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An Overview of the Methods Used to Measure the Impact of Mindfulness-Based Interventions in Sleep-Related Outcomes

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Abstract

Introduction Systematic reviews and metanalyses have shown that mindfulness-based interventions can have positive effects on health, such as reducing anxiety, depression, and chronic pain. However, their effect on sleep-related outcomes is not yet well established. Sleep can be assessed subjectively (questionnaires, sleep logs, self-reporting) and/or objectively (actigraphy, polysomnography, biological markers), and outcomes may differ depending on which type of assessment is used.

Objective In this study, we present a literature overview on mindfulness and sleep, innovatively presenting and discussing studies that address sleep subjectively and objectively.

Methods The search was undertaken using four databases (Pubmed Medline, Scopus, Web of Science, Psychinfo) in September 2019, and repeated in May 2021.

Studies were analyzed through a two-step process: (1) reading titles and abstracts, and (2) full text analysis that met the review's eligibility criteria, with the final sample comprising 193 articles. We observed a growth in the number of studies published, particularly since 2005. However, this was mostly due to an increase in studies based on subjective research. There is a moderate to nonexistent agreement between objective and subjective sleep measures, with results of subjective measures having higher variability and uncertainty.We identified 151 articles (78%) using an exclusively subjective sleep evaluation, which can cause a misperception about mindfulness effects on sleep.

Conclusion Future studies should place greater emphasis on objective measurements to accurately investigate the effects of mindfulness practices on sleep, although subjective measures also have a role to play in respect of some aspects of this relationship.

Keywords
- actigraphy
- polysomnography
- bibliometrics
- sleep quality
- mindfulness
- sleep

Introduction

Mindfulness can be defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment."[1] In the West, it has been operationally defined in as a nonautomatic state and as a trait that is based on a predisposition to a mindful and nonjudgmental attitude.[1–4]

The first evidence-based mindfulness intervention was developed by Jon Kabat-Zinn in 1979, the mindfulness-based stress reduction (MBSR) program. The program is structured

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in the format of 8 weekly formal meetings (lasting 2 to 2.5 hours), informal audioguided practices (~45 minutes), and a day of retreat. It was initially developed for chronic pain management, but it is currently applied to other conditions.[5,6] In formal practices, mindfulness exercises happen in a comfortable, seated posture, and the anchor can be the breathing, body sensations, sounds, and/or thoughts. In informal practices, awareness is encouraged in daily activities, without the need to sit or adopt any formal posture (e.g., mindful walking and mindful eating).[5,6] Although several modalities of mindfulness-based interventions are being developed, some characteristics are essential and common to all: they are grounded in theoretical and practical Buddhist traditions combined with scientific evidence, and their focus is to develop the ability of individuals to recognize triggers and alter their behavior by understanding the transient nature of their reactions to experiences.[7–9]

Several benefits of mindfulness training have already been described in the literature. For instance, studies show that regular and frequent practice develops both state and trait mindfulness, contributing to a more mindful attitude and less distress.[3,4] This practice promotes physical and mental health through the development of resilience (stress management skills) and the reduction of self-judgment and rumination.[4,7] For this reason, mindfulness has been considered as an additional tool for the treatment of anxiety, depression,[10] chronic pain,[11] and drug relapse.[4,12]

Although several benefits of mindfulness have been demonstrated, the evidence about its effects subjective and objective sleep is not yet well established. Recent findings suggest that mindfulness practice can alter the electrical activity of the brain during sleep, especially in respect of subsequent non-rapid eye movement (NREM) sleep, but these data are preliminary and these effects are poorly established in the literature.[13,14] A metanalysis study performed by Rusch et al. [15] found low-to-moderate strength evidence indicating that mindfulness meditation can improve subjective sleep quality when being assessed by questionnaires such as the Pittsburgh sleep quality index, the insomnia severity index, and the medical outcomes study sleep scale.

Sleep can be assessed using subjective or objective measures, with pros and cons for each one, and the results may differ depending on the approach used.

