 46(%)	14 (50%)	
Post-graduate course (e.g. PhD)	3 (11%)	3 (11%)	

Job			
Public or private employee	15 (54%)	16 (57%)	0.35
Freelance (e.g., lawyer, doctor etc)	4 (14%)	3 (11%)	
Student	0 (0%)	1 (4%)	
Unemployed or looking for a job	3 (11%)	0 (0%)	
Housewife	0 (0%)	2 (7%)	
Retired	6 (21%)	6 (21%)	
Type of employment agreement			
Undetermined term	13 (46%)	15 (54%)	0.80
Fixed term	4 (14%)	2 (7%)	
Not applicable	11 (39%)	11 (39%)	
Employee satisfaction			
No	12 (43%)	7 (25%)	0.26
Yes	16 (57%)	21 (75%)	
Sport			
No	5 (18%)	8 (29%)	0.53
Yes	23 (82%)	20 (71%)	
Smoker			
Yes	4 (14%)	4 (14%)	1
No	24 (86%)	24 (86%)	
Knowledge about meditation			
Clear idea	19 (68%)	16 (57%)	0.40
Vague idea	8 (29%)	12 (43%)	
Just heard of	1 (4%)	0 (0%)	
Previous meditation experience			
Yes	22 (79%)	24 (86%)	0.73
No	6 (21%)	4 (14%)	
Religious			
No	13 (46%)	16 (57%)	0.59
Yes	15 (54%)	12 (43%)	
Number of books read in a year			
0 -1	4 (14%)	2 (7%)	0.52
2 -3	6 (21%)	4 (14%)	
>3	18 (64%)	22 (79%)	
Member of a cultural/sportive association			
No	20 (71%)	17 (61%)	0.57
Yes	8 (29%)	11 (39%)	
Diet			
Mediterranean	22 (79%)	24 (86%)	0.69
a	2 (7%)	1 (4%)	
Vegan	3 (11%)	1 (4%)	
Macrobiotic	1 (4%)	2 (7%)	
Disease/disability			
No	20 (71%)	15 (54%)	0.27
Yes	8 (29%)	13 (46%)	
Addiction			
No	27 (96%)	25 (89%)	0.61
Yes	1 (4%)	3 (11%)	
Have you ever gone to a psychologist			
No	10 (36%)	11 (39%)	1
Yes	18 (64%)	17 (61%)	
Drug for insomnia			
No	21 (75%)	17 (61%)	0.39
Yes	7 (25%)	11 (39%)	

[a] p-value for between-groups comparison.

Table 2. Mean, SD and internal consistency for each questionnaire and subscale in the two groups (controls and treated) at both time points (t_o and t_1).

Questionnaire	**Mean (SD) controls t0**	**Mean (SD) treated t0**	**Mean (SD) controls t1**	**Mean (SD) treated t1**	**Internal consistency t0**	**Internal consistency t1**
ERQ						
Reappraisal	4.97 (1.09)	5.09 (1.20)	5.05 (1.13)	4.88 (1.26)	0.89	0.91
Suppression	3.68 (1.05)	3.39 (1.36)	3.52 (1.25)	3.60 (1.04)	0.70	0.61
FFMQ						
All Items	3.26 (0.52)	3.18 (0.51)	3.25 (0.44)	3.30 (0.41)	0.93	0.88
Observing	3.41 (0.84)	3.49 (0.68)	3.37 (0.79)	3.49 (0.67)	0.85	0.83
Describing	3.59 (0.81)	3.50 (0.77)	3.57 (0.73)	3.64 (0.75)	0.92	0.91

