Treating sleep problems in young children: A randomised controlled trial of a group-based, parent-focused behavioural sleep intervention

Declarations of Interest: None.

This study was kindly funded by Australian Rotary Health.

ANZCTR number: ACTRN12618001161213

Abstract

This study tested the efficacy of a 5 x 1.5 hour / session, group-based, parent-focused, behavioural intervention (BI) targeting sleep problems in preschool children. Parents were randomised to either the BI (N=62) or care as usual (CAU; N=66) conditions. Outcomes included sleep, anxiety, behavioural problems, internalising and externalising symptoms, transition to school and academic achievement. Assessments were conducted at pre- and post-BI intervention (in the year prior to formal schooling), and then at follow-ups 1 and 2 in the first year of formal schooling. Relative to the CAU, the BI condition demonstrated significantly greater improvements in sleep, anxiety, behaviour problems and internalising and externalising symptoms from pre- to post-intervention. Improvements in sleep, anxiety, and internalising symptoms were maintained, while behaviour and externalising symptoms were further improved upon at school follow-up 2. For the BI group, improvements in sleep at post-intervention were found to mediate improvements in anxiety, internalising, and externalising symptoms, but not behaviour problems, at school follow-ups 1 and 2. There were no significant effects of condition on school transition or academic outcome measures. The results suggest that the BI is effective for sleep, anxiety, behaviour, internalising and externalising symptoms, but not for school transition or academic outcomes.

Keywords: sleep problems, young children, pre-schoolers, behavioural, treatment, anxiety, behaviour problems

Sleep is vital for optimal childhood development through its demonstrated facilitation of somatic and neurological growth, learning and memory consolidation, and restorative processes (Gomez et al., 2015; Reynaud et al., 2018). The preschool period (ages 3 to 5 years) marks a developmental phase of rapid brain maturation, and a time during which substantial changes occur with respect to a young child's sleep (Bernier et al., 2021). During this period, it has been shown that daytime naps cease, most sleep is consolidated overnight, sleep duration gradually declines, and a child's bedtime becomes later (Iglowstein et al., 2003). Unfortunately, many preschool children do not obtain the 10-13 hours of sleep per day recommended by the National Sleep Foundation (Hirshkowitz et al., 2015) for optimal functioning and development, due to some type of sleep problem (Meltzer & Crabtree, 2016). Indeed, sleep problems are highly prevalent amongst young children, with 34% of preschoolers afflicted with some type of sleep disturbance, and 14% experiencing moderate to severe sleep problems (Hiscock et al., 2007). Although a minority of young children experience respiratory disorders (e.g., sleep apnea) and parasomnias (e.g., nightmares, night terrors, sleep walking, sleep paralysis, and confusional arousals), behavioural sleep problems (which include difficulty falling asleep or staying asleep, bedtime resistance, and / or having difficulty sleeping without parents being present or without parental support) are by far the most common (Hoyniak et al., 2020). Furthermore, sleep problems during the preschool years have been shown to persist over time for many if left untreated, predicting sleep problems during the primary school years (Falch-Madsen et al., 2020).

Insufficient sleep has a demonstrated detrimental impact on the frontal lobe of the brain that regulates emotions, spontaneity, language, and social behaviour (Beebe & Gozal, 2002; Kocevska et al., 2017). As a consequence perhaps, preschool sleep problems have empirically been associated with anxiety and behaviour problems, as well as social and cognitive consequences. Indeed, preschool sleep problems have been found to be associated with anxiety at age 7 years (Gregory et al., 2004), throughout the primary school years (Whalen et al., 2017), during mid-adolescence (Gregory & O'connor, 2002) and adulthood (Gregory et al., 2005). Similarly, preschool sleep problems have been shown empirically to be associated with fewer concurrent positive behaviours, more concurrent behavioural problems (Bates et al., 2002; Hiscock et al., 2007), fewer prosocial behaviours one year later (Hatzinger et al., 2013), greater conduct problems at age 7 years (Gregory et al., 2004), and greater aggression in mid-adolescence (Wang et al., 2016). Finally, it has been demonstrated that preschool sleep problems predict poorer socioemotional adjustment and social skills (Williams et al., 2016), greater working memory deficits (Nelson et al., 2015), a greater need for additional academic support (Simola et al., 2014), school refusal (Hochadel et al., 2014), and poorer academic performance (Paavonen et al., 2000). Indeed, Kocevska et al (2017) demonstrated that sleep disturbances in young children adversely affect brain maturation, and speculate that children demonstrating high level, persistent sleep problems may therefore be at risk for adverse neurodevelopment (Kocevska et al., 2017).

Given the numerous deleterious consequences of preschool sleep problems, it is perhaps not surprising that they can also affect a child's transition to primary school. The first year of formal schooling is a major event in a young child's life, with successful transition being shown to be associated with enhanced academic performance and stronger mental health across development (Gregory & Sadeh, 2012; McIntyre et al., 2006; Perry & Weinstein, 1998; Ramey & Ramey, 1998; Yeboah, 2002). Sleep of adequate quality and quantity is therefore integral for attainment of the cognitive, motor, psychosocial, and self-regulation skills preschoolers need to successfully transition into formal schooling (Hirshkowitz et al., 2015; Mindell & Williamson, 2018). In fact, it has been shown that sleep problems in the preschool years predict poorer health-related quality of life, poorer language skills and learning scores, poorer child mental health, and more severe behaviour problems in the first year of primary school (Quach et al., 2009; Quach et al., 2012). It is therefore critical that sleep problems are identified and effectively treated prior to the child attending formal schooling.