Subjective assessments are commonly used for initial screening to identify sleep disorders and/or for monitoring therapies. These assessments include questionnaires and sleep logs/self-reports, which can be used in conjunction to confirm a diagnosis.[16–18] Subjective measures of sleep onset and offset collected with sleep logs show strong agreement with objective measures, but variables related to wakefulness (e.g., awakenings) are not as accurate. Furthermore, this tool relies on participant compliance, which may result in missing data and poor individual reports.[17,19,20] Simple questionnaires are easiest to fill in than sleep logs, but they are predisposed to rounded estimates, and while validated questionnaires present good psychometric properties, the majority are not self-applicable.[20,21]

Objective measures include actigraphy and polysomnography tests, the latter being considered the gold standard for sleep assessment. Polysomnography allows the evaluation of sleep architecture and the quantification of parameters such as total sleep time, sleep latency, sleep efficiency, and the number of apneas, hypopneas, and awakenings, but it is usually restricted to nocturnal sleep.[18,22–24] Despite its high sensitivity and specificity, this high-cost exam is still limited to specialized clinics because it requires qualified technical personnel and suffers with the "first-night effect" (changes in usual sleep patterns on the first night of polysomnography).[25,26]

Actigraphy, on the other hand, allows for a longitudinal evaluation (day and night sleep) and the estimation of parameters similar to those measured by polysomnography, but it is a more restricted technique for the evaluation of respiratory and limb movement disorders.[17,22–24,27] This exam has a high accuracy and sensitivity, but its specificity is low, which impairs the estimation of variables related to wakefulness.[23,28] In addition to estimating sleep parameters, actigraphy can be used to record circadian rhythms; these parameters allow for the identification of possible syndromes associated with phase and/or period changes (e.g., advanced and delayed sleep phase syndrome; morning and evening tendencies), the adjustment of data to a Cosine curve, and nonparametric analysis to address rhythm fragmentation and stability.[22,24,27,29–31]

Considering other measurements as objective sleep measures and other sleep-related approaches (e.g., analysis of circadian parameters of activity and rest rhythm) may provide useful information about the effects of mindfulness and even elucidate possible mechanisms of action for its benefits. For example, it could demonstrate the potential for mindfulness practices to act as a nonphotic temporal marker, as well as mealtimes and social stimuli.[32,33] Indeed, preliminary data show an increase in melatonin production after non-mindfulness meditation.[34–36] Although preliminary, these findings indicate an effect of meditation on the timing system, which strengthens the need to consider other sleep-related approaches to investigate the effects of mindfulness, especially looking at circadian rhythms.

Therefore, this study aims to investigate trends in publications on mindfulness and sleep research, with a focus on the use of objective or subjective measures and their implications for the interpretation of results. As far as we know, this is the first scoping review on the topic, and as such it can contribute to the existing literature by showing the sleep approaches used in previous studies so researchers can better determine how future studies should be conducted to improve knowledge in this field.

Materials and Methods

The main goal of scoping reviews is to map a topic in the literature, to identify available evidence and possible gaps in the literature, and to clarify key points on the theme, providing the scope and an overview of its focus.[37] The scoping review was conducted in four databases (Pubmed Medline, Scopus, Web of Science, Psychinfo) and was developed according to the PRISMA extension for scoping reviews

checklist.[38] The database search process was undertaken on September 5, 2019, and updated on May 21, 2021.

The search focused on two main topics: mindfulness-based interventions and sleep as an outcome. The search strategy used for Medline is described below. The search strategies used for the other databases were similar, with adaptations according to the database (►**Supplementary File S1**, online only).

(Mindfulness[mesh] OR mindfulness* OR mindfulness-based OR "mindfulness based" OR "dialectical behavioral therapy" OR "acceptance and commitment therapy") AND (Sleep[mesh] OR polysomnography[mesh] OR actigraphy [mesh] OR "sleep wake disorders"[mesh] OR "sleep medicine specialty"[mesh] OR sleep[tiab] OR sleep*[tiab] OR polysomnogra* OR somnogra* OR insomnia* OR actigrap* OR actimet*)

The articles identified through the database search were compared and any duplicates were excluded. Article selection was then based on a two-step process: first, the titles and abstracts were reviewed by a single author. A second reviewer then analyzed the selected articles in full, including information about follow-up and the methodology employed. Both selection steps considered the inclusion and exclusion criteria described below.

Inclusion criteria: Articles that assessed mindfulness-based interventions, had a sleep-related outcome (primary or secondary), and were in Portuguese, English, or Spanish. There was no time limit for inclusion.

Exclusion criteria: Theoretical or review articles (except metanalyses; *i.e.* meta-analyses were accepted), interventions that were not based on mindfulness (e.g., Pilates, yoga, or nonmindfulness meditation), non-sleep related outcomes, and articles whose abstracts and/or titles were not found.

Only published articles were included and, from each one, four main areas of information were extracted:

Article metadata: Title, year of publication, name of the first author, country of the first author, and periodical.

Study characteristics: Type of experimental design (case study, randomized clinical trial, nonrandomized clinical trial, before and after, metanalysis); control type (passive, active, mixed, or uncontrolled). We also looked at the type and duration of the intervention, frequency per week, and duration of each session.