Acting with awareness	3.22 (0.78)	3.01 (0.73)	3.27 (0.77)	3.15 (0.63)	0.91	0.88
Non-judging of inner experience	3.18 (0.92)	3.18 (0.88)	3.22 (0.79)	3.28 (0.84)	0.93	0.91
Non-reactivity to inner experience	2.83 (0.65)	2.68 (0.59)	2.73 (0.73)	2.88 (0.58)	0.81	0.83
PSQI						
All Items	11.61 (3.71)	10.64(3.03)	9.86 (3.97)	6.96 (3.18)	0.60	0.70
Subjective sleep quality (Component 1)	1.86 (0.65)	1.82 (0.72)	1.75 (0.58)	1.18 (0.47)		
Sleep latency (Component 2)	2.14 (1.04)	1.46 (0.79)	1.50 (1.14)	1.04 (0.79)		
Sleep duration (Component 3)	1.79 (0.83)	1.96 (0.69)	1.61 (0.99)	1.25 (0.89)		
Sleep efficiency (Component 4)	1.46 (1.26)	1.29 (0.98)	1.54 (1.35)	0.82 (1.06)		
Sleep disturbance (Component 5)	1.64 (0.68)	1.57 (0.50)	1.50 (0.64)	1.18 (0.48)		
Use of sleep medication (Component 6)	1.29 (1.18)	1.32 (1.36)	0.71 (1.08)	0.86 (1.27)		
Daytime dysfunction (Component 7)	1.43 (0.63)	1.21 (0.63)	1.25 (0.64)	0.64 (0.56)		
APS						
All Items	38.96 (6.24)	37.57 (6.62)	39.00 (7.59)	38.39 (6.05)	0.85	0.86
SCI						
All Items	13.39 (6.78)	13.82 (5.68)	16.46 (5.56)	20.28 (5.01)	0.81	0.78
FIRST						
All Items	22.03 (6.86)	23.07 (5.45)	22.71 (6.51)	23.21 (6.12)	0.90	0.89
ISI						
All Items	11.75 (4.35)	11.64 (4.33)	11.32 (5.00)	7.71 (3.89)	0.82	0.83
SHI						
All Items	29.61 (5.76)	28.11 (4.72)	28.57 (5.80)	26.61 (5.29)	0.61	0.64

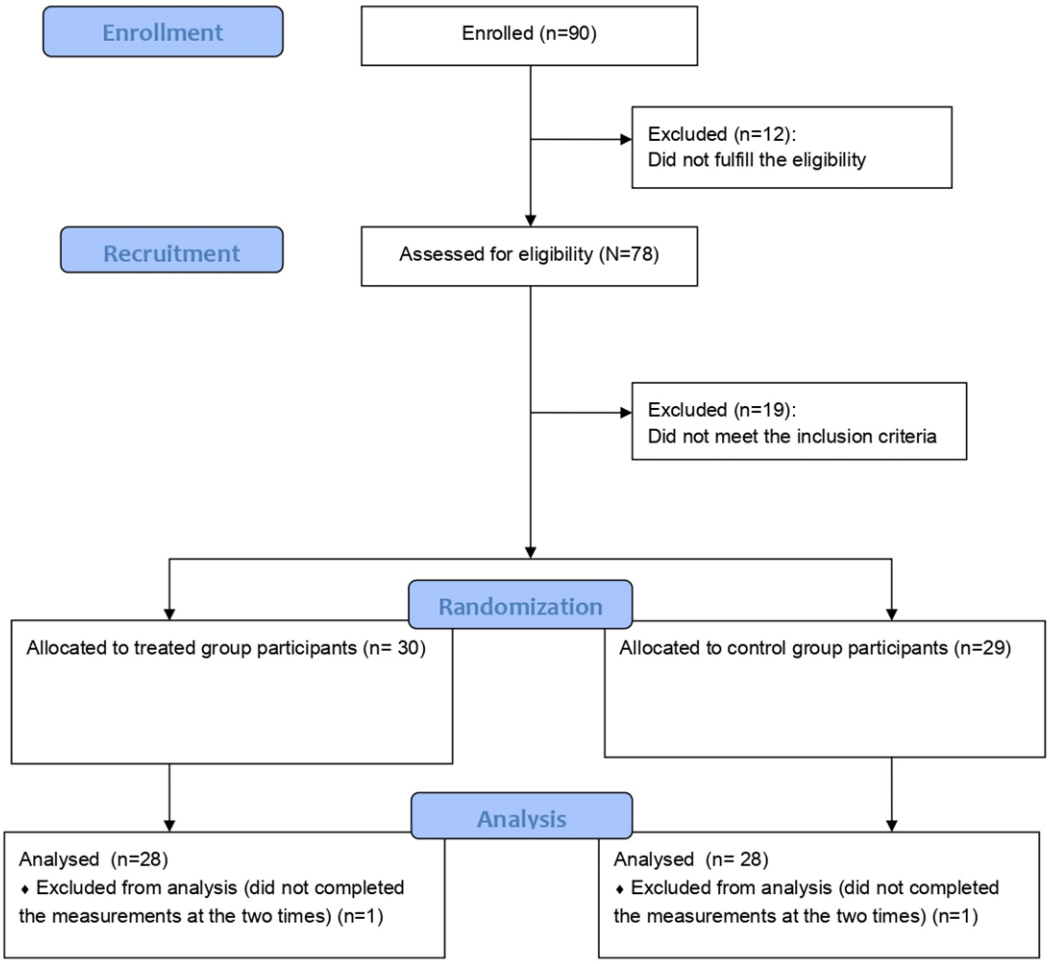
SD: Standard Deviation

Table 3. Between-group differences obtained using a linear mixed model. For each questionnaire and subscale β coefficient of time*group interaction with its 95% CI, and p-value are reported.