Although several meta-analyses and reviews have supported the efficacy of behavioural interventions targeting sleep problems in young children (Fangupo et al., 2021; Kuhn & Elliott, 2003; Meltzer & Mindell, 2014; Meltzer et al., 2021; Mindell, 1999), the majority of component studies focus on infants and toddlers (Fangupo et al., 2021; Meltzer & Mindell, 2014; Meltzer et al., 2021), who have very different developmental needs to those of preschool-aged children. Furthermore, very few of the intervention studies targeting preschool sleep problems have assessed outcomes beyond child sleep (Meltzer et al., 2021), and none have examined the impact of a preschool sleep program on either anxiety or school transition. However, although the impact of treating sleep problems *before* the child begins primary school has not been examined in terms of its impact on transition to school, Quach et al., (2011) and Hiscock et al., (2018) have investigated a multicomponent program targeting a range of sleep problems with children *already* in their first year of formal schooling. In the initial study (Quach et al., 2011), it was found that relative to children in the control conditon, those receiving treatment improved in terms of sleep, maternal depression and psychosocial quality of life (at 3-month but not 6- or 12-month follow-up), and prosocial behaviour (at 12-month but not 3- or 6-month follow-up). However, no changes at any time point were evident for physical health, behaviour problems, academic functioning or parental anxiety or stress. In the second study (Hiscock et al., 2018), although improvements in child sleep and parental depression were found at 6-month follow-up, improvements were attenuated by 12-month follow-up and none of the other measured outcomes (child psychosocial functioning, physical functioning, quality of life, behaviour problems, academic skills, academic achievement, teacher-child relationship, parental quality of life and mental health) demonstrated improvement. The authors suggested that the weaker than expected treatment effects may have been due to an insufficient treatment dose (2-3 brief consultations). We contend that broader and stronger treatment outcomes may also have been demonstrated if treatment had been offered *before* children transitioned into formal schooling, and if key factors known to maintain sleep problems in this age group were better addressed with gold standard treatment approaches.

Standard sleep programs for young children are parent-focussed and include strategies such as psychoeducation, sleep hygiene, setting appropriate bedtimes, establishing bedtime routines, bedtime fading, and relaxation (Meltzer et al., 2021). Although relaxation is often included to target anxiety-related sleep problems, and bedtime routines/behaviour charts included to address behaviour-related sleep problems, gold standard strategies for anxiety (i.e., exposure therapy) and misbehaviour (i.e., providing sound instructions, time-out, and limit-setting) at bedtime are rarely included. Given the strong relationship between preschool sleep problems and anxiety and behaviour problems, and given that both anxiety and behaviour problems underpin and maintain many of the behavioural sleep problems exhibited by young children, addressing bedtime anxiety and behaviour problems with gold standard treatments may not only lead to enhanced sleep outcomes, but may also have a greater impact on outcomes other than sleep.

The Current Study

From the above discussion it is evident that there is a strong need for the development and empirical testing of behavioural sleep interventions that a) focus specifically on preschool aged children (3 to 5 years) prior to the transition to school, b) include gold-standard anxiety and behaviour management strategies, and c) assess anxiety, behaviour problems, and transition to school as outcome variables. This study sought to address these gaps in the literature through a randomized controlled trial (RCT) investigating the efficacy of a parent-focused, group-based behavioural intervention (BI) targeting preschool sleep problems relative to a care-as-usual condition (CAU). The aims of the program were to reduce child sleep, behaviour, and anxiety problems, and to improve the child's transition to formal schooling. Treatment was conducted in the second half of the year before formal schooling commenced.

It was hypothesised that relative to the CAU condition, children in the BI condition would demonstrate significantly greater improvements in sleep, anxiety and behavioural problems from pre- to post-assessment that would be maintained at school follow-ups 1 and 2. Further, it was hypothesised that children in the BI relative to CAU condition would demonstrate enhanced transition to school at school follow-ups 1 and 2. Finally, it was hypothesised that sleep outcomes at post-assessment would mediate the improvements of the BI group on anxiety, behaviour problems, and transition to school at school follow-ups 1 and 2.

Method

Design

The design involved a single-blind RCT in which parents were randomly assigned to either the BI or CAU conditions. For ethical reasons surrounding the importance of sleep in young children, we chose not to include a true Wait List Control that would require enforcement of a 'no treatment whilst waiting' rule. Instead, we included a non-active, CAU control group, who were told they could access other child sleep services during the course of the study, and that they would receive the BI program after school follow-up 2. Indeed, parents in both conditions were able to access other child sleep services during the course of the study if they so chose, and access was measured at the final assessment time point for both groups.

Two cohorts of parents were recruited in two consecutive years (2018 and 2019) of the project to ensure sufficient recruitment and enrolment into the study, and to conicide with timing of the intervention that occurred prior to school transition. In Australia, the school year coincides with the calendar year (i.e., it runs from January to December) and there are four school terms throughout the year, each of which are approximately 10 weeks in duration. In Queensland where this study took place, children enter their first year of formal schooling at 4-5 years of age in January and continue until December, in what is referred to as their 'Prep' year. They then enter Year 1 the following year. The pre-assessment, treatment, and post-assessment phases of this study took place in the year *before* Prep and were conducted from September to November. School follow-up 1 was conducted in the final week of term 1 of Prep (last week of March/beginning of April). School follow-up 2 was conducted in the final week of term 2 of Prep (last week of June).

Participants

Participants were 128 parents aged 19-49 years (M = 37.2 years; SD = 4.86) of preschool children with sleep problems aged 3-5 years (M = 4.5 years; SD = .54), who participated in either the BI (N=62) or CAU conditions (N=66). Recruitment into the study was conducted in south-east Queensland, Australia through referrals from paediatricians, general practitioners, mental health professionals, parenting support organisations, and media publicity. The majority of parents were female (93%), born in Australia (74.8%), worked part-time (46.9%), had a household income between $AUD 100K and $200K (46.1%), held a Bachelor's degree (43%), and were married (78.1%). The majority of children were female (60.2%), lived with both biological parents (87.5%), and were born in Australia (94.5%). Parents reported that 89% and 11% of children had moderate and severe sleep problems respectively (see below). Further demographic characteristics of the sample can be found in Supplementary Table 1.

