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The SENSE Study: Post Intervention Effects of a Randomized Controlled Trial of a Cognitive–Behavioral and Mindfulness-Based Group Sleep Improvement Intervention Among At-Risk Adolescents

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Objective: Sleep problems are a major risk factor for the emergence of mental health problems in adolescence. The aim of this study was to investigate the post intervention effects of a cognitive–behavioral/mindfulness-based group sleep intervention on sleep and mental health among at-risk adolescents. ***Method:*** A randomized controlled trial (RCT) was conducted across High schools in Melbourne, Australia. One hundred forty-four adolescents (aged 12–17 years) with high levels of anxiety and sleeping difficulties, but without past or current depressive disorder, were randomized into either a sleep improvement intervention or an active control 'study skills' intervention. Both programs consisted of 7 90-min-long group sessions delivered over 7 weeks. One hundred twenty-three participants began the interventions (female = 60%; mean age = 14.48, *SD* = 0.95), with 60 in the sleep condition and 63 in the control condition. All participants were required to complete a battery of mood and sleep questionnaires, 7 days of wrist actigraphy (an objective measure of sleep), and sleep diary entry at pre- and-post intervention. ***Results:*** The sleep intervention condition was associated with significantly greater improvements in subjective sleep (global sleep quality [with a medium effect size], sleep onset latency, daytime sleepiness [with small effect sizes]), objective sleep (sleep onset latency [with a medium effect size]), and anxiety (with a small effect size) compared with the control intervention condition. ***Conclusion:*** The SENSE study provides evidence that a multicomponent group sleep intervention that includes cognitive–behavioral and mindfulness-based therapies can reduce sleep initiation problems and related daytime dysfunction, along with concomitant anxiety symptoms, among at-risk adolescents.

What is the public health significance of this article?
Given the high prevalence of adolescent sleep and internalizing problems, the implications of an effective adolescent sleep intervention for clinical practice and public policy are potentially significant. However, changing sleep behavior, especially objective measures, in this age group has been challenging. This paper shows that the Sleep-SENSE program can improve objective and subjective indices of sleep, as well as anxiety symptoms, when compared with an active control intervention. Furthermore, the program is likely to be cost-effective—it involves a simple screening process and a group intervention format—and could be disseminated to a wide range of clinical and nonclinical settings in primary care, mental health, adolescent health, and sleep medicine, and may assist in the treatment and prevention of adolescent sleep and mental health problems. The intervention also lends itself to flexible modes of delivery (e.g., nonspecialist practitioners, group settings, individual settings, school based, Internet, and other e-health modes of delivery), further enhancing its translational potential.

Keywords: adolescence, anxiety, depression, intervention, sleep
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Recent systematic reviews and meta-analyses have suggested that many adolescents achieve insufficient sleep (less than 8 hours), especially on school nights (Crowley, Acebo, & Carskadon, 2007; Gradisar et al., 2011). Studies have also found that between 54% and 87% of adolescents report the need for more sleep (Mercer et al., 1998; Strauch & Meier, 1988; Wolfson & Carskadon, 1998) and most wake feeling unrefreshed at least a few times per week (Gradisar et al., 2013).

A number of factors combine to make sleep vulnerable to disruption in adolescence. First, sleep during adolescence is affected by physiological maturation (Feinberg & Campbell, 2010). Adolescence is associated with a progressive reduction in the accumulation of homeostatic sleep pressure during wakefulness. This results in a reduction in sleep drive and slow-wave sleep levels (Feinberg, Higgins, Khaw, & Campbell, 2006). Adolescence is also associated with a delay in sleep timing (Carskadon, Acebo, & Jenni, 2004). Second, parental control over bedtime is lessened during adolescence (Short et al., 2011). Third, adolescents develop social interests and obligations (e.g., homework, sport, hobbies, part-time employment) that encourage remaining awake later into the evening (Adam, Snell, & Pendry, 2007; Maume, 2013). Finally, electronic devices have a negative impact on sleep in adolescence, including shorter sleep duration and delayed sleep onset (for reviews, see Bartel et al., 2015, and Hale & Guan, 2015). This delay in sleep onset has two potential sleep related consequences: (a) sleep restriction, because school start times tend to be relatively inflexible and early in the morning, and (b) reduced restorative value of sleep, because recovery sleep tends to occur at an inappropriate circadian phase (Carskadon et al., 2004).

Sleep and mental health are intimately related (Harvey, Murray, Chandler, & Soehner, 2011). In particular, there is robust evidence that sleep complaints are highly prevalent among anxious youth (McMakin & Alfano, 2015; Willis & Gregory, 2015). Sleep onset and maintenance poses particular problems for children and adolescents with high levels of anxiety, possibly because their self-regulatory skills are underdeveloped compared with adults and are compromised by excessive physiologic and cognitive arousal (Alfano, Reynolds, Scott, Dahl, & Mellman, 2013; Forbes et al., 2008). Indeed, researchers have proposed a reciprocal relationship between anxiety and sleep difficulties in adolescence, whereby disturbed sleep increases vulnerability to developing anxiety, while anxiety, in turn, interferes with sleep (Dahl, 1996). There is also a strong relationship between sleep and depression in adolescence. A recent systematic review and meta-analysis found that adolescents with depression report significantly more sleep disturbance compared with nonclinical adolescents, and sleep disturbance in adolescents acts as a precursor to the development of depression in adolescence more than the converse (Lovato & Gradisar, 2014). Wakefulness in bed (longer sleep onset latency and decreased sleep efficiency) was the most consistent indicator of current and future depression. The authors concluded that early treatment programs for insomnia might reduce the risk for developing depression.

Thus, the likelihood that sleep disturbance plays a critical etiological role in adolescent anxiety and depression suggests that the treatment of disturbed sleep might improve resilience against the development of anxiety and depression. Sleep disturbance in children and adolescents can be treated using a range of approaches, but only a few studies have evaluated their effectiveness. School-based sleep education programs have the potential to reach large numbers of adolescents, however recent reviews (Blunden, Chapman, & Rigney, 2012; Blunden & Rigney, 2015) and large-scale randomized controlled trials (Rigney et al., 2015; Wing et al., 2015) have found that although these programs are effective in increasing students' knowledge about sleep and insomnia, they are less effective in improving sleep quality or mental health. These findings suggest that active interventions that incorporate supported decision making (e.g., motivational interviewing) may be more effective (Wensing, Bosch, & Grol, 2010). Furthermore, sleep interventions may be more effective when they are delivered to students who are already experiencing early signs of sleep and/or mental health problems - when they are targeted to "at-risk" adolescents.