Questionnaire	**β time*group[95%CI]**	**p-value**
ERQ		
Reappraisal	-0.29 [-0.90;0.36]	0.34
Suppression	0.37 [-0.25;0.98]	0.24
FFMQ		
All Items	0.12 [-0.01;0.26]	0.06
Observing	0.03 [-0.22;0.29]	0.78
Describing	0.16 [-0.04;0.37]	0.11
Acting with awareness	0.08 [-0.17;0.34]	0.51
Non-judging of inner experience	0.07 [-0.30;0.44]	0.72
Non-reactivity to inner experience	0.29 [0.06;0.52]	0.01
PSQI		
All Items	-1.93 [-3.43;-0.42]	0.01
Subjective sleep quality	-0,53 [-0.85;-0.22]	0.001
Sleep latency	0.21 [-0.21;0.63]	0.31
Sleep duration	-0.54 [-0.92;-0.15]	0.007
Sleep efficency	-0.54 [-1.16;0.09]	0.09
Sleep disturbance	-0.25 [-0.58;0.08]	0.13
Use of sleep medication	0.11 [-0.39;0.60]	0.66
Daytime dysfunction	-0.39 [-0.76;-0.03]	0.03
APS		
All Items	-0.79 [-1.68;3.25]	0.52
SCI		
All Items	3.39 [0.66;6.13]	0.02
FIRST		
All Items	-0.54 [-2.97;1.90]	0.66
ISI		
All Items	-3.50 [-5.86;-1.14]	0.004
SHI		
All Items	-0.46 [-2.44;1.52]	0.64

P-values 0.05 are considered statistically significant. All models are adjusted for sex, age, previous meditation experience and use of drugs for insomnia.

Figure 1. Participant flow diagram



References

[1] M.G. Terzano, L. Parrino, F. Cirignotta, L. Ferini-Strambi, G. Gigli, G. Rudelli, S. Sommacal, E. Bonnani, A. Iudice, O. Bruni, S. Ottaviano, P. Dolso, R. Ferri, F. Cosentino, F. Ferrillo, L. Nobili, M. Guazzelli, L. Palagini, E. Lugaresi, F. Provini, G.F. Mennuni, G. Della Marca, S. Mondini, F.M. Puca, M. Savarese, M. Raffaele, G. Mento, A. Scrofani, V. Fassari, S. Smirne, A. Tartara, R. Manni, E. Ubiali, M. Viscardi, Studio Morfeo: insomnia in primary care, a survey conducted on the Italian population, Sleep Med. 5 (2004) 67–75. https://doi.org/10.1016/J.SLEEP.2003.09.006.

[2] M.M. Ohayon, S. Smirne, Prevalence and consequences of insomnia disorders in the general population of Italy, Sleep Med. 3 (2002) 115–120. https://doi.org/10.1016/S1389-9457(01)00158-7.

[3] N.E. Varghese, A. Lugo, S. Ghislandi, P. Colombo, R. Pacifici, S. Gallus, Sleep dissatisfaction and insufficient sleep duration in the Italian population, 10 (2020) 17943. https://doi.org/10.1038/s41598-020-72612-4.

[4] S. Marelli, A. Castelnuovo, A. Somma, V. Castronovo, S. Mombelli, D. Bottoni, C. Leitner, A. Fossati, L. Ferini-Strambi, Impact of COVID-19 lockdown on sleep quality

in university students and administration staff, J. Neurol. 268 (2021) 8–15. https://doi.org/10.1007/S00415-020-10056-6.

[5] M. Casagrande, F. Favieri, R. Tambelli, G. Forte, The enemy who sealed the world: effects quarantine due to the COVID-19 on sleep quality, anxiety, and psychological distress in the Italian population, Sleep Med. 75 (2020) 12–20. https://doi.org/10.1016/J.SLEEP.2020.05.011.