Children were included in the study if they a) were scheduled to begin primary school the following year, b) scored above 41 on the Child Sleep Habits Questionnaire (CSHQ: Owens, Spirito, & McGuinn, 2000) and c) were rated as having a parent-reported '*moderate*' to '*severe*' sleep problem through parent report on the screening survey (see below). Children were excluded from the study if they had a parent-reported intellectual or developmental disorder.

Figure 1 illustrates the flow of participants through the study. As is evident from Figure 1, for the BI group, 84%, 81% and 77% of parents completed the assessment at post-treatment, school follow-up 1, and school follow-up 2 respectively. For the CAU group, 88%, 88%, and 74% of parents completed the assessment at post-treatment, school follow-up 1 and school follow-up 2 respectively. In regards to teacher report, 68% and 61% of teachers of children in the BI condition completed school follow-up 1 and 2 assessments respectively, while 62% and 56% of teachers of CAU children completed school follow-up 1 and 2 assessments respectively.

Measures

Demographic information was collected at pre-asseessment only. Parent-rated sleep, anxiety and behaviour problem measures were assessed at pre-assessment, post-assessment, school follow-up 1 and school follow-up 2. Teacher-rated school transition and academic achievement measures were assessed at school follow-ups 1 and 2. Access to additional sleep assistance was assessed at school follow-up 2 only.

Demographic information. Parents were required to report their own age, gender (male, female, other), country of birth, annual household income, highest level of education and marital status, as well as the age, gender (male, female, other), country of birth, and living arrangements of their child.

Sleep

Presence / Absence of a Sleep Problem (parent-rated). In line with the studies conducted by Quach et al (2011) and Hiscock et al (2018), parents were asked to rate their child's sleep problem severity as '*none*', '*mild*', '*moderate*', or '*severe*'. A parental rating of moderate or severe was required for study eligibility.

Sleep Problems (parent-rated). The parent-rated 33-item Child Sleep Habits Questionnaire (CSHQ: Owens, Spirito, & McGuinn, 2000) was used to assess the frequency of common paediatric sleep difficulties and has been used with children aged 2 to 12 years (Boergers et al., 2007). Respondents are required to rate the frequency with which each item occurs on a 3-point scale (1 = *rarely* [0-1 times per week], 2 = s*ometimes* [2-4 times per week], 3 = *usually* [5-7 times per week]). Items are summed to produce a total score that may range from 33 to 99, with higher scores indicating greater sleep problems. A total score greater than 41 has been found to sensitively identify a clinical paediatric sleep disorder (Owens et al., 2000), and was an inclusion criterion in the present study. The CSHQ total score has been shown to demonstrate adequate reliability, with Cronbach's alphas of α=.72 and α=.78 for community and clinical samples respectively (Owens, Spirito, McGuinn, et al., 2000; Tyler et al., 2019). In this study, the Cronbach's coefficient alpha for the total score was α=.77.

Anxiety

Anxiety Symptoms (parent-rated). Anxiety symptoms were measured using the parent-rated, 34-item Preschool Anxiety Scale (PAS: Spence et al., 2001). Respondents are required to rate how true each item is for their child on a 5-point Likert scale from 0 (*not true at all*) to 4 (*very often true*). Twenty-eight of the items are summed to produce a total score that may range from 0 to 112, with higher scores reflecting higher levels of anxiety. The total score of the PAS has demonstrated a sound Cronbach's coefficient alpha of .70 in previous studies (Edwards, 2007), and a Cronbach's coefficient alpha of α=.89 in the current study.

Internalising Symptoms (parent-rated). The 36-item, parent-rated internalising subscale of the Child Behaviour Checklist 1.5-5 years (CBCL-Int: Achenbach & Rescorla, 2000) was used to assess broader internalising symptoms. The CBCL-Int is a higher order subscale, subsuming the component anxious-depressed, withdrawn/depressed and somatic complaints subscales. Respondents are required to rate how true each item has been for their child over the last 6 months on a 3-point scale from 0 (*not true*) through 1 (*somewhat or sometimes true*) to 2 (*very true or often true*). Scores for the CBCL-Int are summed to produce an internalising subscale score that may range from 0-72, with higher scores reflecting greater internalising symptoms. The psychometrics of the CBCL-Int are well established. The Cronbach's alpha of the CBCL-Int in the present study was α = .88.

Behaviour Problems

Behaviour Problem Symptoms (parent-rated). The Intensity subscale of the 36-item, parent-rated Eyberg Child Behaviour Inventory (Eyberg & Ross, 1978) was used to measure behaviour problem symptoms. Respondents are required to rate the frequency with which each item occurs for their child on a 7-point scale from 1 (*never occurs*) to 7 (*always occurs*). Scores are summed to produce a total score that may range from 36 to 252, with higher scores reflecting greater behaviour and conduct problems. The Intensity scale of the ECBI has been shown to demonstrate excellent internal consistency (.91: Morawska & Sanders, 2006), good test-retest reliability (.75: Funderburk et al., 2003), and good convergent validity with the CBCL externalising subscale (r=.65: Boggs et al., 1990). The Cronbach's alpha for the Intensity scale in the current study was α=.92.