There is accumulating evidence that adolescent sleep problems can be treated successfully using multimodal interventions that incorporate cognitive–behavioral techniques. Cognitive-Behavioral Therapy for Insomnia (CBT-I) is recommended as a first line treatment for adult insomnia (Morgenthaler et al., 2006; Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016). Moreover, there is robust evidence from multiple systematic reviews and meta-analyses that CBT-I improves sleep in adults, with medium-large effect sizes (e.g., Koffel, Koffel, & Gehrman, 2015; Trauer, Qian, Doyle, Rajaratnam, & Cunnington, 2015). Effects tend to be strongest for wakefulness in bed variables compared with sleep duration variables, and subjective sleep variables compared with objective sleep variables. There is also emerging evidence that CBT-I leads to improvements in mental health symptoms in adults, including depression and anxiety (Belleville, Cousineau, Levrier, & St-Pierre-Delorme, 2011; Taylor & Pruiksma, 2014).

There is also accumulating evidence that sleep problems can be treated successfully using protocols that include a mindfulness component. Mindfulness can be defined as "the awareness that emerges through paying attention on purpose, in the present moment, and non-judgmentally to the unfolding of experience" (Kabat-Zinn, 2003, p. 145). Several randomized controlled trials have evaluated mindfulness based therapies in adults with sleep problems (Britton, Haynes, Fridel, & Bootzin, 2010, 2012; Garland et al., 2014; Gross et al., 2011; Ong et al., 2014), and have found significant improvements in subjective and objective measures of sleep, especially sleep onset latency and sleep efficiency, but not beyond active control conditions (Garland et al., 2014; Gross et al., 2011). However all these studies were limited by small sample sizes.

Only eight trials have evaluated the efficacy of cognitive–behavioral sleep interventions among adolescents. Two of the studies were large-scale RCTs (de Bruin et al., 2015; Gradisar, Dohnt, et al., 2011), one was a prospective RCT (Clarke et al., 2015), and five were uncontrolled feasibility trials (Bei et al., 2013; Bootzin & Stevens, 2005; de Bruin, Oort, Bogels, & Meijer, 2014; Roeser, Schwerdtle, Kubler, & Schlarb, 2016; Schlarb, Liddle, & Hautzinger, 2011). In general, the interventions were associated with improvements in subjective and objective sleep, and mental health (emotional distress and depression), with small-medium effects across controlled trials, and medium-large effects within-treatment conditions. As with adults, improvements tended to be stronger for wakefulness in bed variables (particularly sleep onset latency) compared with sleep duration variables, and subjective sleep variables compared with objective sleep variables.

However, these interventions were limited in several ways, including small sample sizes (Bei et al., 2013; de Bruin et al., 2014; Schlarb et al., 2011), lack of control groups (Bei et al., 2013; Bootzin & Stevens, 2005; de Bruin et al., 2014; Roeser et al., 2016; Schlarb et al., 2011), wait-list control groups (de Bruin et al., 2015; Gradisar, Dohnt, et al., 2011), high attrition rates (Bootzin & Stevens, 2005; Gradisar, Dohnt, et al., 2011), lack of follow up (Bei et al., 2013; Schlarb et al., 2011), short-follow up (de Bruin et al., 2015, 2014), low generalizability (de Bruin et al., 2015, 2014; Gradisar, Dohnt, et al., 2011; Schlarb et al., 2011), and/or reliance on subjective measures of sleep (Gradisar, Dohnt, et al., 2011; Roeser et al., 2016; Schlarb et al., 2011).

The SENSE (Sleep and Education: learning New Skills Early) Study is a randomized controlled trial (RCT) investigating whether a 7-week, cognitive–behavioral and mindfulness-based group sleep intervention could improve subjective and objective indices of sleep and internalizing symptoms among a group of at-risk adolescents (aged 12–17) who were experiencing elevated sleep problems and anxiety symptoms (Waloszek et al., 2015). Key features of the SENSE study were the randomized controlled trial design, the large sample size, the well-defined manual-driven treatment consisting of components demonstrated to improve sleep in prior research, the time- and format-equated active control 'study skills' condition with good face validity to address salient issues for adolescents, and the use of subjective and objective measures of sleep duration and quality. The ultimate goal of the project was to target disturbed sleep as a key mechanism in the prevention of mental health problems among at-risk adolescents, using an indicated prevention approach to identify and treat high-risk adolescents. That is, the primary aim of the project was to test whether an intervention for improving sleep could prevent the emergence of Major Depressive Disorder (MDD) at 18- to 24-month follow-up. Adolescents were defined as being at-risk for MDD if they reported high levels of anxiety and sleep problems. Previous research has shown that sleep disturbance may be a mediating factor in the sequential comorbidity between anxiety and depression in adolescents (Johnson et al., 2006). Here we report the immediate effects of the intervention on sleep and internalizing symptoms but not the follow-up component, which is currently being undertaken. It was hypothesized that the sleep intervention would improve both subjective and objective indices of sleep, and reduce anxious and depressive symptoms immediately after the intervention, relative to the control condition.

Method

Design

The study used a parallel RCT design that followed all CONSORT RCT requirements for nonpharmacological trials to ensure the quality, accuracy, and integrity of the trial (Moher et al., 2012). The study utilized appropriate statistical power, randomization sequence generation, and allocation concealment, attempted to minimize interventional contamination and operator bias, provided blinded assessment of study endpoints, and included a detailed record of participant flow (see Figure 1; for full study protocol see Waloszek et al., 2015).

The experimental group took part in a CBT/mindfulness-based group sleep intervention (Sleep SENSE) and the active control group took part in a group study skills educational program (Study SENSE). The control intervention was chosen to have strong face validity as an intervention that addresses salient issues for adolescents, and to entail similar delivery format, levels of effort, and engagement with facilitators, as did the Sleep SENSE intervention. Participants were recruited via a school-based screening to identify students from the general community with high levels of anxiety and sleeping difficulties. Participants underwent assessments of sleep and psychopathology before and immediately after the intervention phase. As adolescent sleep is strongly affected by school schedules (Bei et al., 2014), the intervention and sleep assessments were conducted during the school term.

Ethics, Consent, and Permissions

Participants were recruited from secondary schools in the Melbourne Metropolitan Area, Australia. The study, and all procedures, including data management and participant confidentiality, were approved by the University of Melbourne Human Research Ethics Committee (HREC#1237312), the Department of Education and Early Childhood Development (DEECD) (2012_001659), and the Catholic Education Office Melbourne (CEOM) (GE12/000091819), and it complied with the Australian National Health and Medical Research Council guidelines. All participants and their guardians gave written informed consent before participating in the study.