[6] A. Qaseem, D. Kansagara, M.A. Forciea, M. Cooke, T.D. Denberg, M.J. Barry, C. Boyd, R.D. Chow, N. Fitterman, R.P. Harris, L.L. Humphrey, S. Manaker, R. McLean, T.P. Mir, H.J. Schünemann, S. Vijan, T. Wilt, Management of Chronic Insomnia Disorder in Adults: A Clinical Practice Guideline From the American College of Physicians, Ann. Intern. Med. 165 (2016) 125–133. https://doi.org/10.7326/M15-2175.

[7] H.L. Rusch, M. Rosario, L.M. Levison, A. Olivera, W.S. Livingston, T. Wu, J.M. Gill, The effect of mindfulness meditation on sleep quality: a systematic review and meta-analysis of randomized controlled trials, Ann. N. Y. Acad. Sci. (2019). https://doi.org/10.1111/nyas.13996.

[8] H. Gong, C.X. Ni, Y.Z. Liu, Y. Zhang, W.J. Su, Y.J. Lian, W. Peng, C.L. Jiang, Mindfulness meditation for insomnia: A meta-analysis of randomized controlled trials, J. Psychosom. Res. (2016). https://doi.org/10.1016/j.jpsychores.2016.07.016.

[9] A. Chiesa, T. Fazia, L. Bernardinelli, G. Morandi, Citation patterns and trends of systematic reviews about mindfulness, Complement. Ther. Clin. Pract. 28 (2017) 26–37. https://doi.org/10.1016/j.ctcp.2017.04.006.

[10] C. Gardi, T. Fazia, B. Stringa, F. Giommi, A short Mindfulness retreat can improve biological markers of stress and inflammation, Psychoneuroendocrinology. 135 (2022). https://doi.org/10.1016/J.PSYNEUEN.2021.105579.

[11] C.F. Schlechta Portella, R. Ghelman, V. Abdala, M.C. Schveitzer, R.F. Afonso, Meditation: Evidence Map of Systematic Reviews, Front. Public Heal. 9 (2021) 742715. https://doi.org/10.3389/FPUBH.2021.742715.

[12] N.Y. Winbush, C.R. Gross, M.J. Kreitzer, The effects of mindfulness-based stress reduction on sleep disturbance: a systematic review, Explore (NY). 3 (2007) 585–591. https://doi.org/10.1016/J.EXPLORE.2007.08.003.

[13] C.A. Espie, Insomnia: Conceptual issues in the development, persistence, and treatment of sleep disorder in adults, Annu. Rev. Psychol. (2002). https://doi.org/10.1146/annurev.psych.53.100901.135243.

[14] J.C. Ong, C. Moore, What do we really know about mindfulness and sleep health?, Curr. Opin. Psychol. (2020). https://doi.org/10.1016/j.copsyc.2019.08.020.

[15] H.S. Dashti, F.A.J.L. Scheer, P.F. Jacques, S. Lamon-Fava, J.M. Ordovás, Short sleep duration and dietary intake: epidemiologic evidence, mechanisms, and health implications, Adv. Nutr. 6 (2015) 648–659. https://doi.org/10.3945/AN.115.008623.

[16] Zoom Video Communications, Inc. Global Infrastructure and Security Guide Global Infastructure & Security Guide, (2016).

[17] T. Fazia, F. Bubbico, I. Iliakis, G. Salvato, G. Berzuini, S. Bruno, L. Bernardinelli, Short-Term Meditation Training Fosters Mindfulness and Emotion Regulation: A Pilot Study, Front. Psychol. 11 (2020) 2828. https://doi.org/10.3389/fpsyg.2020.558803.

[18] T. Fazia, F. Bubbico, G. Berzuini, L.D. Tezza, C. Cortellini, S. Bruno, L. Bernardinelli, Mindfulness meditation training in an occupational setting: Effects of a 12-weeks mindfulness-based intervention on wellbeing, Work. (2021) 1–11. https://doi.org/10.3233/WOR-210510.

[19] T. Fazia, F. Bubbico, G. Salvato, G. Berzuini, S. Bruno, G. Bottini, L. Bernardinelli, Boosting psychological well-being through a social mindfulness-based intervention in the general population, Int. J. Environ. Res. Public Health. 17 (2020) 1–15. https://doi.org/10.3390/ijerph17228404.

[20] H. Binks, G.E. Vincent, C. Gupta, C. Irwin, S. Khalesi, Effects of Diet on Sleep: A Narrative Review, Nutrients. 12 (2020). https://doi.org/10.3390/NU12040936.

[21] K. Vielhaber, D. Riemann, B. Feige, A. Kuelz, C. Kirschbaum, U. Voderholzer, Impact of experimentally induced serotonin deficiency by tryptophan depletion on saliva cortisol concentrations, Pharmacopsychiatry. 38 (2005) 87–94. https://doi.org/10.1055/S-2005-837808.