Externalising Symptoms (parent-rated). The 24-item, parent-rated externalising subscale of the Child Behaviour Checklist 1.5-5 years (CBCL-Ext: Achenbach & Rescorla, 2000) was used to assess externalising symptoms. The CBCL-Ext is a higher order subscale, subsuming the component attention, rule-breaking behaviours, and aggressive behaviours subscales. Respondents are required to rate how true each item has been for their child over the last 6 months on a 3-point scale from 0 (*not true*) through 1 (*somewhat or sometimes true*) to 2 (*very true or often true*). Scores for the CBCL-Ext are summed to produce an externalising score that may range from 0-48, with higher scores reflecting greater externalising symptoms. The psychometrics of the CBCL-Ext are well established. The Cronbach's alpha of the CBCL-Ext subscale in the present study was $\alpha = .91$.

Transition to School

Physical, Social and Cognitive Development (teacher-rated). A modified teacher-rated Australian version of the Early Development Instrument (AvEDI: Brinkman et al., 2007) was used to assess transition to school in terms of child physical, social and cognitive development. For the purposes of this study, the Physical Health and Wellbeing (PW), Language and Cognitive Skills (LC), and Social and Emotional Development (SE) subscales were used. The AvEDI was modified for use in the current study in a number of ways: seven items on the Language and Cognitive Skills subscale assessing 'special abilities' were removed; one item, "Does the child attend a school/community breakfast club?" was not included on the Physical Health and Wellbeing subscale; and the original scoring system (Department of Education, 2018) was modified so that each item was rated on a 5-point scale.

The PW subscale used in the current study consisted of 18 items. The 5 items assessing days absent (e.g., *"How many days has this child been absent since the start of the year?"*) were rated on a 5-point scale from 1 (*0 days*) to 5 (*10 days or more*). For 7 items, teachers were required to rate the frequency with which the child exhibited particular behaviours *(e.g., "Is well coordinated i.e., moves without running into or tripping over things)* on a 5-point scale from 1 (*never*) to 5 (*always / consistently*). For 6 items *(e.g., overall physical development)*, teachers were required to rate the child on a 5-point scale from 1 (*consistently low*) to 5 (*consistently high*). After reverse-scoring several items, the PW subscale score was derived by summing all items. The PW score could therefore range from 18-90, with higher scores reflecting greater physical wellbeing. The Cronbach's alpha for the PW scale used in the current study was α=.87.

The LC subscale used in the current study consisted of 33 items. For 7 of the items *(e.g., ability to listen)*, teachers were required to rate the child on a 5-point scale from 1 (*unable to do this*) through to 5 (*consistently able to do thi*s). For the remaining 18 items (e.g., *Is able to read simple words*), teachers rated the child on a 5-point scale from 1 (*never*) to 5 (*always/consistently*). The LC subscale score was derived by summing all items and could therefore range from 33 to 165, with higher scores indicating greater language and cognitive development. The Cronbach's alpha for the LC scale used in the current study was α=.97.

The SE subscale used in the current study consisted of 52 items. For two of the items *(e.g., overall social/emotional development)*, teachers were required to rate the student on a 5-point scale from 1 (*consistently low*) to 5 (*consistently high*). For the remaining 50 items *(e.g., demonstrates self-control)*, teachers rated the child on a 5-point scale from 1 (*never*) to 5 (*always / consistently*). The SE subscale score was derived by summing all items on the subscale and could therefore range from 52-260, with higher scores reflecting greater social and emotional development. The Cronbach's alpha for the SE scale used in the current study was α=.83.

Academic Achievement (teacher-rated). Academic achievement was assessed using three teacher-rated questions derived from national Australian teacher reporting standards. For each of the three questions, teachers were asked to use their professional judgement to determine where they would place the child with regards to the expected achievement standard of a child at the end of term 1 (approximately 10 weeks after beginning formal schooling) and the end of term 2 (approximately 22 weeks after beginning formal schooling). Teachers were required to rate each of three areas (receptive modes (listening, reading and viewing), productive modes (speaking, writing and creating) and mathematics) on a 5-point scale from 1 (*is beginning to work towards expected* *standard*) to 5 (*is working well above expected standard*). Items were summed to produce a total academic achievement score that could range from 3 to 15, with higher scores indicating higher academic achievement. The Cronbach's alpha for the academic achievement scale used in the current study was α=.92.

Access to Additional Sleep Services (parent-rated)

At school follow-up 2, parents in both conditions were asked if they had accessed additional services for their child's sleep problem during the course of the study. Specifically, parents were required to indicate whether they had, in relation to their child's sleep problem: a) not accessed additional support, b) visited a psychologist or counsellor, c) consulted with a general practitioner or paediatrician, d) accessed assistance via the internet and / or d) accessed other additional support (which they were then required to specify).

Procedure

Ethics was obtained from the Griffith University Human Research Ethics Committee (2017/962), and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR number ACTRN12618001161213). Referrals into the study were screened by telephone interview and an online survey to ascertain broad inclusion and exclusion criteria before going on to trial enrolment. A randomisation schedule was created using a computer-generated random number sequence. The assignment ratio was 1:1 for the BI and CAU conditions, with randomisation stratified by clinic location (Griffith University Gold Coast and Griffith University Brisbane) to ensure balance between groups, and block sizes of four and six to align with estimated group sizes. This schedule was kept in a locked file with a research assistant informing families of their allocation after they completed the first online baseline survey. Teachers were informed that the family was part of a study, but were not informed of allocated condition.

Parents in the BI condition completed the treatment program in groups of up to 5 participants in two, south-east Queensland (Australia) Griffith University Psychology Clinics (Brisbane and the Gold Coast) that are located approximately one hour drive from each other.

