



Guest editorial

Finding a balance between principles and practice in internet-delivered CBT-I trials



Insomnia is a highly prevalent, debilitating condition defined as trouble falling asleep, staying asleep, or waking up too early, leading to clinically significant distress or impairment in daytime functioning [1]. It is well established and well accepted that cognitive behavioral therapy for insomnia (CBT-I) is the gold standard treatment for insomnia, often outperforming pharmacological approaches [2–4]. Notably, internet-delivered CBT-I, (iCBT-I) has decades of literature demonstrating its effectiveness across healthy, as well as medical and psychiatric populations [5,6].

In their manuscript, “*Time to take the Declaration of Helsinki seriously? A systematic review of comparison conditions in clinical trials on internet-delivered cognitive behavioral therapy for insomnia*”, Dr. Grolig and colleagues raise an important question about the application of the Declaration of Helsinki for control conditions in clinical trials testing iCBT-I [7]. Specifically, the Declaration states that patients in research trials who are randomized to the control arm should have access to the “best proven ... therapeutic method” because their well-being should take precedence over the interests of scientists hoping to prove (at $p < .05$) their intervention is efficacious. At face value, this suggests that in-person CBT-I should be the control condition against iCBT-I. While Grolig et al. accurately report that most of the iCBT-I studies utilize education or wait list controls, it is noteworthy that the comparison between in-person CBT-I against iCBT-I has been studied. For example, Dr. Taylor and colleagues compared in-person to iCBT-I in a military population. It was concluded that while effect sizes were slightly higher for in-person CBT-I across sleep outcomes, both delivery modalities showed meaningful efficacy [8].

It is important to consider the reasons why the Declaration of Helsinki principles may not be applicable when considering the control condition for trials of iCBT-I. First, across studies testing iCBT-I, the researcher's choice of a control may be influenced by various pragmatic study design factors. First, where a treatment is known to be effective (such as the case with iCBT-I), the intent of the trial may be to focus not only on impact on insomnia symptoms, but also other research questions. There is important ongoing research studying whether delivery modality could make treatment more accessible for a greater proportion of the population, what resources are requirements with various approaches to CBT-I delivery, or other considerations such as improving program engagement.

Second, the Declaration of Helsinki includes the following guideline: “patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.” Patients with insomnia who do not receive iCBT-I immediately are not subject to additional risks of serious or irreversible

harm, as long as they receive access to the best proven treatment at the study conclusion. While insomnia certainly has a negative impact on health, a delay in the receipt of CBT-I is unlikely to cause “serious or irreversible harm.”

The Declaration of Helsinki is rightly intended to protect patients and minimize risk [9–11]. However, suggesting that all trials studying CBT-I (including those delivered using novel modalities) must incorporate standard CBT-I as the control condition may hurt more than it helps. Based on the thought-provoking questions raised by Dr. Grolig and colleagues, we suggest that researchers conducting iCBT-I trials consider the following, in the spirit of the Declaration of Helsinki principles. Researchers should.

- 1) Provide participants with information about clinicians offering CBT-I at the conclusion of the trial.
- 2) Improve adverse event reporting and supervision by institutional review boards so that we can improve our “knowledge about harms in self-guided iCBT-I without any personal contact.”
- 3) Better characterize who drops out of iCBT-I treatment. There is a growing body of literature focused on this question, both for in-person and internet-delivered CBT-I programs [12–16], [12–16] with some trials of iCBT-I demonstrating intervention engagement >80%, which is generally accepted in clinical trials as a reasonable threshold [17,18].
- 4) Consider key implementation science questions, namely which elements of delivery or content can be adapted while maintaining fidelity to the core CBT-I elements. These modifications should be well documented following best practice frameworks in order to ensure that modifications are well studied [19].

In the wake of the COVID19 pandemic-related growth in telemedicine, and increasing sophistication and access to technology, there is great potential in delivering behavioral therapies including iCBT-I in the home, with limited in-person supervision. For the estimated 30% of the U.S. population and 10% of the global population with insomnia [20–22] employing strong study methodology in iCBT-I studies as suggested above should address the concerns expressed by Grolig et al. without demanding a control group that relies on a very expensive and very hard to access resource, which even if superior, still will not be widely available to the population with insomnia.

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