Sample characteristics: Gender, age-range, and associated pathologies and/or comorbidities were collected.

Sleep measures: Subjective (validated questionnaires, self-report, sleep log) or objective (polysomnography, actigraphy, or others) evaluation.

Based on the extracted data, a descriptive scoping review was produced.

Results and Discussion

After removal of duplicates, from the 3,152 articles identified in the search, 1,932 articles remained. Having analyzed abstracts and titles, 1,647 articles were removed with the remaining 285 articles undergoing a second review of the full articles. A further 92 articles failed to meet the inclusion criteria, with the remaining 193 articles constituting the final sample. ►**Fig. 1** shows the flowchart of the article selection process.

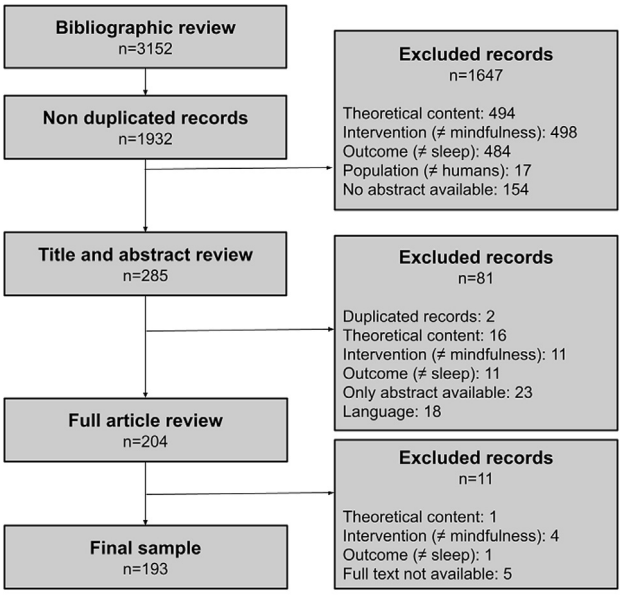

Fig. 1 Flow-chart of article selection.

Article Metadata

Despite being a new field, the frequency of publications over the years has grown considerably. The first recorded publication was in 1993, with more substantial growth from mid-2005, reaching an annual peak in 2018 (►**Fig. 2**).

Our search showed that there has been a significant increase in the number of studies on the effects of mindfulness on sleep-related outcomes, and that this trend represents an emerging phenomenon.[39–41] The number of studies on mindfulness surpassed the publications output on meditation in general in mid-2010.[40] The growth in publications was mainly due to an increase in research using subjective data, with the number of studies using objective data remaining constant over time, which is evidence of a gap in the literature on which future research can focus (►**Fig. 2**).

Regarding the country of origin, the greatest number of articles were published in the United States (100, 52%), followed by China (17, 9%), Australia (15, 8%), and Sweden (10, 5%). Brazil was the only country in South America that conducted this type of study, with 5 published articles (3%) (►**Fig. 3**).

These differences in publication output can be explained by the amount of research funding spent by the countries. It is estimated that Brazil invests around 1.3% of its gross domestic product in research versus 2.7% from United States and 2% from China,[42] the top two countries that have published the most about mindfulness and sleep.