Although both parents (where there were two parents) were invited and strongly encouraged to attend the sessions, in all cases only one parent attended, usually due to practicalities associated with childcare. Attending participants were therefore encouraged to share the information gleaned from the session with the other parent. The BI program included both standard paediatric sleep strategies as well as gold standard treatment strategies targeting bedtime fears (i.e. exposure therapy) and behavioural problems at bedtime (i.e., providing sound instructions, time-out, and limit-setting), and was conducted weekly over 6 weeks (5 x 1.5 hours face-to-face small group sessions, and one personalised phone call). The content of Session 1 consisted of psychoeducation and training in sleep hygiene, while Session 2 comprised training in sleep routines, praise and rewards, and dealing with oppositional behaviour. Session 3 focussed on strategies for dealing with night-time fears, while Session 4 included additional strategies for dealing with difficult behaviours as well as bedtime fading. In Week 5, parents received a 15 minute phone call from the therapist to check-in and fine-tune the strategies that had been implemented. Finally, Session 5 involved a recap of the strategies, planning for the future and training in parental self-care. Supplementary Table 2 provides a more detailed outline of each session.

Groups were co-facilitated by two provisionally registered psychologists undertaking post-graduate study in clinical psychology at Griffith University Mt Gravatt or Gold Coast campuses. Therapists received 6 hours of training by the lead researcher to ensure sufficient and identical training across the two sites, and a number of therapists facilitated groups on both sites to ensure consistency. Therapists also received weekly 1-hour supervision from the lead researcher. Parents in the CAU condition were offered the behavioural intervention after the second school follow-up assessment (i.e., in July of the Prep year).

Data Analytic Plan

Pre-treatment comparisons. In order to test for pre-existing differences between the BI and CAU groups at pre-treatment, between groups ANOVAs were used for child age and parent age, and chi square were used for parent and child gender as well as parent and child country of birth. In addition, a between groups ANOVA was used for the total score on the CSHQ, and a between groups MANOVA was used for the PAS, CBCL-Int, ECBI, and CBCL-Ext.

Differences between those retained and not retained. In order to test for differences between those who were retained versus those who were not at post-assessment, school follow-up 1 and school follow-up 2, between groups (retained vs not retained) ANOVAs were used for child age and parent age, and chi square were used for parent and child gender. In addition, a between groups (retained vs not retained) ANOVA was used for the total score on the CSHQ, and a between groups (retained vs not retained) MANOVA was used for the PAS, CBCL-Int, ECBI, and and CBCL-Ext.

Intervention effects. Repeated measures mixed effect models were undertaken to examine the effects of the intervention on sleep problems, anxiety symptoms, internalising symptoms, behaviour problems and externalising symptoms. Significant interactions between intervention condition and time were followed up with tests of simple effects and pairwise comparisons. The intercept was random to account for repeated measures of the same individual. The mixed effect models were conducted as intention-to-treat using direct maximum likelihood estimation on the full dataset, and therefore all cases were included. Mixed effect modelling was conducted using Stata. Chi square analyses were conducted on parent-rated presence/absence of a sleep problem at post-assessment, school follow-up 1 and school follow-up 2 assessment points.

Mediation. In order to test for the mediating role of sleep on other outcome variables, longitudinal mediation models were first constructed for each outcome variable using the structural equation modelling framework, employing an autoregressive model with cross-lagged *b* paths. Model fit was evaluated using the comparative fit index (CFI), root means squared error of approximation (RMSEA), and chi-square test. Criteria included a CFI above 0.9 to indicate acceptable model fit (Kline, 2015). Models were estimated in Mplus using maximum likelihood estimation. Cases with missing data on exogenous variables were dropped using listwise deletion (n=11). Confidence intervals for the path estimates were obtained by percentile bootstrap using 1000 replications (Goldsmith et al., 2018).

Mediation was tested using indirect effects. As the models included repeated measures of the mediator and outcome variables, more than one indirect (mediated) effect could be tested per model. The approach taken by Goldsmith et al. (2018) and Cole and Maxwell (2003) was used, allowing determination of the timing of mediation effects. An indirect effect included all possible paths from the intervention variable to the outcome at a certain time point that passed through one or more mediator time points. Time-specific indirect effects for all possible paths leading to the outcome at post-assessment and follow-up time points were calculated. Indirect effects were calculated using the products of the intervention-mediator and mediator-outcome paths. Confidence intervals for the indirect and direct effects were obtained by percentile bootstrap using 1000 replications (Goldsmith et al., 2018).

Results

Pre-treatment Comparisons

The means and standard deviations for outcomes of the BI and CAU groups at each assessment point are reported in Table 1. The between-groups ANOVAs showed no significant differences between groups on parent age $F(1,126)=.292$, $p=.590$, or child age $F(1,126)=.272$, $p=.603$. Similarly, chi square analyses showed no significant differences between groups on parent gender (chi square = 3.337, $p=.068$), child gender (chi square = .012, $p=.915$), whether the parent was born in Australia (chi square = 2.205, $p=.138$), or whether the child was born in Australia (chi square = 1.170, $p=.279$). The between-groups ANOVA showed no significant pre-treatment differences between the BI and CAU groups on the CSHQ, F (1,125)=.367, $p=.546$. Similarly, the between groups MANOVA showed no significant pre-treatment differences between the BI and CAU groups on the PAS, ECBI, CBCL-Int or CBCL-Ext, $F(4,122)=.471$, $p=.757$.

There were no significant differences between those retained and those not retained at any time point on parent gender, child gender, child age or the CSHQ. However, there was a significant difference between those retained and not retained on parent age at post-assessment

F(1,126)=7.632, p=.007, and at school follow-up 1 $F(1,126)=4.748$, $p=.031$ (but not school follow-up 2), with those retained at post-assessment and school follow-up 1 being significantly older than those not retained. In addition, although the between groups MANOVA showed no significant differences between those retained and those not retained on the PAS, ECBI, CBC-Int and CBCL-Ext at post-assessment and school follow-up 1, the between groups MANOVA at school follow-up 2 was significant $F(4,122)=3.816$, $p=.006$. Subsequent univariate analyses indicated no significant differences between those retained and not retained at school follow-up 2 on the PAS, CBCL-Int and CBCL-Ext. However, a significant difference on the ECBI $F(1,125)=7.574$, $p=.007$ was found, with those retained reporting lower scores on the ECBI than those not retained.