Procedure

The overall SENSE Study has five data collection 'Phases' in addition to the Intervention itself (Waloszek et al., 2015). The present paper reports on the first four phases (screening to post intervention). Phase 5 (18- to 24-month follow-up) is ongoing and will be completed by January 2017. Details of phases 1 through 4, the recruitment process, and participant numbers can be found in Figure 1. Participants were reimbursed for their time and travel expenses with a department store voucher for each assessment phase.

Participant Recruitment

Participants were recruited using a two-stage procedure, consisting of an in-school screening followed by a diagnostic interview for those meeting screening criteria, to identify students with high levels of anxiety and sleeping difficulties but without a history of depressive disorder. One hundred one schools were contacted via letters or emails describing the study in detail and were offered information booklets and tailored presentations on adolescent wellbeing to increase interest in the study. Schools who did not wish to participate in the study ($n = 78$) indicated they did not have enough time due to a full curriculum, were already participating in other research studies (i.e., decline, $n = 47$) or the school coordinator was not contactable (i.e., passive decline, $n = 29$). One school consented but did not participate and another school withdrew consent after participating. All students in Years 7 through 10 were invited to participate in the study. One thousand, seven hundred thirty-seven students provided written parental consent to participate in the screening and were asked to attend the screening assessment session (see online supplementary Table

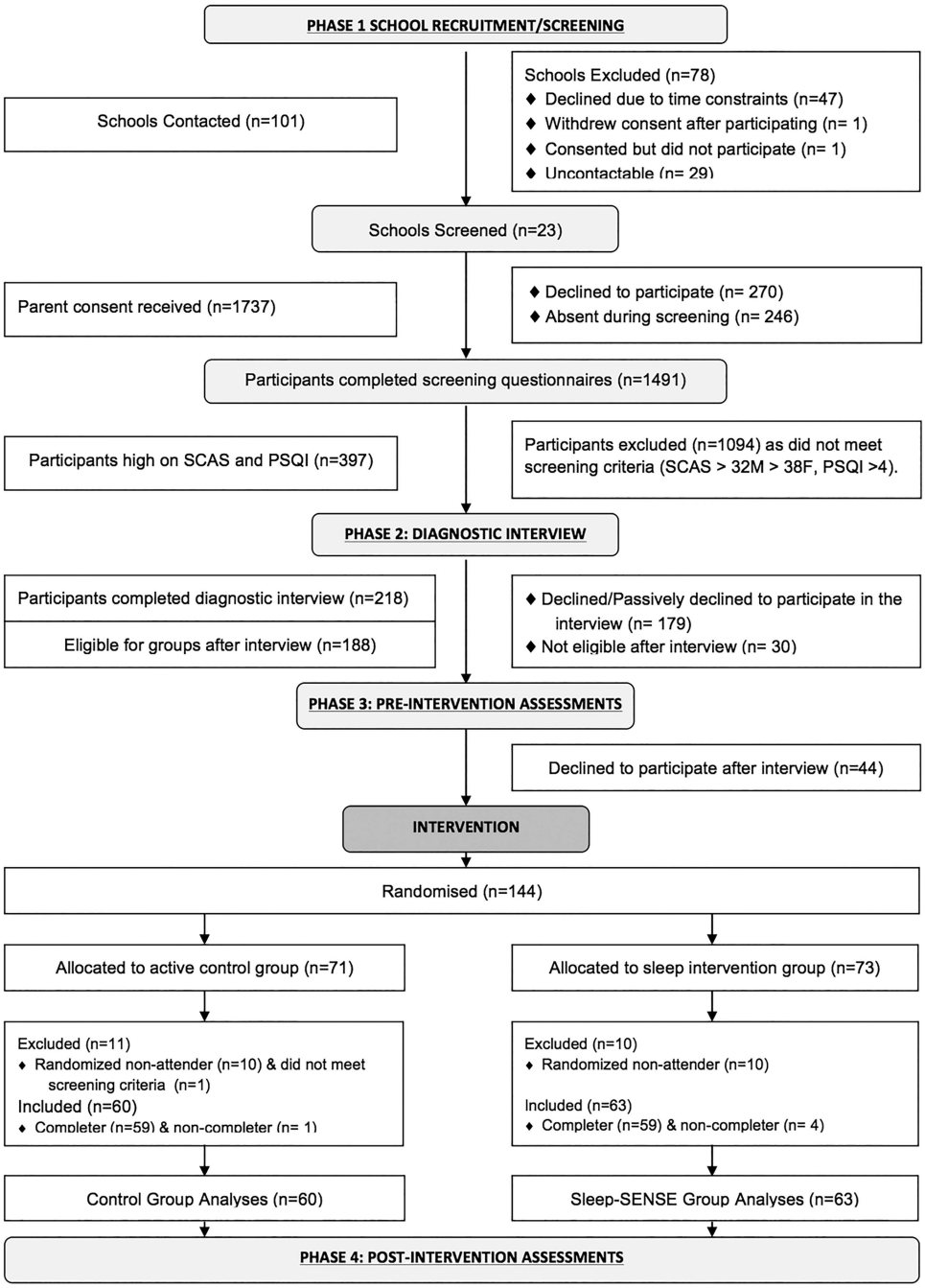

Figure 1. Flowchart of participant flow through the SENSE Study (Phases 1–4).

1 for details of measures). Fourteen hundred ninety-one students completed the screening questionnaire. Two hundred seventy participants declined to participate after their parents had provided consent, and 246 participants were absent from school during the screening.

Inclusion and Exclusion Criteria

Participants whose ratings on the screening questionnaire indicated high anxiety (Spence Children's Anxiety Scale ([SCAS] Total Score >32 and >38 for males and females respectively; Spence, 1998), as well as the likely presence of sleep problems (Pittsburgh Sleep Quality Index ([PSQI] Global Score >4; Schwartz et al., 1999) were invited to take part in a face-to-face diagnostic interview based on *DSM–IV–TR* criteria (the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version [K-SADS-PL]; Axelson, Birmaher, Zelazny, Kaufman, & Kay Gill, 2009) with trained interviewers. Three hundred ninety-seven participants met criteria

after the school screening and were invited to participate in the interview; 218 consented to participate, Participants who scored above the cut-off in the SCAS and PSQI in the screening assessment, and who had never met criteria for Major Depressive Disorder were invited to participate in the intervention stage of the study. In instances where there was a period of more than two months between the K-SADS-PL interview and the interventions, the depression module of the K-SDAS-PL was readministered prior to the intervention. Those with a history of MDD (n = 30, 13.7%) were excluded because of the study's ultimate goal to prevent first incidence of depressive disorders. Other exclusion criteria were current or past diagnoses of bipolar or psychotic disorder, history of significant head injury, current use of anxiolytic or hypnotic medications, and inadequate comprehension of written and spoken English. No participants were excluded for these reasons.

