Does a brief, behavioral intervention, delivered by pediatricians or psychologists improve sleep problems for children with ADHD? Protocol for a cluster-randomised, translational trial

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doi: 10.1136/bmjopen-2016-014158

Abstract

Introduction
Up to 70% of children with attention-deficit/hyperactivity disorder (ADHD) experience sleep problems. We have demonstrated the efficacy of a brief behavioral intervention for children with ADHD in a large randomized controlled trial (RCT) and now aim to examine whether this intervention is effective in real-life clinical settings when delivered by pediatricians or psychologists. We will also assess the cost-effectiveness of the intervention.

Methods and analysis
Children aged 5–12 years with ADHD (n=320) are being recruited for this translational cluster RCT through pediatrician practices in Victoria and Queensland, Australia. Children are eligible if they meet criteria for ADHD, have a moderate/severe sleep problem and meet American Academy of Sleep Medicine criteria for either chronic insomnia disorder or delayed sleep–wake phase disorder; or are experiencing sleep-related anxiety. Clinicians are randomly allocated at the level of the pediatrician to either receive the sleep training or not. The behavioral intervention comprises 2 consultations covering sleep hygiene and standardized behavioral strategies. The primary outcome is change in the proportion of children with moderate/severe sleep problems from moderate/severe to no/mild by parent report at 3 months postintervention. Secondary outcomes include a range of child (eg, sleep severity, ADHD symptoms, quality of life, behavior, working memory, executive functioning, learning, academic achievement) and primary caregiver (mental health, parenting, work attendance) measures. Analyses will address clustering at the level of the pediatrician using linear mixed effect models adjusting for potential a priori confounding variables.

Ethics and dissemination
Ethics approval has been granted. Findings will determine whether the benefits of an efficacy trial can be realized more broadly at the population level and will inform the development of clinical guidelines for managing sleep problems in this population. We will seek to publish in leading international pediatric journals, present at major conferences and through established clinician networks.

Trial registration number ISRCTN50834814, Pre-results.