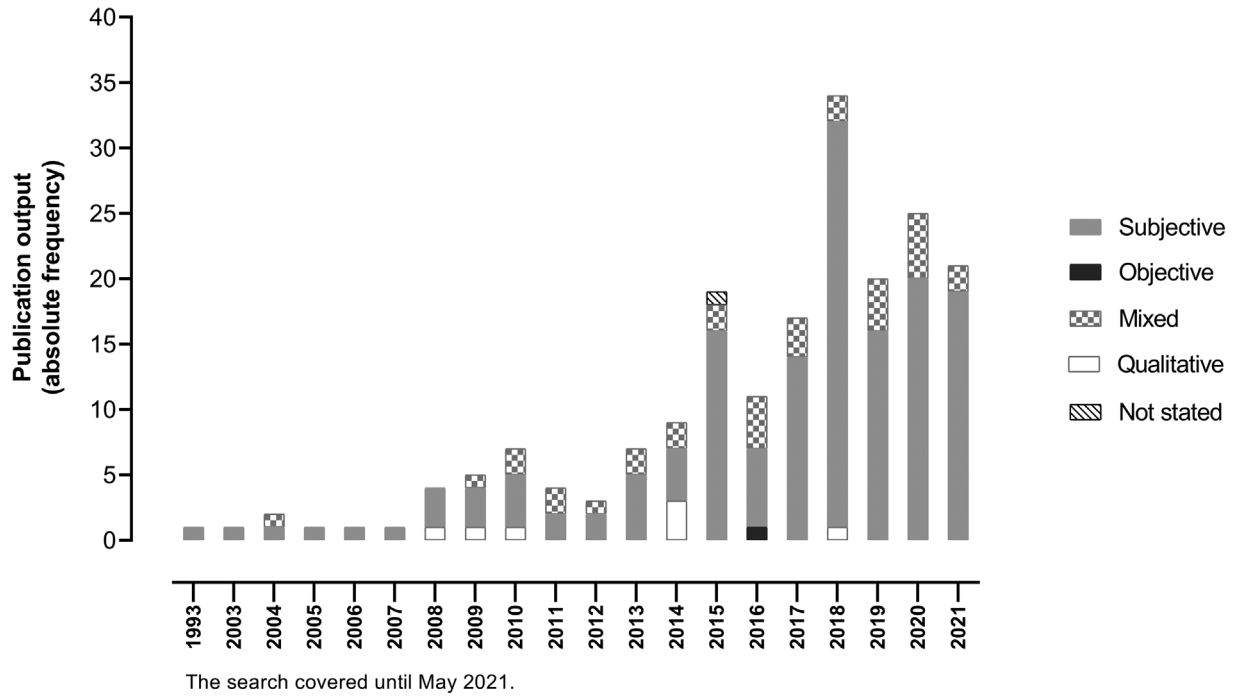

Fig. 2 Publication output through the years. The publication record in each year is further specified according to the type of sleep assessment methodology used.

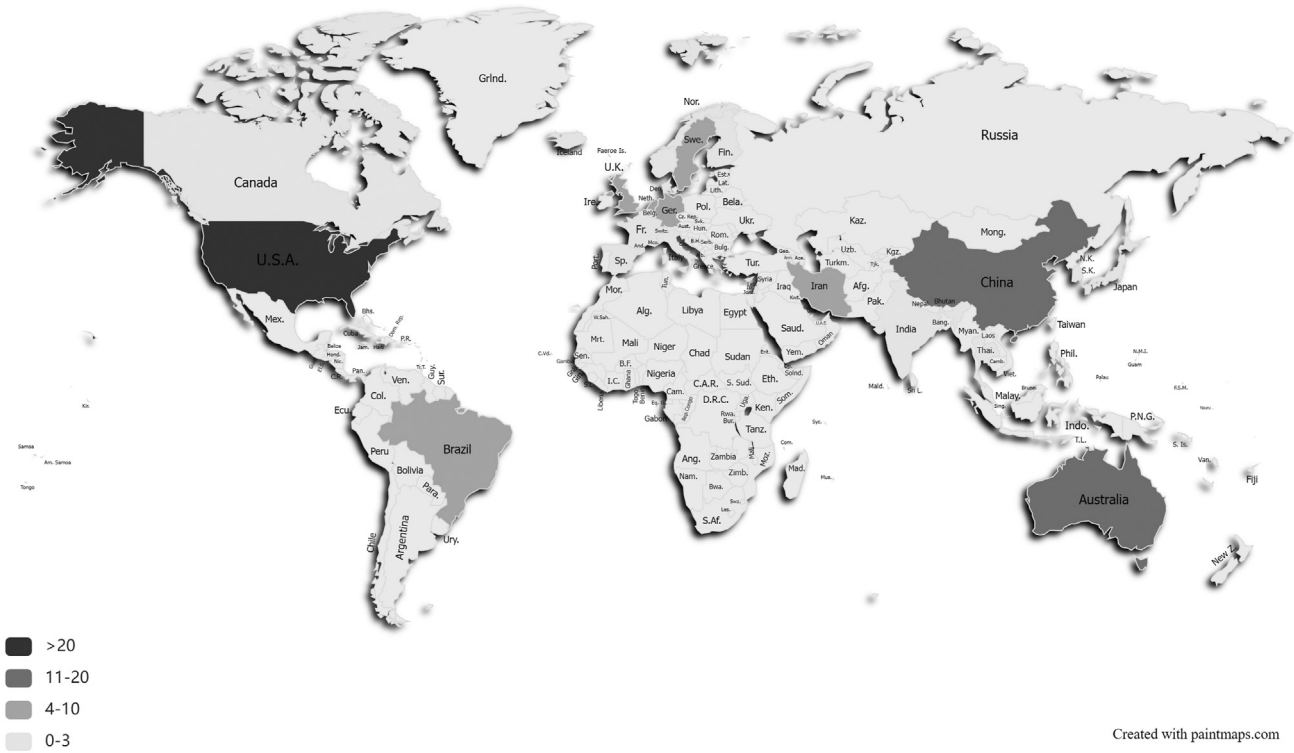

Fig. 3 Publication output according to the country of origin of the first author.