[22] M.M. Thakkar, Histamine in the regulation of wakefulness, Sleep Med. Rev. 15 (2011) 65–74. https://doi.org/10.1016/J.SMRV.2010.06.004.

[23] D.J. Buysse, C.F. Reynolds, T.H. Monk, S.R. Berman, D.J. Kupfer, The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research, Psychiatry Res. 28 (1989) 193–213. https://doi.org/10.1016/0165-1781(89)90047-4.

[24] C.A. Espie, S.D. Kyle, P. Hames, M. Gardani, L. Fleming, J. Cape, The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder, BMJ Open. 4 (2014). https://doi.org/10.1136/BMJOPEN-2013-004183.

[25] C.M. Morin, G. Belleville, L. Bélanger, H. Ivers, The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response, Sleep. 34 (2011) 601–608. https://doi.org/10.1093/SLEEP/34.5.601.

[26] D.F. Mastin, J. Bryson, R. Corwyn, Assessment of sleep hygiene using the Sleep Hygiene Index, J. Behav. Med. 29 (2006) 223–227. https://doi.org/10.1007/S10865-006-9047-6.

[27] C. Drake, G. Richardson, T. Roehrs, H. Scofield, T. Roth, Vulnerability to stress-related sleep disturbance and hyperarousal, Sleep. 27 (2004) 285–291. https://doi.org/10.1093/SLEEP/27.2.285.

[28] S. Coren, K.B. Mah, Prediction of physiological arousability: a validation of the Arousal Predisposition Scale, Behav. Res. Ther. 31 (1993) 215–219.

https://doi.org/10.1016/0005-7967(93)90076-7.

[29] J.J. Gross, O.P. John, Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being., J. Pers. Soc. Psychol. 85 (2003) 348–62. http://www.ncbi.nlm.nih.gov/pubmed/12916575 (accessed November 15, 2018).

[30] R.A. Baer, G.T. Smith, J. Hopkins, J. Krietemeyer, L. Toney, Using Self-Report Assessment Methods to Explore Facets of Mindfulness, Assessment. 13 (2006) 27–45. https://doi.org/10.1177/1073191105283504.

[31] D. V. Cicchetti, Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology., Psychol. Assess. 6 (1994) 284–290. https://doi.org/10.1037/1040-3590.6.4.284.

[32] J.C. Pinheiro, D.M. Bates, Mixed-effects models in S and S-PLUS, Springer, 2000.

[33] J.A. Rice, Mathematical statistics and data analysis, (2013).

[34] R Development Core Team, R: a language and environment for statistical computing, Vienna, Austria R Found. Stat. Comput. (2017). http://www.r-project.org/.

[35] G. Medic, M. Wille, M.E.H. Hemels, Short- and long-term health consequences of sleep disruption, Nat. Sci. Sleep. 9 (2017) 151–161. https://doi.org/10.2147/NSS.S134864.

[36] M.A. Grandner, Sleep, Health, and Society, Sleep Med. Clin. 12 (2017) 1–22. https://doi.org/10.1016/J.JSMC.2016.10.012.

[37] F. Favieri, G. Forte, R. Tambelli, M. Casagrande, The Italians in the Time of Coronavirus: Psychosocial Aspects of the Unexpected COVID-19 Pandemic, Front. Psychiatry. 0 (2021) 279. https://doi.org/10.3389/FPSYT.2021.551924.

[38] M. Gorgoni, S. Scarpelli, A. Mangiaruga, V. Alfonsi, M.R. Bonsignore, F. Fanfulla, L. Ferini-Strambi, L. Nobili, G. Plazzi, L. De Gennaro, D. Arnaldi, E. Bonanni, G.A. Bonetti, C. Castronovo, M. Maestri, S. Garbarino, B. Guarnieri, R. Manni, L. Palagini, M. Puligheddu, R. Ferri, A. Silvani, C. Vicini, Pre-sleep arousal and sleep quality during the COVID-19 lockdown in Italy, Sleep Med. 88 (2021) 46–57. https://doi.org/10.1016/J.SLEEP.2021.10.006.

[39] D.A. Kalmbach, V. Pillai, J.T. Arnedt, C.L. Drake, Identifying At-Risk Individuals for Insomnia Using the Ford Insomnia Response to Stress Test, Sleep. 39 (2016) 449. https://doi.org/10.5665/SLEEP.5462.