Baseline Data Collection

One hundred eighty-eight participants met inclusion criteria after the diagnostic interview. Participants who met inclusion criteria after the diagnostic interview and who consented to participate in the intervention stage of the trial (n = 144) were asked to complete a number of assessments prior to the group sessions. One week prior to the group session, participants were sent a 'Welcome Pack' that included mood (SCAS and Centre for Epidemiologic Studies—Depression Scale [CESD]) and sleep (PSQI and Pediatric Daytime Sleepiness Scale) questionnaires, a sleep diary, and an Actiwatch. Participants were asked to wear the Actiwatch and to complete the sleep diary for the seven days prior to the commencement of the groups, and complete the questionnaires.

Randomization and Blinding

Eligible participants who consented to participate in the intervention stage of the trial were randomly allocated to receive either the sleep intervention (Sleep SENSE, n = 71) or the active control group (Study SENSE, n = 73). A blinded statistician randomized the eligible participants stratified by gender, age, and presence/absence of current anxiety disorder using a minimization method available in the MINIM program (Evans, McGee, & Williams, 1990). Participants and their guardians were not told the status of each group (i.e., intervention vs. control) or the expected outcome of the study. Twenty participants were randomized to receive either the Sleep SENSE interventions (n = 10) or Study SENSE interventions (n = 10) but declined participation before the start of the baseline assessment, and were counted as 'randomized nonattenders.' Reasons provided were illness, travel distance, transportation issues, homework, and extracurricular activities. Five participants did not complete at least 4/7 intervention sessions (Sleep SENSE = 4, Study SENSE = 1) and were classified as noncompleters. Reasons provided were illness, travel distance, homework, and other extracurricular activities. Four of the five noncompleters indicated that they did not wish to complete the post intervention assessments.

Intervention Group Sessions

The sleep intervention builds on the work of Bootzin, Dahl and Harvey (Bootzin & Stevens, 2005; Cousins, Bootzin, Stevens, Ruiz, & Haynes, 2007; Dahl & El-Sheikh, 2007; Harvey & Payne, 2002), and like evidence-based treatments for adult insomnia (Koffel et al., 2015; Trauer et al., 2015), is cognitive–behavioral in approach, incorporating sleep education, sleep hygiene, stimulus control, and cognitive restructuring, but also has added mindfulness- and anxiety-specific components. The intervention is tailored to the unique developmental challenges and opportunities of adolescence, including the social, cultural and maturational factors known to affect sleep patterns in adolescence. It has a specific focus on tracking behavioral change and identifying and overcoming barriers to change via incorporation of motivational interviewing techniques. It involves seven weekly 90-min group sessions supported by a range of psycho-educational materials, including a 172-page participant workbook that contains information, worksheets, and at-home tasks. Clinical psychologists or graduate clinical psychologists in training delivered the intervention sessions, along with a cofacilitator. Parents/care-givers were given information sheets about the material covered.

The Study SENSE intervention was administered by a trained teacher and a cofacilitator for the same duration, and in the same format, as the Sleep SENSE intervention. Table 1 provides a summary of the content of the sleep and study intervention sessions.

Treatment Integrity

The following quality assurance processes maintained treatment fidelity: (a) piloting of the interventions to refine treatment protocols and assess program acceptability, (b) detailed facilitator training, (c) comprehensive facilitator manuals, (d) weekly supervision sessions, and (e) facilitator logbooks. The group sessions were also audio-recorded and 20% of sessions were randomly selected and rated by two independent researchers for integrity. Checklists for each session (ranging from 8–19 elements) were rated by using a 3-point scale (2 = *fully addressed*, 1 = *partially addressed*, 0 =

Table 1
Session Outline of Sleep Intervention and Active Control Groups

Session	Sleep intervention	Control intervention
1	Sleep education; sleep goals; motivation to change	Importance of study skills; goals
2	Sleep hygiene; stimulus control; mindfulness practice	Personal organization
3	Circadian rhythms; media use; sleep plan; mindfulness practice	Active listening; note-taking
4	Mindfulness (qualities, raisin, breath, body scan)	Memory
5	Cognitive-behavioral model; savoring and switching, mindfulness practice	Test-taking; critical reading
6	Managing worries during the day and night, mindfulness practice	Speech writing and presentations
7	Review; setback prevention; mindfulness practice	Review

not addressed). Mean integrity was 94.61% for the sleep condition and 84.84% for the control condition, indicating very good integrity. Interrater reliability was assessed using 2-way mixed intraclass correlations (ICCs) under the assumption of absolute agreement (McGraw & Wong, 1996). The ICCs were 0.91 for the sleep condition and 0.97 for the control condition.

Post Intervention Data Collection

Upon completion of the group sessions, all participants were readministered the mood and sleep questionnaire pack, and were asked to wear an Actiwatch and complete a sleep diary for the following seven days. Assessment packs and a program evaluation form were distributed in the last session of both interventions.

Measures

Psychopathology measures. (a) *The Spence Children's Anxiety Scale* (SCAS; Spence, 1998) is a 44 item self-report measure designed to measure the frequency at which children and adolescents experience six domains of anxiety; generalized anxiety, panic/agoraphobia, social phobia, separation anxiety, obsessive–compulsive disorder, and physical injury fears.

(b) *The Center for Epidemiologic Studies – Depression Scale* (CES-D; Radloff, 1977) is a 20-item self-report inventory, designed to measure current levels of depressive symptomatology in the general population (Radloff, 1977) and adolescents (Radloff, 1991) and an effective screening instrument for depressive symptoms and disorders among adolescents (Dierker et al., 2001).

(c) *The Kiddie Schedule of Affective Disorders and Schizophrenia Children's Version – Present and Lifetime Version* (K-SADS-PL; Axelson et al., 2009) is a semistructured diagnostic interview designed to identify past or present psychopathology in children and adolescents (aged 6 to 18 years). The KSADS-PL is has been shown to be a reliable and valid measure of *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (*DSM–IV*) Axis I disorders among children and adolescents (Kaufman et al., 1997). The following modules were administered: depression, mania, psychosis, panic disorder, social phobia, specific phobia/agoraphobia, generalized anxiety, obsessive–compulsive disorder, separation anxiety, and posttraumatic stress disorder. Graduate clinical psychology students and research assistants administered the interviews. A clinical psychologist provided regular clinical supervision to all interviewers. Approximately 20% of interviews were double-scored by another interviewer who listened to a de-identified audio recording of the interview. IRR was assessed using Byrt, Bishop, and Carlin's (1993) prevalence-adjusted and bias-adjusted kappa (PABAK) statistic. Analyses were conducted at the item level, which included symptoms and diagnoses. PABAK kappa (Byrt et al., 1993) was calculated at 0.98 for this study.