In respect of the journal's field, most articles were found in those related to behavioral medicine and psychology (48, 25%), followed by oncology (24, 12%). Although the outcome was sleep, only 9 articles (5%) were published in sleep medicine journals (►**Fig. 4**). This result indicates that most of the mindfulness/sleep-related studies are concentrated in the field of psychology,[40] probably because many of these interventions are applied for therapeutic purposes.[4]

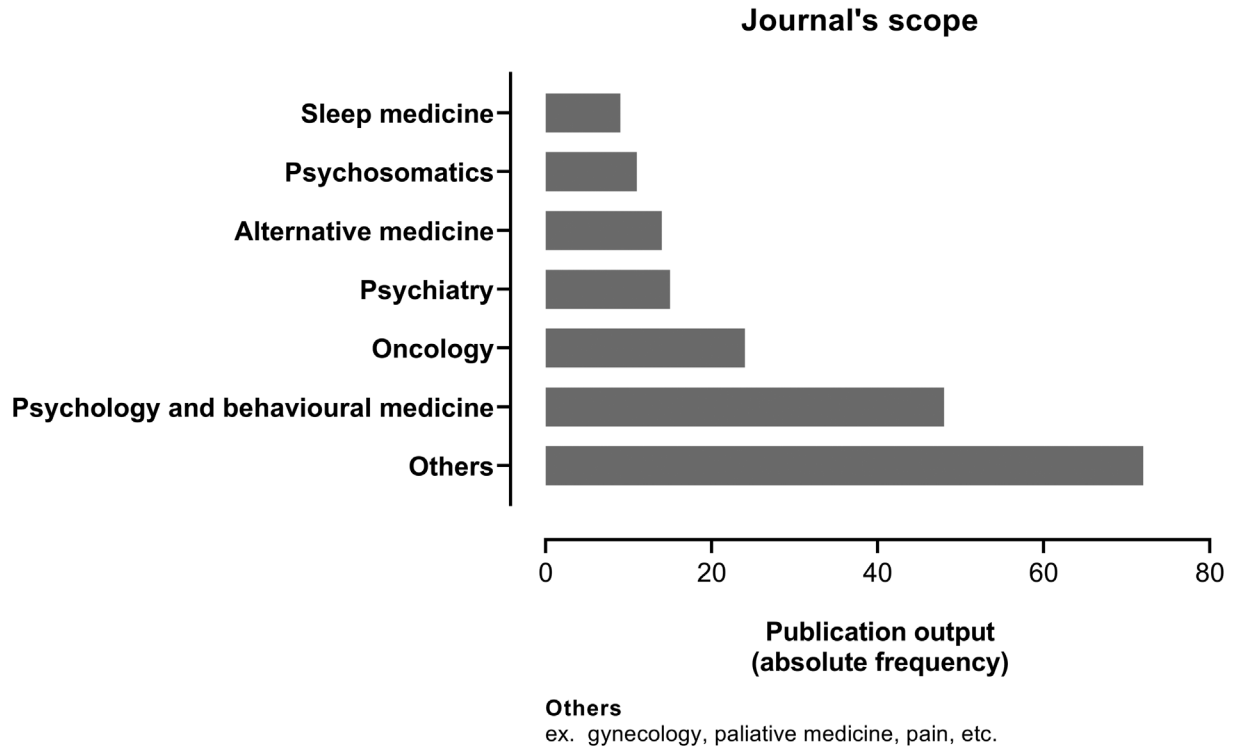

Fig. 4 Publication output according to the journal's scope.

Study Characteristics

Of the studies evaluated, 108 articles (56%) were randomized trials, and, of these, 45 (42%) used at least one active and parallel control (►**Fig. 5**), a practice validated and considered relevant for mindfulness-based intervention studies.[43]

Randomized clinical trials are considered the gold standard for experimental designs, as they are more likely to distribute possible confounding variables to all groups.[44,45] However, it is worth noting that this approach was designed initially for pharmacological studies, in which the motivation does not influence the treatment very much, while in