Sleep

Presence / Absence of a Sleep Problem. At pre-treatment, 100% of children were reported by their parents as having a moderate or severe sleep problem. By post-treatment, 55.2% of the CAU compared to 28.8% of the BI condition children (chi square=7.7652, $p=.005$) were rated by their parents as having a sleep problem in the moderate or severe range. By school follow-up 1, these numbers had reduced further to 48.3% for the CAU and 8% for the BI condition (chi square=20.89, $p<.001$), and at school follow-up 2, 32.7% for the CAU and 8.3% for the BI group (chi square=8.762, $p=.003$).

Sleep Problems (CSHQ). A repeated measures mixed model indicated that, compared to the CAU group, the BI group exhibited a significantly greater reduction in CSHQ sleep problems across the study period (Table 2; Supplementary Figure 1). For the BI group, post hoc contrasts indicated that sleep problems significantly decreased from baseline to post-assessment ($p<.001$), but did not change from post-assessment to school follow-up 1 ($p=.274$), or from school follow-up 1 to school follow-up 2 (p=.504). For the CAU group, sleep problems significantly decreased from baseline to post-assessment ($p<.001$), but did not change from post-assessment to school follow-up 1 ($p=.254$) or from school follow-up 1 to school follow-up 2 ($p=.249$). There was no significant difference between the BI and CAU groups at baseline on CSHQ sleep problems ($p=.558$).

However, CSHQ scores were significantly lower for the BI compared to CAU condition at post-assessment (p<.001, d=1.00), school follow-up 1 (p<.001, d=1.01), and school follow-up 2 (p<.001, d=.84).

Anxiety

Anxiety Symptoms (PAS). A repeated measures mixed model indicated that, compared to the CAU group, the BI group exhibited a significantly greater reduction in anxiety across the study period (Table 2; Supplementary Figure 2). Post hoc contrasts indicated that there was a significant reduction in anxiety for the BI group from baseline to post-assessment (p<.001), but no change from post-assessment to school follow-up 1 (p=.449), or from school follow-up 1 to school follow-up 2 (p=.319). For the CAU group, there was no change in anxiety from baseline to post-assessment (p=.062), or from school follow-up 1 to school follow-up 2 (p=.588). However, there was a significant reduction in anxiety from post-assessment to school follow-up 1 (p=.036). There was no significant difference between the BI and CAU group at baseline on PAS anxiety symptoms (p=.629). However, PAS scores were significantly lower for the BI compared to CAU condition at post-assessment (p<.001, d=.62), school follow-up 1 (p=.003, d=51), and school follow-up 2 (p<.001, d=.72).

Internalising Symptoms (CBCL-Int). A repeated measures mixed model indicated that, compared to the CAU group, the BI group exhibited a significantly greater reduction in internalising symptoms across the study period (Table 2; Supplementary Figure 3). Post hoc contrasts for the BI group indicated there was a significant reduction in internalising symptoms from baseline to post-assessment (p=.002), but not from post-assessment to school follow-up 1 (p=.235), or from school follow-up 1 to school follow-up 2 (p=.077). For the CAU group, there was no difference in internalising symptoms from baseline to post-assessment (p=.125) or from school follow-up 1 to school follow-up 2 (p=.816). However, there was a significant reduction from post-assessment to school follow-up 1 (p<.001). There was no significant difference between the BI and CAU group at baseline on CBCL-Int symptoms (p=.193). However, CBCL-Int scores were significantly lower for the BI compared to CAU condition at post-assessment (*p*<.001, *d*=.60), school follow-up 1 (*p*=.030, *d*=.45), and school follow-up 2 (*p*=.002, *d*=.65).

Behaviour Problems

Behaviour Problem Symptoms (ECBI). A repeated measures mixed model indicated that, compared to the CAU group, the BI group exhibited a significantly greater reduction in behaviour problems across the study period (Table 2; Supplementary Figure 4). The post hoc contrasts indicated that for the BI group, there was significant reduction in behaviour problems from baseline to post-assessment (*p*<.001), and from school follow-up 1 to school follow-up 2 (p=.046), but no significant change from post-assessment to school follow-up 1 (p=.518). For the CAU group, there was no significant change in behaviour problems from baseline to post-assessment (p=.196), post-assessment to school follow-up 1 (p=.774), or school follow-up 1 to school follow-up 2 (p=.960). There was no significant difference between the BI and CAU group at baseline on ECBI behaviour problem symptoms (p=.629). However, ECBI scores were significantly lower for the BI compared to CAU condition at post-assessment (p=.002, *d*=.60), school follow-up 1 (p=.010, *d*=.47), and school follow-up 2 (p<.001, *d*=.65).

Externalising Symptoms (CBCL-Ext). A repeated measures mixed model indicated that, compared to the CAU group, the BI group exhibited a significantly greater reduction in externalising problems across the study period (Table 2; Supplementary Figure 5). For the BI group, post hoc contrasts indicated that there was a significant reduction in externalising symptoms from baseline to post-assessment (p<.001) and from school follow-up 1 to school follow-up 2 (p=.002), but not from post-assessment to school follow-up 1 (p=.864). Post hoc contrasts for the CAU group indicated there was no significant change in externalising symptoms from baseline to post-assessment (p=.398), or from school follow-up 1 to school follow-up 2 (p=.654), but that there was a significant reduction from post-assessment to school follow-up 1 (p<.001). There was no significant difference between the BI and CAU group on CBCL-Ext symptoms at baseline (p=.419) or school follow-up 1 (p=.090, *d*=.33). However, CBCL-Ext scores were significantly lower for the

BI compared to CAU condition at post-assessment ($p<.001$, $d=.61$) and school follow-up 2 ($p=.002$, $d=.55$).

