The effects of improving sleep on mental health (OASIS): a randomised controlled trial with mediation analysis


Summary
Background Sleep difficulties might be a contributory causal factor in the occurrence of mental health problems. If this is true, improving sleep should benefit psychological health. We aimed to determine whether treating insomnia leads to a reduction in paranoia and hallucinations.

Methods We did this single-blind, randomised controlled trial (OASIS) at 26 UK universities. University students with insomnia were randomly assigned (1:1) with simple randomisation to receive digital cognitive behavioural therapy (CBT) for insomnia or usual care, and the research team were masked to the treatment. Online assessments took place at weeks 0, 3, 10 (end of therapy), and 22. The primary outcome measures were for insomnia, paranoia, and hallucinatory experiences. We did intention-to-treat analyses. The trial is registered with the ISRCTN registry, number ISRCTN61272251.

Findings Between March 5, 2015, and Feb 17, 2016, we randomly assigned 3755 participants to receive digital CBT for insomnia (n=1891) or usual practice (n=1864). Compared with usual practice, the sleep intervention at 10 weeks reduced insomnia (adjusted difference 4·78, 95% CI 4·29 to 5·26, Cohen’s d=1·11; p<0·0001), paranoia (–2·22, –2·98 to –1·45, Cohen’s d=0·19; p=0·0001), and hallucinations (∼1·58, ∼1·98 to ∼1·18, Cohen’s d=0·24; p=0·0001). Insomnia was a mediator of change in paranoia and hallucinations. No adverse events were reported.

Interpretation To our knowledge, this is the largest randomised controlled trial of a psychological intervention for a mental health problem. It provides strong evidence that insomnia is a causal factor in the occurrence of psychotic experiences and other mental health problems. Whether the results generalise beyond a student population requires testing. The treatment of disrupted sleep might require a higher priority in mental health provision.

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Introduction
Sleep problems are a common occurrence in patients with mental health disorders. The traditional view is that disrupted sleep is a symptom, consequence, or non-specific epiphenomenon of the disorders; the clinical result is that the treatment of sleep problems is given a low priority. An alternative perspective is that disturbed sleep is a contributory causal factor in the occurrence of many mental health disorders. An escalating cycle then emerges between the distress of the mental health symptoms, effect on daytime functioning, and struggles in gaining restorative sleep. From this alternative perspective, the treatment of sleep problems attains a higher clinical importance. We are particularly interested in the putative causal association between disturbed sleep and psychotic experiences. The approach therefore informs both theoretical understanding and clinical practice.

The most common form of sleep disruption is insomnia, comprising sustained difficulties in initiating or staying asleep, or both, which cause problems during the day. The association of insomnia with psychotic experiences in the general population has been established. There are multiple, independent, psychotic experiences. Each psychotic experience exists on a spectrum of severity in the general population with differing heritability and differing strength of association with insomnia. Paranoia and hallucinations have the strongest links with insomnia. However, the effect of altering the amount of sleep disruption—eg, by targeted sleep treatment—on these psychotic experiences remains to be established. Clinical guidelines recommend the use of cognitive behavioural therapy (CBT) as the first-line treatment for insomnia. Digital forms of CBT for insomnia that require substantiated further by use of mediation analysis. In the present study, we aimed to improve sleep in individuals with insomnia to determine the effect on psychotic experiences. This approach therefore informs both theoretical understanding and clinical practice.
Evidence before this study
If insomnia is a contributory cause of psychotic experiences, then the key test is whether improving sleep will lead to a reduction in psychotic experiences. We therefore searched for randomised controlled studies that set out to reduce insomnia and examine the effects on psychotic experiences. On June 23, 2017, we searched the entire archive (ie, using no date restrictions) of PubMed for: (Sleep OR Insomnia) AND (Delus* OR Hallucinat* OR Psychosis OR Psychotic OR Schizophren*) AND (CBT OR hypnот OR medication) AND (Random* OR RCT). 130 papers were identified and only two were randomised controlled trials that tested the effects of sleep treatment on psychotic experiences, with the larger of the trials being our own with 50 patients with schizophrenia or related disorders. These trials were underpowered to determine with any precision the potential link between insomnia and psychotic experiences.

Methods

Study design and participants
We did this single-blind, randomised controlled trial (OASIS; Oxford Access for Students Improving Sleep) of digital CBT versus treatment as usual (usual practice). Screening, informed consent, assessments, allocation to condition, and the delivery of the intervention were carried out online using an automated system, a specially configured instance of True Colours, which is a system for the scheduled collection of outcome measures. Participants in the control group were given access to the sleep intervention after their final assessment. The study received overall ethical approval from the University of Oxford Medical Sciences Inter-Divisional Ethics Committee and then local approvals at the other participating universities. The OASIS trial protocol has been published. 

Participants were eligible if they were attending university; had a positive screen for insomnia, as indicated by a score of 16 or lower on the Sleep Condition Indicator (SCI); and were 18 years or older. We had no exclusion criteria. 26 UK universities took part (appendix 1), ensuring a range in geographical locations and academic ability. The principal method of recruitment was sending a circular email within universities that contained a link to the web-based screening. When a circular email was not possible, recruitment was via advertisement on websites.

Research in context

Implications of all the available evidence
Sleep disruption might have a contributory causal role in the occurrence of psychotic experiences and a wide range of other mental health problems. Adequately powered tests in other populations would be helpful, but research indicating that the treatment of disrupted sleep requires a higher priority in mental health provision is accumulating.

Added value of this study
We undertook what might be the largest randomised controlled trial to date of a psychological treatment. It is the first study adequately powered to determine the effects of treating sleep dysfunction on psychotic experiences. It shows very clearly that treatment of insomnia in students leads to a reduction in psychotic experiences. A mediation analysis supports this interpretation. Furthermore, the trial is consistent with a small number of other randomised controlled trials that indicate multiple other benefits for mental health when treating sleep problems.

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