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Review Article

How are normal sleeping controls selected? A systematic review of cross-sectional insomnia studies and a standardized method to select healthy controls for sleep research

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ABSTRACT

There appears to be some inconsistency in how normal sleepers (controls) are selected and screened for participation in research studies for comparison with insomnia patients. The purpose of the current study is to assess and compare methods of identifying normal sleepers in insomnia studies, with reference to published standards. We systematically reviewed the literature on insomnia patients, which included control subjects. The resulting 37 articles were systematically reviewed with reference to the five criteria for normal sleep specified by Edinger et al. [2]. In summary, these criteria are as follows: evidence of sleep disruption, sleep scheduling, general health, substance/medication use, and other sleep disorders. We found sleep diaries, polysomnography (PSG), and clinical screening examinations to be widely used with both control subjects and insomnia participants. However, there are differences between research groups in the precise definitions applied to the components of normal sleep. We found that none of the reviewed studies applied all of the Edinger et al. criteria, and 16% met four criteria. In general, screening is applied most rigorously at the level of a clinical disorder, whether physical, psychiatric, or sleep. While the Edinger et al. criteria seem to be applied in some form by most researchers, there is scope to improve standards and definitions in this area. Ideally, different methods such as sleep diaries and questionnaires would be used concurrently with objective measures to ensure normal sleepers are identified, and descriptive information for control subjects would be reported. Here, we have devised working criteria and methods to be used for the assessment of normal sleepers. This would help clarify the nature of the control group, in contrast to insomnia subjects and other patient groups.

1. Introduction

Given the significance of sleep to well-being [1], consistency in how research participants are selected is important. Indeed, this is accepted among clinicians, with diagnostic systems used to identify different sleep disorders [2–4]. While it is acknowledged that adherence to consensus categorization systems is important with clinical groups, such high standards have not always been applied to the selection of normal sleepers (controls). As a result, the precise definitions, and consequently methods, applied to identify normal sleepers are variable within sleep research. The purpose of the current study was to investigate exactly how control subjects are assessed, in comparison to insomnia patients. The selection of control subjects is important, as group differences may be caused by these subjects rather than the patient group, if normal sleepers are not well defined and selected. Furthermore, consistency in how normal sleepers are defined is important in order to compare results between studies. These results have broader implications for the selection of normal sleepers or control subjects within sleep research overall.

A definition of normal sleepers (controls) has been provided, and five criteria have been identified. The research diagnostic criteria (RDC) for normal sleepers specifies that normal sleepers should show no evidence of sleep disruption (Criterion A) and that the timing of sleep should be both regular and conventional (Criterion B) [2]. As such, both the quality of sleep and its timing are thought to be important in defining normal sleepers. However, these components of normal sleep are not always applied in practice. For example, the Pittsburgh Sleep Quality Index (PSQI) [5], and the Insomnia Severity Index (ISI) [6], have been used to categorize participants as poor and normal sleepers [7–11]. In this approach, those participants scoring below threshold are categorized as normal sleepers.

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Others seem to define acceptable levels of sleep disruption or to select healthy subjects based on the absence of insomnia disorder rather than the presence of normal or good sleep. However, such differences in methods may lead to different groups being used as a comparison, with some subjects being better sleepers than others. Furthermore, evidence of sleep disruption is only one component of research diagnostic criterion for control subjects [2].

The second component of research diagnostic criterion for control subjects includes two elements. First, sleep timing is conventional [2]. Some authors specify habitual bedtimes and rise times as inclusion criteria. This is also pertinent to circadian rhythm sleep disorders (CRSDs), and an individual's preference for morningness or eveningness is relevant to their sleep scheduling. The morningness–eveningness questionnaire (MEQ) was developed to assess diurnal preference [12], and it has been used to identify morning and evening types [13–17]. Second, the RDC also specifies that the timing of sleep is stable. Sleep diaries can be used to monitor adherence to a sleep schedule [15,18,19], and assess reported sleep patterns and habits, as well as their variability [20–22]. They provide information about the daily timing of sleep, as well as measures of sleep continuity (eg, wake after sleep onset), and its qualitative experience, and sleep diaries are regarded as the "gold standard" in measuring subjective sleep experience [23]. However, while a routine sleep schedule is thought to be important to normal sleep [24,25], there seems to be a lack of clarity as to how much variability in sleep scheduling is acceptable in practice.