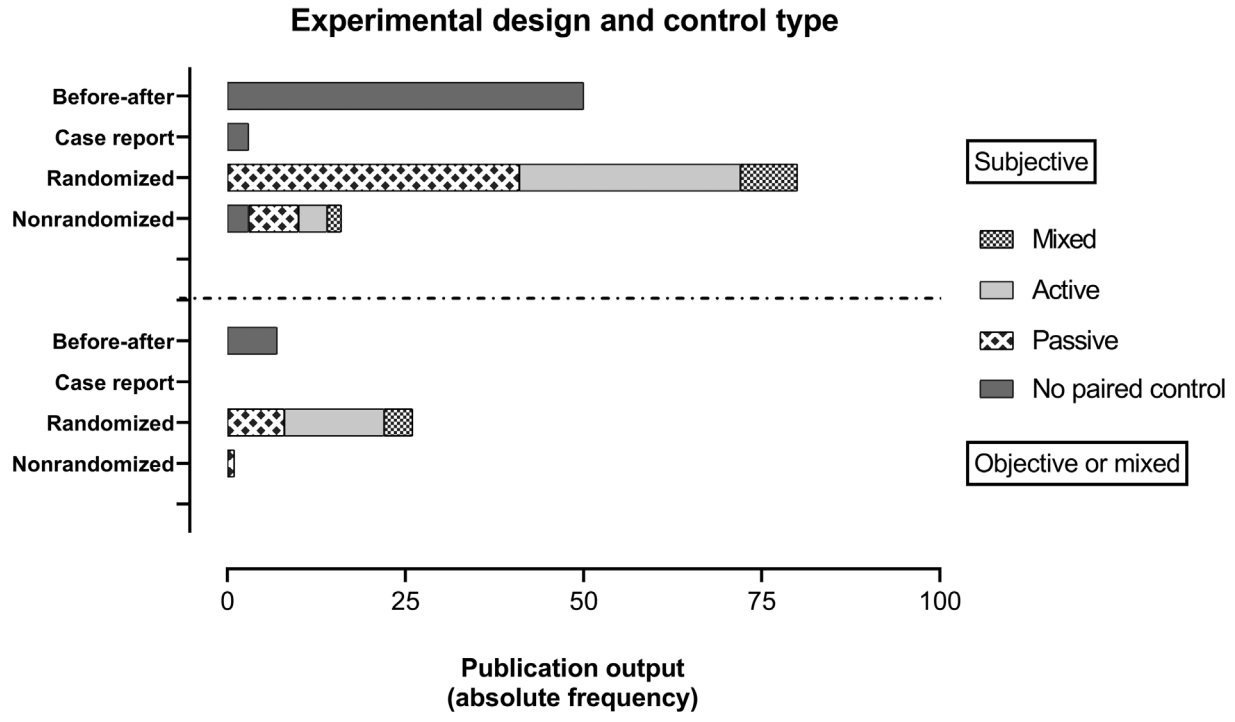

Fig. 5 Publication output according to the experimental design and type of control.

mindfulness-based interventions the adherence and engagement of the volunteer greatly influence the outcome.[45]

In our sample, 70 articles (36%) did not control the intervention by a parallel group and 62 (32%) adopted the before-after experimental design (►**Fig. 5**). This type of design is discouraged by organs such as Cochrane and the Emergency Medical Journal because it may overestimate the effects of the intervention, resulting in misleading information.[46]

Having an active control is important for three reasons: first, to ensure the balance of researcher compromise to the control group – which is responsible for approximately 10% of the variability in outcomes and 69% of the differences between interventions.[43,47] Second, in respect of the equality of experience, the use of so-called "waiting list" controls may expose participants to different experimental conditions, which may lead to results that are not associated with the intervention mechanism itself.[48] Active controls prevent this bias because they enable those nonspecific factors to be controlled, such as engagement in other activities at the time of the intervention.[43]

Based on this evidence, it is interesting to point out that 66% of the evaluated studies used the waiting list as a control (passive control) or did not have any parallel control group. This does not invalidate the findings, but it is a characteristic that should be considered when evaluating these results and designing future studies.

As can be seen in ►**Table 1**, most articles used MBSR as the protocol, following the original description (8 weekly sessions lasting from 2 to 2.5 hours).[5] Kabat-Zinn's objective was to make mindfulness concepts and practices accessible in a Western context through scientific language, with the aim of reducing stress by understanding body sensations through the use of techniques such as body scan and yoga.[5,49]

Following MBSR, other mindfulness-based protocols with specific outcomes were developed such as the mindfulness-based cognitive therapy (MBCT), which was the second most commonly used type of intervention in the articles evaluated in this study. It was developed by John Teasdale, Zindel Segal, and Mark Williams as a 8-week skill development program for the management of recurrent episodes of major depression, integrating MBSR and cognitive–behavioral therapy for depression.[12] Another mindfulness-related protocol is the acceptance and commitment therapy (ACT), a third wave psychotherapy based on behavioral analytical thinking that aims to increase physiological flexibility combining mindfulness practices (informal or formal) and acceptance process.[50,51] Other mindfulness-based interventions with adapted protocols (e.g., shorter duration and online format) are also described in the literature.[49] However, each protocol was designed to achieve distinct necessities and with different populations in mind, so it is not possible to compare them.