Sleep measures.

Subjective measures. (a) *The Pittsburgh Sleep Quality Index* (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) is a well-validated self-rated questionnaire that has been widely used in adolescent and young adult populations to assess subjective sleep quality and disturbances and the impact of poor sleep on functioning (Devine, Hakim, & Green, 2005; Lund, Reider, Whiting, & Prichard, 2010; Megdal & Schernhammer, 2007). It demonstrates strong reliability and validity and moderate structural validity among adolescents and young adults (Biddle et al., 2015; de la Vega et al., 2015). Scores range from 0 to 21, with higher scores indicating poorer sleep quality.

(b) The *Pediatric Daytime Sleepiness Scale (PDSS)* is an 8-item self-report questionnaire designed to assess daytime sleepiness in children and adolescents (Drake et al., 2003). It has been shown to have robust psychometric properties and to correlate strongly with daily sleep patterns, school achievement, mood and extracurricular activities (Drake et al., 2003).

Objective measures. The Actiwatch is an actigraphy device that measures the degree and intensity of motion by means of a multidirectional piezoelectric accelerometer and has software to analyze the data as activity counts. Wrist actigraphy is widely used in adolescent populations to assess sleep-wake patterns in participant's normal environment over extended periods of time (Sadeh, 2011; Weiss, Johnson, Berger, & Redline, 2010). At the pre- and postassessment phases, participants were provided with a wristwatch monitor (either an Actiwatch L/64 or Actiwatch 2 [Mini-Mitter, Bend, OR], which generate comparable sleep statistics) and instructed to wear it on their nondominant wrist for 7 days, removing it only when bathing. To allow for cross-validation of the actigraphy variables (Boyne, Sherry, Gallagher, Olsen, & Brooks, 2013; Werner, Molinari, Guyer, & Jenni, 2008), participants were also asked to complete a paper sleep diary for one week during the period they were wearing the actiwatch.

Program Evaluation Form

Upon completion of the interventions, participants were asked if they got something of lasting value from the program (Yes or No) and to rate how useful and interesting they found the programs (5-point scales). Participants in the Sleep SENSE condition were also asked to report on the frequency and duration of their mindfulness practice during the program and to rate the helpfulness of the different program components (5-point scales).

Data Processing

Objective sleep variables. Objective sleep variables were generated using Actiware 6 software. Bedtime and rise times were determined by visually screening the actograms using the collective information of movement, light (when available), event markers (when available), and sleep diary (when available). A recent study suggests this procedure ('human scoring') has a good correlation with polysomnography and a superior correlation to automated machine algorithms in determining bedtime and rise time among adolescent samples (Boyne et al., 2013). The following objective sleep variables were calculated: total sleep time (TST), sleep onset latency (SOL), sleep efficiency (SE), wake after sleep onset (WASO) and bedtime (BT). Separate analyses were conducted for 'average scores' (mean score across days) and 'variability scores' (individual standard deviation across days) for all objective sleep variables. Average score variables use the suffix 'avg' (e.g., TST_{avg}) and variability score variables use the suffix 'isd' (e.g., SE_{isd}).

Subjective variables. PSQI component variables examined in this study were SOL, TST, SE. Global PSQI Score was calculated using standard methods (Buysse et al., 1989), with high scores indicating subjective poor sleep. This study used the cut-off of a

total PSQI Global Score of 5 and above (Schwartz et al., 1999). The total and subscale scores for the daytime sleepiness (PDSS) and psychopathology (SCAS, CES-D) measures were calculated using standard methods recommended by authors of the scales.

Statistical Analyses

A series of one-way between group analyses of covariance were conducted to compare the impact of the two interventions (Sleep-SENSE [treatment] and Study-SENSE [active control]) on outcomes across the two time periods (preintervention [T1] and post intervention [T2]). Within sleep condition analyses were also conducted, as this was the first comprehensive trial of the intervention (online supplementary Table 11). A 'modified intention to treat' approach was taken; intervention completers ($n = 118$) and noncompleters ($n = 5$) were included in analyses, but randomized nonattenders ($n = 20$; defined above) were excluded. Given that many previous studies have not used strong control conditions and/or have failed to examine or observe improvements in objective sleep behavior, our primary concern in this study was to test the efficacy of the intervention among those receiving an adequate exposure to the intervention. In each of the main classes of outcome measures, false discovery rate (FDR) adjustments were made to the predefined alpha level of .05 to have improved control over familywise false rejection error rates (see, e.g., Benjamini, Drai, Elmer, Kafkafi, & Golani, 2001). For this adjustment, we used methods proposed by Benjamini and Liu (1999) that takes into account possible negative dependencies among outcome measures. Missing data were imputed using the multiple imputation procedure with five imputation data sets in SPSS. There was a low incidence of missing data across objective and subjective variables (4.75% average).

Results

Demographic Statistics

Demographic statistics for the screening and intervention samples are presented in online supplementary Table 2. Fourteen hundred and 91 students completed the screening questionnaires (Female = 58%; Mean Age = 14.40, $SD = 1.13$). One hundred twenty-three participants began the interventions (Female = 60%; Mean Age = 14.48, $SD = 0.95$), with 60 in the sleep condition and 63 in the control condition. There were no statistically significant differences in gender, age, or year level between the conditions. Nine separate sleep and control intervention groups were conducted (i.e., 18 groups in total); sleep intervention groups ranged from 6–9 participants per group ($M = 6.7$) and the control intervention groups from 4 to 9 participants per group ($M = 7$).

Screening

Descriptive statistics for the screening sample are presented in online supplementary Table 3. The screening data showed that many adolescents have difficulties sleeping: average score on the PSQI was close to 6 (scores greater than 5 indicate sleeping problems [Schwartz et al., 1999]); average SOL was close to 30 min; and average TST was less than 8 hours. The screening data also showed that many adolescents have elevated anxious and depressive symptoms. The clinical prevalence of sleep problems and anxiety and depressive symptoms using cut-off scores are presented in online supplementary Table 4.

Differences between the nonparticipating sample (i.e., participants who completed the screening questionnaire but who were not selected for the interventions) and the intervention sample were examined using a series of independent samples t tests. Results showed that the intervention sample was characterized by longer SOL and elevated internalizing symptoms (with larger effect sizes), and lower TST and poorer SE (with smaller effect sizes), compared with the nonparticipating sample (see online supplementary Table 5).