Mediation Effects of Sleep on Anxiety and Behaviour Problems

The results of the longitudinal mediation models for anxiety symptoms (PAS) are presented in Figure 2 as an example, while the longitudinal models for internalising symptoms (CBCL-Int), behaviour problem symptoms (ECBI) and externalising symptoms (CBCL-Ext) are reported in Supplementary Figures 6-8. Evidence that improvement in sleep problems at post-assessment mediated the effect of the BI on behavioural/psychological outcomes at school follow-ups 1 and 2 was identified in the longitudinal models examining anxiety symptoms (PAS), internalising symptoms (CBCL-Int), and externalising symptoms (CBCL-Ext). No evidence of longitudinal mediation was detected for behaviour problem symptoms (ECBI). The indirect effects examining mediation are reported in Table 3. A total indirect effect was detected at school follow-up 2 in the models examining anxiety symptoms (PAS), internalising symptoms (CBCL-Int), and externalising symptoms (CBCL-Ext). The effect of the intervention on the outcome was significantly mediated through sleep problems (CSHQ) at post-assessment only, with this effect carried through to school follow-ups 1 and 2. The effect of intervention on the outcome did not mediate through sleep problems (CSHQ) at school follow-up 2.

School Transition

The results of the longitudinal mediation models for teacher rated personal wellbeing, language and communication, socio-emotional development, and academic achievement are reported in Supplementary Figures 9-12. None of the fit indices reached an acceptable level in the initial run of any of the longitudinal mediation models for social, cognitive and physical development. Modification indices were requested, and the findings were consistent across all models in the recommendation to allow for covariance between sleep problems at post-assessment and school follow-up 1. This inclusion improved model fit to an acceptable level, but did not change the significance of the path estimates or indirect effects. The inclusion did not violate any theoretical assumptions underpinning mediation. The analyses did not suggest that improvements in sleep problems mediated the effect of the intervention on teacher rated personal wellbeing, teacher rated language and communication, teacher rated socio-emotional score, or teacher rated academic outcomes. No indirect effects were detected, as reported in Table 4.

Access to Additional Sleep Services

Access to additional sleep services by parents in both conditions was assessed at school follow-up 2. As is evident from Table 5, very few additional sleep services were accessed by parents in either the BI or CAU conditions.

Discussion

This study aimed to evaluate the efficacy of a parent-focused, group-based behavioural intervention that focused specifically on preschool aged children (3 to 5 years) prior to the transition to school, and that included gold-standard anxiety and behaviour management strategies. The RCT assessed the efficacy of the behavioural intervention (BI) relative to a care-as-usual condition (CAU), with assessments conducted at pre- and post-intervention (in the year prior to formal schooling) as well as follow-ups conducted at the end of terms 1 and 2 of the first year of formal schooling. It was predicted that relative to the CAU group, children in the BI group would demonstrate greater improvements in child sleep problems, anxiety, and behaviour problems, and would demonstrate enhanced transition to school. It was further predicted that changes in sleep problems at post-assessment would predict improvements in child anxiety and behaviour problems, as well as a better transition to school, at school follow-ups 1 and 2.

As predicted, the intervention was successful in improving the sleep of these young children. Although children in both groups demonstrated a significant reduction in sleep problems across the study period, those receiving the intervention showed a significantly greater improvement, as evidenced by both the percentage of children rated by their parents as having a moderate to severe sleep problem, and by reductions in parental ratings on the CSHQ. The improvement in sleep problems demonstrated by the CAU children over the course of the study highlights a natural remission of sleep problems common in this age group. However, it is also evident that for approximately one third of these young children, sleep problems did not spontaneously remit and treatment was required. Although previous reviews and meta-analyses have concluded that behavioural interventions are efficacious for treating sleep problems in the 0-5 year-old age group (Fangupo et al., 2021; Kuhn & Elliott, 2003; Meltzer & Mindell, 2014; Meltzer et al., 2021; Mindell, 1999), there has been a dearth of RCTs conducted on sleep interventions for children in the preschool age group specifically. This study, therefore, represents a useful addition to the literature, demonstrating that a parent-focused, group-based behavioural sleep intervention is successful in reducing sleep problems in this age group.

Not only was the sleep intervention successful in improving preschool sleep problems, it was also successful in improving anxiety and behaviour problems. Indeed, relative to the CAU condition, those in the BI group demonstrated a significantly greater reduction in anxiety symptoms, internalising symptoms, behaviour problems, and externalising symptoms. Furthermore, it was found that improvements in sleep evident at post-intervention, mediated the improvements in anxiety, internalising and externalising symptoms (but not behaviour problem symptoms) at school follow-ups 1 and 2. These results make an exciting and novel contribution to the literature as very few studies assessing sleep interventions with preschoolers have assessed outcomes other than sleep, and those that have, report mixed results (e.g., Hiscock et al., 2018; Quach et al., 2011). The results also suggest that sleep problems represent a transdiagnostic risk factor / mechanism for other psychological and behavioural problems, and are consistent with the results of numerous studies demonstrating the temporal precedence of preschool sleep problems over anxiety (Gregory et al., 2005; Gregory et al., 2004; Gregory & O'connor, 2002; Hatzinger et al., 2013; Whalen et al., 2017), and behaviour problems (Bates et al., 2002; Gregory et al., 2004; Hatzinger et al., 2013; Hiscock et al., 2007).