The possible benefits of a second generation of mindfulness-based interventions are under investigation.[52] These interventions consider a different definition of mindfulness, namely: "the process of engaging a full, direct, and active awareness of experienced phenomena that is: (i) psychospiritual in aspect, and (ii) maintained from one moment to the next".[53,54] Some characteristics of these interventions are shared with those of the first generation in respect of duration, frequency (weekly), guided meditation, psychoeducational sessions, group discussions, and home practice recommendations. Among the differences is, for example, the possibility to meet individually with the facilitators.[52]

Of the studies evaluated, 50% did not perform follow-up. This is important to obtain information after the trials end to understand the long-term effects of the intervention, thereby providing data on the validity of the results obtained.[55]

Table 1 Intervention characteristics.

TYPE	ABSOLUTE FREQUENCY
MBSR	56
MBCT	19
ACT	16
Others	115
DURATION (overall sessions)	
1 to 4	32
5 to 8	140
9 or more	18
Not stated	3
FREQUENCY (times per week)	
1	146
2	4
3 or more	17
Mixed	2
Not stated	24
SESSION DURATION (hours)	
Less or equal to 1	41
1 to 2	82
2 to 3	42
Not stated	28
FOLLOW-UP	
Failed to perform	97
1 to 3 months	55
3 to 6 months	23
More than 6 months	9
Mixed	9

Abbreviations: ACT, acceptance and commitment therapy; MBCT, mindfulness-based cognitive therapy; MBSR, mindfulness-based stress reduction. **Notes:** Some articles used more than one type of intervention as an experimental approach, so the total number differs in the sample size described in the search.

Sample Characteristics

Of the studies evaluated, 139 (72%) had mixed samples composed of both men and women, 42 (22%) included only women in their sample, 5 (2%) only men, and 7 (4%) did not provide this information. Studies show that women

are more likely to volunteer in general studies than men but less likely to take part in physically or emotionally stressful research.[56]

Regarding the age of the volunteers, 116 (60%) of the evaluated studies included only adults, 13 (7%) was conducted only with adolescents, 5 (2%) only with older adults, and 1 (1%) only with children. The remaining studies either worked with more than one age group or did not specify this information.

Of the studies evaluated, 144 (75%) described at least one comorbidity or clinical condition of the volunteers, the most frequent being cancer (21%), followed by insomnia and/or sleep complaints (20%), mental health (11%), and chronic pain (10%). Studies show that individuals with more severe clinical conditions may benefit more from mindfulness-based interventions than participants without these vulnerabilities.[57]

Methods of Sleep Assessment

Of the 193 articles, 151 (78%) evaluated sleep subjectively, 1 (1%) objectively, and 33 (17%) used both approaches. The remaining studies did not specify or undertook a qualitative evaluation. ►**Fig. 6** shows the type of outcome assessment and the tools used.

Subjective sleep parameters should not be considered worse than objective ones. The choice for using either objective of subjective sleep assessments depends on the hypothesis and conditions of each study. The agreement between subjective and objective assessments is controversial in the literature, with some studies showing discrepancies between subjective and objective data.[17,19] Additionally, studies show that some clinical conditions (e.g., chronic fatigue, mood disorders, and cognitive changes) can alter an individual's perception of sleep and thereby make subjective measures less reliable.[58–61]

The differences between measures do not necessarily invalidate the results obtained but they highlight the importance of future studies undertaking both subjective and objective approaches if possible, as both may offer insights into the different mechanisms by which mindfulness acts on sleep. Most of the studies evaluated here had some associated clinical condition and assessed sleep subjectively. Since we know that mindfulness-based interventions have significant suggestive potential, objective measures can help remove this interpretation bias.

A Spotlight on Objective Assessment

Given the aforementioned findings, we thought it would be interesting to describe the studies that evaluated sleep objectively. This new analysis identified 34 articles published between 2004 and 2021 that used polysomnography, actigraphy, or any biological marker.

As observed in respect of all studies, the United States was also the country that published the most studies when considering only those that included objective measures (15, 44%). However, unlike what was observed in respect of the overall analysis, Australia was in second place (10, 29%), followed by China (3, 9%). Randomized clinical trials comprised 77% of the total of these studies (26 articles), of which 14 controlled actively, 8 passively, and 4 used mixed controls (►**Fig. 5**).

The studies that used actigraphy did so to measure classical sleep parameters such as total sleep time, sleep latency, sleep efficiency, and the number of awakenings. This method is valid and safe for use in healthy adult populations, with a correlation ranging from 80 to 90% with polysomnography, which is considered the gold standard for sleep assessment.[22,23] These two techniques are complementary, with advantages and disadvantages associated with their use, depending on the research's aims.