Diagnostic Interview

There was a low incidence of psychiatric disorder in the intervention sample; only 11%, 7% and 15% met criteria for a current, past, and lifetime (past and/or current) diagnosis respectively prior to the commencement of the interventions (see online supplementary Table 6). Twelve percent met criteria for any lifetime anxiety disorder, and 4% met criteria for any lifetime depressive disorder. Only one participant had a comorbid sleep and depressive disorder. There were no statistically significant differences between the two treatment conditions on incidence of past and/or current psychiatric diagnoses.

Noncompleter Analysis

The preintervention scores of noncompleters ($n = 5$) were compared with the preintervention scores of intervention completers ($n = 118$) using a series of independent samples t tests. Results showed that noncompleters had lower PDSS, $t(121) = 2.45$, $p = .01$, scores compared with intervention completers, suggesting that they had less daytime sleepiness prior to the commencement of the interventions, suggesting that they may have been less motivated to attend the sessions for this reason. There were no other differences between noncompleters and completers at preintervention (all $p > .05$).

Program Acceptance

A summary of the program acceptance results is presented in online supplementary Tables 7 and 8. Participants attended approximately 76% of sessions on average, and rated the programs as useful, interesting, and of good quality overall. All Sleep SENSE participants, and 96% of Study SENSE participants, answered 'Yes' to the question, "Do you think you got something of lasting value or importance from the program?" Participants rated the sleep program as more useful than the control program ($t = [116] = 3.30$, $p < .01$), but there were no other statistically significant differences between the groups on program acceptability (all $p > .05$). On average, Sleep SENSE participants reported practicing mindfulness 1 to 2 times per week for 5 min at a time at the completion of the intervention. Mindfulness of the breath, going to bed and getting up at the same time each day, and gaining knowledge about sleep were rated as the most helpful components of the program (online supplementary Table 8).

Baseline Characteristics

Descriptive statistics for the intervention sample are presented in online supplementary Table 9. The intervention sample was characterized by poor sleep prior to the commencement of the interventions. Average objective TST was 6:56 hours, SOL 27.98 min, SE 79%, and BT 11.08 p.m. Although no specific quantitative sleep parameters define insomnia disorder (Merrigan, Buysse, Bird, & Livingston, 2013; Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008) an average SOL greater than 30 min, SE less than 85%, and/or a TST less than 6:30 hours are common manifestations (Lichstein, Durrence, Taylor, Bush, & Riedel, 2003). Participants also reported poor sleep quality prior to the commencement of the interventions. Average PSQI Global was 6.3, SOL 27.03 min and TST 7:41 hours. Finally, participants reported elevated internalizing symptoms prior to the commencement of the interventions. Average SCAS Total was 28.5 for males and 36.17 for females, and average CESD was 15.77. The clinical prevalence of sleep problems and anxiety and depressive symptoms using cut-off scores are presented and online supplementary Table 4. Correlations among variables at preintervention are presented in online supplementary Table 10.

Intervention Effects on Subjective Sleep Measures

After adjusting for preintervention scores, compared with participants who completed the control condition, participants who completed the sleep intervention reported better global sleep quality (with a medium effect size), as well as shorter SOL and less daytime sleepiness (with small effect sizes; see Table 2). There were no between-condition effects for subjective TST or *SE*.

Intervention Effects on Objective Sleep (Average)

After adjusting for preintervention scores, compared with participants who completed the control condition, participants who completed the sleep intervention exhibited shorter objective SOL_{avg}, with a medium effect size (see Table 2). There were no between condition effects for objective TST_{avg}, SE_{avg}, $WASO_{avg}$ or BT_{avg}.

Intervention Effects on Objective Sleep (Variability)

After adjusting for preintervention scores, compared with participants who completed the control condition, participants who completed the sleep intervention exhibited marginal improvements in SOL_{isd}, SE_{isd}, and BT_{isd}, with small effect sizes (see Table 2). There were no between condition effects for objective TST_{isd} or $WASO_{isd}$.

Intervention Effects on Mental Health

After adjusting for preintervention scores, compared with participants who completed the control condition, participants who completed the sleep intervention reported less anxiety, with a small effect size (see Table 2). There was no between condition effect for depression.

Summary of Primary Outcome Results

A summary of the primary outcome results is provided in Figure 2. The sleep intervention condition was associated with significantly greater improvements in subjective sleep (particularly SOL and daytime sleepiness), objective sleep (SOL), and anxiety, com-

Table 2
Results of ANCOVAs Comparing the Effectiveness of the Sleep and Control Conditions on the Sleep and Mental Health Variables From Pre–Post Intervention

Domain	Variable	Beta coefficient			t	η^2	Rank-ordered observed p values	FDR critical p values	Observed $p <$ FDR critical value
		β	*SE*	Confidence interval					
Subjective sleep	PSQI global	1.07	.32	.43, 1.70	3.30	.06	.001	.010	TRUE
	PSQI SOL	5.48	1.88	1.80, 9.16	2.92	.05	.003	.016	TRUE
	PDSS	2.40	.83	.78, 4.02	2.90	.05	.004	.028	TRUE
	PSQI TST	−.29	.18	−.64, .06	−1.60	.02	.109	.050	FALSE
	PSQI SE	−.04	.10	−.23, .14	−.46	<.01	.673	.050	FALSE
Objective sleep (average)	SOL_{avg}	11.40	3.00	5.51, 17.28	3.80	.08	<.001	.010	TRUE
	$WASO_{avg}$	−4.09	2.89	−9.76, 1.58	−1.42	.01	.157	.016	FALSE
	SE_{avg}	−1.28	.92	−3.08, .52	−1.39	.01	.163	.028	FALSE
	TST_{avg}	−3.97	5.72	−15.18, 7.25	−.69	<.01	.488	.050	FALSE
	BT_{avg}	1.43	6.74	−11.78, 14.64	.21	<.01	.832	.050	FALSE
Objective sleep (variability)	SOL_{isd}	11.17	4.43	2.49, 19.84	2.52	.05	.012	.010	FALSE
	SE_{isd}	1.70	.80	.13, 3.27	2.12	.04	.034	.016	FALSE
	BT_{isd}	9.95	5.17	−.18, 20.07	1.93	.03	.054	.028	FALSE
	TST_{isd}	7.31	5.99	−4.43, 19.06	1.22	.01	.222	.050	FALSE
	$WASO_{isd}$	.03	2.21	−4.31, 4.36	.01	<.01	.990	.050	FALSE
Anxiety	SCAS	3.49	1.67	.23, 6.75	2.10	.02	.036	.050	TRUE
Depression	CESD	1.21	1.42	−1.57, 3.98	.85	.01	.394	.050	FALSE

Note. PSQI = Pittsburgh Sleep Quality Index; PDSS = Pediatric Daytime Sleepiness Scale; SCAS = Spence Children's Anxiety Scale; CESD = Center for Epidemiologic Studies Depression Scale; SOL = Sleep Onset Latency; TST = Total Sleep Time; SE = Sleep Efficiency; WASO = Wake After Sleep Onset; β = Unstandardized Beta Co-efficient; *SE* = Standard Error; t = t value; η^2 = eta squared effect size statistic; p = p value; FDR = false discovery rate.

pared with the control intervention condition. There were also marginal improvements in variability of objective SE, SOL and BT. The sleep intervention condition was not associated with significantly greater improvements in objective or subjective TST, objective WASO, or depression, compared with the control intervention condition.