Given the demonstrated results in relation to anxiety and behaviour problems, this study has a number of clinical implications. The program represents a clinically efficient means by which to alleviate a range of highly prevalent childhood afflictions. Sleep, anxiety, internalising, behaviour, and externalising symptoms were all significantly reduced in just 5 sessions, while the majority of programs targeting each of these afflictions separately are each of longer duration. There is also less stigma attached to child sleep problems compared to psychological or behavioural problems, and as a result, parents may be more likely to seek and access assistance for their child's sleep. Given the significant comorbidity between sleep, anxiety and behaviour problems amongst these youngsters, and the ability of this program to effectively target them all, greater help-seeking on behalf of the parent for child sleep problems may simultaneously (if not inadvertently) lead to greater assistance for anxiety and behaviour problems. Finally, there is significant symptom overlap between sleep, anxiety and behaviour problems in this age group that makes diagnosis and the determination of 'what to focus on first' in therapy, challenging. This program tested in this study may therefore be recommended as a transdiagnostic intervention that can be used with young children to alleviate a range of prevalent and frequently intertwined disorders.

Despite strong effects of the intervention on sleep, anxiety, and behaviour problems, it was not found to improve transition to school or academic outcomes. The findings of the current study are therefore consistent with those of Quach et al (2011) and Hiscock et al (Hiscock et al., 2018), who similarly failed to find improvements on learning outcomes in young children following a behavioural sleep intervention. The results are inconsistent however, with extant research suggesting a relationship between sleep problems and cognitive performance (e.g., Hochadel et al., 2014; Nelson et al., 2015; Paavonen et al., 2000; Simola et al., 2014). Quach et al (2011) suggested that their lack of results for learning may have been due to a lagging of learning effects. However, as two follow-ups were conducted in the present study, the last of which was approximately half-way through the first year of formal schooling (and approximately 9 months post-treatment), one might reasonably expect that any learning and / or school transition effects of the intervention would have occurred by that time. An alternative explanation for the lack of findings for school transition and academic achievement is the operationalization of these constructs in the present study. The measures employed may not have been sensitive or objective enough to detect potential differences between groups. Teacher ratings may have been influenced by many factors, and it may be that the teachers had had insufficient time by the school follow-up assessment time points to adequately assess the children. Future research should therefore employ more objective and sensitive measures of cognitive ability and academic achievement to better determine any effect of the sleep program on transition to school. The final explanation is that school transition and academic achievement are multi-determined, with sleep representing only one potentially influential factor. Indeed, researchers have examined a range of biopsychosocial factors influencing child transition to primary school, including age, gender, language, socioeconomic status, parenting style and practices, social and emotional competence, and early child care experiences (see Hirst et al., 2011 for a review). It may simply be that a behavioural sleep program alone is insufficient to affect significant change on school transition and academic outcome. Future research should therefore further examine the potential role of sleep as a mediator or moderator of other factors influencing school transition, and determine whether or not sleep may affect transition to school in other, indirect ways.

Despite strengths including the randomized controlled design, multiple measures, and mediational analyses, this study was not without weaknesses. First, it did not include a clinical interview to determine diagnostic sleep, anxiety or behaviour problem status. As diagnostic interview is considered gold standard for the measurement of anxiety and behaviour problems, future research should incorporate this approach. Second, parent and family outcomes such as parental sleep, burden, psychopathology, and self-efficacy were not assessed in the present study. Given the associations between child sleep problems and parental sleep and wellbeing (Bates et al., 2002; Crowe et al., 1996; Robinson & Richdale, 2004), and the beneficial effects of treating child sleep on maternal outcomes (Wiggs & Stores, 2001), the inclusion of parent and family measures is warranted in future trials of the intervention. Third, there was no way to ascertain the degree to which the non-attending parent was informed of program content, 'took it on board', and / or complied with the program. Future research should include assessments of program compliance for both parents (where there are two parents) to determine the effect of parental compliance on treatment outcome. Fourth, the categorical parent-rated measure of child sleep problems (none, mild, moderate or severe) has not been psychometrically validated. Although it was included to remain consistent with the studies by Quach et al (2011) and Hiscock et al (2018), and the psychometrically validated CSHQ was also included, future studies should ensure that only sleep measures with strong psychometric validity are used. Fifth, although parents were asked if they had received additional services for their child's sleep problem during the course of the study, and if they had, the type of service they received, they were not asked to provide information on the content, duration or frequency of support received. Furthermore, they were not asked about any services they may have received for their child's anxiety and / or behaviour problems. Future research should ensure that this information is obtained and reported. Finally, the sample employed was somewhat homogenous, and largely Caucasian, wealthy, and from intact families. Future research should ensure a more heterogenous sample in terms of ethnicity, socioeconomic status, and family structure.

In addition to the suggestions for future research suggested above, there are also a number of other avenues for empirical enquiry. In particular, although there are many benefits of group-based interventions, including efficiency of delivery, peer support, and 'normalisation' of difficulties being experienced, it is difficult to organise therapy times convenient for all group members, and the majority of private practitioners are not equipped to conduct group therapy. Indeed, of those assessed for eligibility in the present study, 19 declined an invitation to participate because it was too difficult to attend face-to-face groups at the allocated times. The uptake of the group-based mode of delivery by clinicians and parents is therefore likely to be less than optimal. Future efficacy and implementation research is required to determine the feasibility and effectiveness of alternative modes of program delivery, including individual, videoconferencing, and internet-based approaches, that may increase the uptake of this evidence-based, efficacious program.

In conclusion, the results of this study suggest that a parent-focussed, group-based behavioural sleep intervention is effective in reducing not only child sleep problems, but also anxiety, behaviour problems and internalising and externalising symptoms in preschoolers. Given the high prevalence rates and deleterious short- and long-term consequences of sleep problems in young children, programs such as this have enormous potential to influence the mental health trajectories of young people. These are novel, exciting findings, and it is now important to identify and test methods for ensuring access to, and uptake of, this program, so that the number of families able to benefit from this evidence-based treatment can be optimised. If rolled out on a large scale in a format that is highly accessible, this program has the potential for significant public health impact.

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