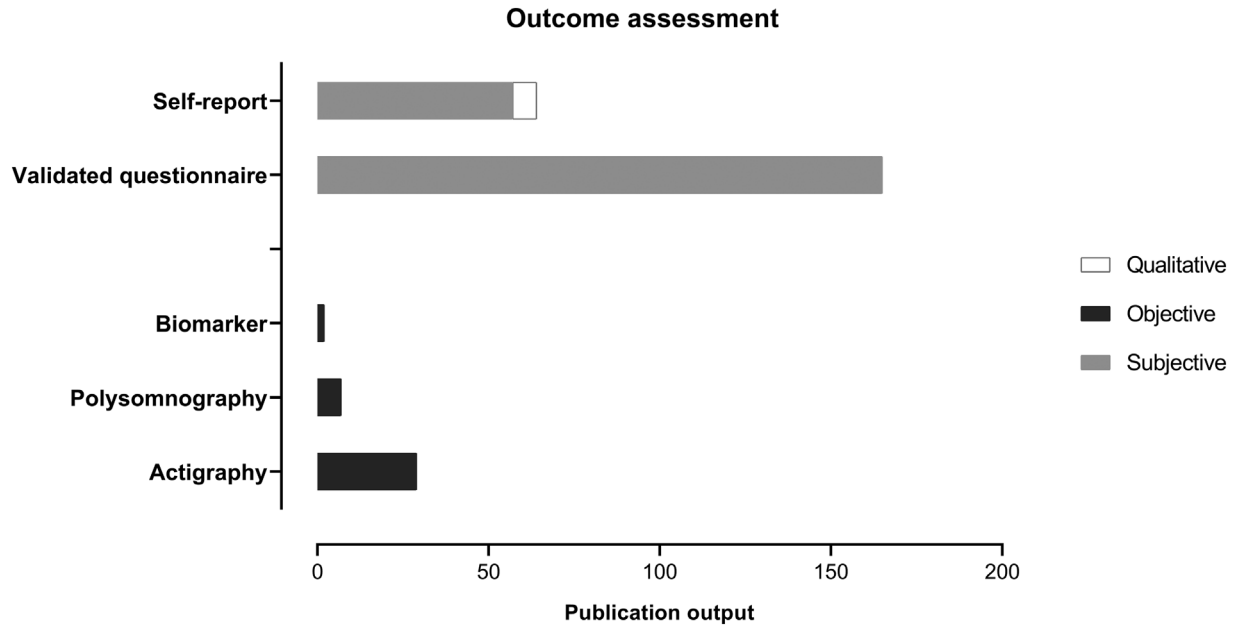

Fig. 6 Publication output using subjective and objective measures and the tools used.

The method used in all the objective studies was either actigraphy and/or polysomnography, except for two studies that used biological markers (salivary melatonin and electrocardiogram) (►**Fig. 6**). This finding highlights another gap that should be considered in future studies, as the lack of data on biomarkers prevents a better description of the mechanisms by which mindfulness training works and a clearer clarification of its effects on the body.

In respect of future studies, they should consider the effects of mindfulness on a wider set of parameters such as sleep architecture (changes in sleep stage ratios), circadian rhythms, and biomarkers (e.g., melatonin and cortisol), in addition to using both subjective and objective approaches to better establish the effects of mindfulness on sleep-related parameters (total sleep time, efficiency, and latency).[32]

Mindfulness is increasingly being used in respect of sleep related issues, making it extremely important to understand the effects of the practice. However, our results show that there is a lack of objective evidence in this area. Future studies, therefore, need to focus on objective as well as subjective measures to provide reliable evidence in respect of the effectiveness of this practice and to fill this gap in the literature.

Study Limitations

As this study is based on a database search and a time-consuming metadata extraction, it is possible that some studies were not included, especially after the last update in 2021. Although it is interesting to include the newest updates, this is a limitation inherent to scoping reviews.[37] Another feature that is associated with scoping reviews is the little critical appraisal, due to the absence of quality assessments of the studies included.[37] Also, bias in database selection and the exclusion of studies that were not in Portuguese, English, or Spanish can be considered as a limitation.

Ethical Committee Permission (includes Permission Number, if applicable)
Not applicable.

Declaration of All Sources of Funding
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Conflict of Interests
The author GNSP is a shareholder at SleepUp (a Brazilian online CBTi company) but attests that this position has no relationship with the aims, preparation, or execution of this study. The other authors declare no conflict of interests.

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