Discussion

This study provides evidence, using a methodologically rigorous design, that a multicomponent group sleep intervention based on cognitive–behavioral and mindfulness principles can improve subjective and objective indices of sleep, particularly SOL and daytime sleepiness, among at-risk adolescents. The sleep outcomes on which the participants improved were consistent with their preintervention problem areas. For example, participants selected for the interventions were characterized by longer SOL, but not lower TST, compared with those not selected for the interventions. These results are also consistent with emerging empirical evidence showing that children and adolescents with anxious and depressive symptoms have particular difficulties with wakefulness in bed (Lovato & Gradisar, 2014), especially sleep initiation (Alfano et al., 2013; Forbes et al., 2008), and with the results of other sleep interventions that have found SOL among the most improved variables (Bei et al., 2013; Bootzin & Stevens, 2005; Clarke et al., 2015; de Bruin et al., 2015, 2014; Garland et al., 2014; Gradisar, Dohnt, et al., 2011; Gross et al., 2011; Koffel et al., 2015; Schlarb et al., 2011; Trauer et al., 2015).

The results of the study also provide evidence that cognitive–behavioral and mindfulness-based sleep interventions may be useful in decreasing variability in SOL, SE, and BT, although improvements were marginal. Behavioral changes as a consequence of sleep scheduling and stimulus control may have contributed to these more regular bedtimes and sleep initiation periods, consistent with research showing that behavioral techniques are effective in regularizing sleep-wake schedules and daily rhythms (Carney, Edinger, Meyer, Lindman, & Istre, 2006; Manber, Bootzin, Acebo, & Carskadon, 1996) and can lead to improved sleep and daytime function.

The magnitude of the sleep effects found in the current study was smaller than those reported in previous studies. RCT's of pure CBT-I among adolescents (de Bruin et al., 2015; Gradisar, Dohnt, et al., 2011) and adults (for reviews, see Koffel et al., 2015; Trauer et al., 2015) have found medium-large effects favoring the treatment condition for wakefulness in bed variables (sleep onset latency, sleep efficiency, and wake after sleep onset), whereas the current study only demonstrated small-moderate effects for sleep onset latency. However, previous studies have used wait-list comparators (de Bruin et al., 2015; Gradisar, Dohnt, et al., 2011; 30% to 40% of studies reviewed by Koffel et al., 2015 and Trauer et al., 2015), clinical samples (de Bruin et al., 2015; Gradisar, Dohnt, et al., 2011; Koffel et al., 2015; Trauer et al., 2015), and/or subjective measures of sleep (Gradisar, Dohnt, et al., 2011; Koffel et al., 2015; Trauer et al., 2015), whereas the current study used an active control comparator, community sample, and subjective *and* objec-

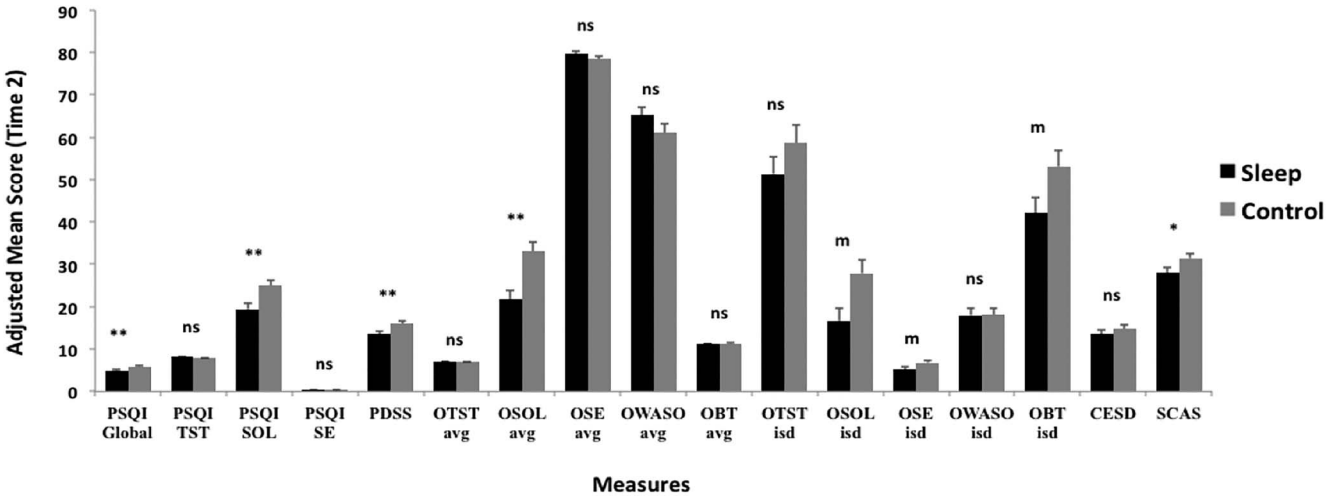

Figure 2. Summary of results from ANCOVAs comparing the impact of the sleep and control interventions on post intervention (Time 2) outcomes. Pre-intervention scores (Time 1) were used as covariates to control for individual differences. ** $p < .01$, * $p < .05$. m = marginal improvement ($p < .06$, but analysis did not survive false discovery rate adjustment); ns = not significant. Error bars are standard errors. PSQI Global = Pittsburgh Sleep Quality Index Global Score; PSQI TST = Pittsburgh Sleep Quality Index Total Sleep Time (hours); PSQI SOL = Pittsburgh Sleep Quality Index Sleep Onset Latency (minutes); PSQI SE = Pittsburgh Sleep Quality Index Sleep Efficiency (component score); PDSS = Pediatric Daytime Sleepiness Scale; OTST avg = Objective Total Sleep Time average score (hours); OSOL avg = Objective Sleep Onset Latency average score (minutes); OSE avg = Objective Sleep Efficiency average score (percent); OWASO avg = Objective Wake After Sleep Onset; OTST isd = Objective Total Sleep Time variability score (minutes); OSOL isd = Objective Sleep Onset Latency variability score (minutes); OSE isd – Objective Sleep Efficiency variability score (percent); OBT isd = Objective Bedtime variability score (minutes); CESD = Center for Epidemiologic Studies – Depression Scale; SCAS = Spence Children's Anxiety Scale.

tive indices of sleep, likely to result in smaller effect sizes. The relatively smaller improvement in TST variables compared with wakefulness-in-bed variables found in the current study is most likely related to the techniques used in CBT-I. As described by Koffel and colleagues (2015), the goal of stimulus control and sleep restriction is to initially limit sleep opportunities to increase the drive for sleep and ultimately improve homeostatic regulation of sleep. As a result, one would expect more immediate improvements in the sleep variables linked to homeostatic regulation of sleep, including SOL and SE, whereas other variables (i.e., TST and BT), may show greater improvements over time as participants practice these skills and gradually increase their opportunity for sleep.