To fully understand the development and maintenance of sleep disorders, such as insomnia, it is necessary to understand the processes in normal sleep [24–26]. However, this is hampered when the methods of assessment of normal sleepers differ, and this seems especially pertinent when research subjects are recruited from a student population, whose sleep can be irregular and of poor quality [27]. A majority of potential participants (ie, normal sleepers) might be expected to show a moderate level of vulnerability towards poor sleep or insomnia, in keeping with a normal distribution (eg, Yiend [28]). When insomnia subjects and normal sleepers are compared on the effects of poor sleep, the daytime effects of poor sleep are similar, although more severe for insomnia patients [29], and both groups use comparable criteria to judge sleep quality [30]. However, in insomnia patients, the daytime effects associated with sleep seem especially important, both in theory [25,31] and to patients themselves [29,32]. Current research is aimed at investigating the etiology of insomnia disorder, for example, the development of chronic insomnia from acute insomnia [33], and this suggests the importance of additional factors in the development of insomnia disorder. For example, insomnia patients might experience the effects of sleep disruption more severely or report more frequent nights of poor sleep [28], and changes in sleep architecture could contribute towards this transition [33]. Furthermore, in keeping with a normal distribution [28], some normal sleepers could show evidence of sleep disruption, while not quite endorsing insomnia (eg, Ref. [25]). Normal sleepers could also be different from good sleepers, who would be expected to report good sleep without sleep disruption. Although investigating the differences between good sleep and normal sleep is beyond the scope of the current paper, understanding definitions applied to control subjects seems an important first step. As such, we have conducted a systematic review on how control subjects are assessed for study inclusion within insomnia research. We then outline recommendations for assessing normal sleep, and we suggest methods of assessment.

2. Methods

A literature search was conducted within six key sleep society-affiliated journals. In particular, *Sleep* is the official publication of the Associated Professional Sleep Societies, the *Journal of Sleep Research* is published on behalf of the European Sleep Research Society, and *Sleep Medicine* is the official journal of the World Association of Sleep Medicine and International Pediatric Sleep Association. *Behavioral Sleep Medicine* is the official journal of the Society of Behavioral Sleep Medicine; *Chronobiology International* is the official journal for the International Society for Chronobiology, the American Association for Medical Chronobiology and Chronotherapeutics, and the Society for Light Treatment and Biological Rhythms. The *Journal of Biological Rhythms* is the official publication of the Society for Research on Biological Rhythms. The *Journal of Clinical Sleep Medicine*, an official publication of the American Academy of Sleep Medicine, was not included due to a lack of institutional access. The literature search was confined to these journals, as they were expected to apply more stringent criteria towards how sleep groups are defined. The anticipated effect of this was to bias the literature search towards more conservative or stringent methodologies with respect to sleep.

The "Web of Knowledge" (http://wok.mimas.ac.uk/) search engine was used to access database entries for these journals. The key search terms were "poor sleep" or "insomnia," and a large number of results were found initially (24,782 search results). These results were filtered by selecting article types that were published in English, and we selected those studies based on adults (see Fig. 1). We further refined these results to identify those papers where an insomnia sample was compared against controls, and 64 abstracts were then manually reviewed (Fig. 1). These papers were all published from 2005 until present, following the publication of the RDC in 2004. As the focus of this review was on methods of assessment, sample size was not considered as an exclusion criterion.

Papers without a suitable control group were excluded (eg, intervention studies), giving a final sample of 37 (Table 1). All papers included an insomnia patient group, and the majority (30) used patients with primary insomnia. Data were extracted by selecting those methods relevant to each of the five criteria in the RDC [2]. In general, specific details as to insomnia and methods of sleep assessment were coded within Criterion A. Information relevant to CRSDs and test time, as well as work and travel, was contained within Criterion B. In keeping with the RDC, methods relevant to physical and psychiatric health, medication use and substance abuse, and sleep disorders in general were coded separately under Criteria C, D, and E. All data were coded as described in the original papers, and not subject to interpretation at initial encoding.

3. Results

3.1. Criterion A

We recorded how control groups were defined with regard to Criterion A, that is, "the individual has no complaints of sleep disturbance or daytime symptoms attributable to unsatisfactory sleep." First, the definitions applied to control subjects are summarized. These definitions varied from "healthy" to "normal/good sleepers" to "typically good sleepers," and they included descriptions such as no subjective complaints of sleep difficulties or insomnia, or sleep or insomnia complaints. More detailed definitions included subjects characterizing their sleep as restorative or refreshing, sleep satisfaction, relatively imperturbable sleep, and falling asleep as soon as their head touches the pillow. Additional specifications included that subjects report no history of sleep disorders or insomnia, either currently or in the past, and objective sleep thresholds were also used. Sleep questionnaires can be used to quantify sleep-related thresholds, and 5% of studies reported cutoff scores or descriptive information for the PSQI, with the ISI similarly used by 30% of papers. Many studies (51%) reported sleep diary