Finally, the Sleep SENSE intervention led to small improvements in anxiety among at-risk adolescents. This finding is also consistent with research among adults. A recent systematic review found that CBT-I results in marginal-small improvements in anxiety symptomatology among psychiatric populations (Taylor & Pruiksma, 2014). The relatively smaller improvement in anxiety symptoms, compared with that of sleep variables found in the current study, might be attributable to a number of factors. First, although the sleep program had added anxiety-specific components, it specifically targeted sleep complaints, with the focus on anxiety generally restricted to its relation to sleep. Second, the improvements in objective sleep may not have been sufficient to improve symptoms of anxiety considerably. Third, changes in sleep/wake behaviors may not immediately translate into improved subjective experiences of anxiety. The results highlight that, although sleep and anxiety are related, they remain distinct processes, and optimal assistance for a young person with anxiety and poor sleep is likely to involve targeting both phenomena. Effects on depression were not anticipated at this time point, as the hypothesized effect is resistance to the longer-term development of case level depression. Results of the 18- to 24-month follow-up (Phase 5) of the SENSE participants will elucidate any delayed onset improvements in sleep and mental health outcomes.

The brief in-school screening was well accepted by students and caused minimal disruption to school routines. High scores on the PSQI, SCAS, and CESD across the screening sample are consistent with research showing that sleep disturbance is common among adolescents (Gradisar, Gardner, et al., 2011; Millman, 2005) and is associated with internalizing symptoms (Chase & Pincus, 2011; Moore et al., 2009; Talbot et al., 2010).

Program completion rate was high (96%) compared with similar interventions (83%; Bei et al., 2013; Bootzin & Stevens, 2005; Clarke et al., 2015; de Bruin et al., 2014, 2015; Gradisar, Dohnt, et al., 2011; Schlarb et al., 2011), which may be attributable to the increased focus on engagement in the SENSE interventions and the relatively lower levels of psychopathology among participants. Positive feedback from participants suggested the program was well accepted, particularly the mindfulness and stimulus control components.

The SENSE Study has a number of strengths. First, it included a large sample size compared with other similar studies (Bei et al., 2013; Bootzin & Stevens, 2005; Clarke et al., 2015; de Bruin et al., 2014; Gradisar, Dohnt, et al., 2011; Schlarb et al., 2011). Second, it used an RCT design, attempting to attain the highest standard of evidence, including a time- and format-equated *active* control 'study skills' intervention with good face validity as an intervention that could address salient issues for adolescents. Third, it assessed subjective *and* objective indices of sleep. Fourth, the study utilized a multicomponent group sleep intervention specifically designed for use with high-risk adolescents who were experiencing high levels of anxiety and sleep problems. For example, Sleep SENSE has an innovative structure, with a particular focus on engagement, identifying and overcoming barriers to change, reviewing key information to increase recall and retention, and ensuring adequate opportunities to practice techniques in session and at-home. Fifth, the in-school screening for sleep and anxiety problems prior to the intervention not only helped identify students who were more likely to benefit from the program, but also provided an opportunity for early detection and early intervention; the study was not only outcome focused, but also proactive and preventative. Sixth, delivering the interventions in a group format may have helped to normalize adolescents' experience with poor sleep and anxiety by providing peer support. Seventh, given simple process of screening and the group format of the intervention, this approach might be a cost-effective way to improve adolescents' sleep and mental health (Koffel et al., 2015; Wergeland et al., 2014). Finally, Sleep SENSE can be considered a general wellbeing enhancing intervention and a novel approach to resiliency.

Of course, the study was not without its limitations. Actigraphy does not provide information on many important aspects of sleep, such as sleep architecture. Also, the multicomponent therapeutic approach does not reveal the most effective component. Moreover, those with more severe symptoms were more likely to participate (and remain engaged) in the intervention—therefore it is not known whether the same effects would be seen in less severe samples. Additionally, the exclusion of participant's with previous episodes of MDD may restrict the external validity of the study. The active control (study skills) condition may not have controlled for all nonspecific factors associated with the active (sleep) intervention. However the design of the intervention does provide a good control for many of these factors, including regression toward the mean, the natural course of symptoms, change over time, the Hawthorne effect, and the placebo effect. Furthermore, the control intervention included many of the nonspecific elements of psychotherapy, such as empathetic listening, being nonjudgmental, and self-monitoring. Finally, it is not possible to draw conclusions regarding the stability of treatment-induced improvements from the data reported here. The next phase of the SENSE Study will be to investigate whether improvements in sleep and anxiety will persist and can prevent transition to depression at 18- to 24-month follow-up. Previous research has shown that sleep disturbance may be a mediating factor in the sequential comorbidity between anxiety and depression in adolescents (Johnson et al., 2006) and that wakefulness in bed, particularly longer sleep onset latency, during childhood and adolescence predicts later depression (Lovato & Gradisar, 2014).

Given the high prevalence of adolescent sleep and internalizing problems, the implications of an effective adolescent sleep intervention for clinical practice and public policy are potentially significant. However, changing sleep behavior, especially objective measures, in this age group have been challenging. This paper shows that the Sleep-SENSE program can improve objective and subjective indices of sleep, as well as anxiety, when compared with an active control intervention. Sleep SENSE is one of the only interventions demonstrated to be efficacious in improving sleep

and mental health among vulnerable adolescents. The program is likely to be cost-effective—it involves a simple screening process and a group intervention format—and could be disseminated to a wide range of clinical and nonclinical settings in primary care, mental health, adolescent health, and sleep medicine, and may assist in the treatment and prevention of adolescent sleep and mental health problems. Many individuals are reluctant to seek help for anxiety and depression, but may be more likely to seek help for sleep problems, as they see them as less stigmatizing. The Sleep SENSE intervention may therefore be a good way to engage at-risk adolescents in the therapy process. The intervention also lends itself to flexible modes of delivery (e.g., nonspecialist practitioners, group settings, individual settings, school based, Internet, and other e-health modes of delivery), further enhancing its translational potential.

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