Pilot Study of a Tailored Behavioral Intervention for Insomnia in Children with Autism Spectrum Disorder: Preliminary Results

Margaret C. Souders PhD CRNP, Whitney Eriksen, BSN, PhD c, Stefanie Zavodny, BSN, Jordana Popovich, MSN, CRNP, James Connell, PhD, Roseanne Schaaf, PhD, Lisa Guy, PhD, Connor Kerns, PhD, Rebecca Sinko, OT, Alexandra Ellison, MSN,CRNP, Beth Malow, MD

Note: 2 pages

Background: Children with Autism Spectrum Disorder (ASD) have demonstrated elevated rates of chronic insomnia, possibly stemming from an arousal dysregulation that produces a constellation of behavioral symptoms that include anxiety, sensory differences, and difficulties sleeping. Based on the theory that a subset of children with ASD are in a hyper-aroused state, we developed a **Tailored Behavioral Intervention (TAB)** for insomnia to supplement the **Standard Care (SC)** established by the ATN: Sleep Tool Kit. The **TAB** developed for this study includes: (1) positive routines, (2) the **Calming Module (CM)**, a novel component designed to decrease arousal levels with 12 soothing, relaxing activities, (3) faded bedtime protocol, and (4) **Performance feedback procedures (PFP)**, a highly effective feedback consultative strategy used to support parents and foster study fidelity. Based on the child's arousal profile, selected activities from the CM are incorporated into an evening routine to relax the child and promote sleep.

Objectives: (1) Determine the feasibility of implementing randomized control trial of a **TAB and SC** (n = 20) or **SC only** (n = 20) protocol for children with ASD and insomnia, evaluating recruitment, randomization, retention, and implementation of interventions by a multi-disciplinary team with parents of a child with ASD. (2) Complete a comparative cost analysis of the interventions, in terms of training and parent resources needed to teach the interventions, measure fidelity, and collect data on the primary outcome, sleep, as measured by actigraphy. (3) Compare the effects of the interventions on sleep parameters.

Methods: Children ages 6-10 years with ASD and insomnia, stable medical conditions and daytime behaviors and their families are eligible to participate. Measures for all participants include sleep history, 10 days of Actigraphy, sleep diary, and Sensory Profile, Children's Sleep Habits Questionnaire, and Pediatric Anxiety Rating Scale taken at baseline and 8 weeks post-intervention, and a Parent Acceptability Survey following completion. Arousal profiles for each child are developed by the interdisciplinary team. **SC** is led by the nurse or OT. Families are randomized to either **TAB and SC** or **SC** only. The **TAB** and SC group receives 8 (1hr) home-based sessions with **PFP**.

Results: To date, 37 families have been enrolled, with completed data sets for N = 13 **TAB and SC** and N = 11 **SC only**. Protocol was very acceptable to families (M = 6.5, Scale: 0-7) and all subjects have tolerated wearing the actigraph. The intervention significantly decreased wake minutes (M = 55.91 minutes), and activity mean ($p < .05$) based on actigraphy for children in the TAB and SC, compared to those receiving SC only. The intervention significantly increased sleep minutes (M = 32.88 minutes; $p < .05$). Both groups showed decreases in sleep latency (time to fall asleep), but those receiving the TAB and SC showed significantly greater improvement. Following intervention, the TAB and SC group fell asleep 15 minutes faster than baseline, and 11 minutes faster than the control group post-intervention. The mean sleep latency at week 8 in the TAB and SC group was (M = 18.91 minutes) and on average the participants in the TAB and SC group no longer met criteria for early insomnia. Total CSHQ score decreased significantly in the TAB and SC group, with no significant changes noted in the SC only group. Parents in the TAB group reported significantly fewer night wakings than the control group. Significant decreases are also noted in

the TAB group in the total CSHQ score and the bedtime resistance and parasomnia subscales, but these changes were not significantly different from the SC only group. Many children in the sample were taking more than one behavioral medication during the study, with nearly half of the children taking melatonin (48%) and meeting criteria for insomnia at baseline. Medication doses remained the same throughout the study. One child in the SC only group had no change in sleep parameters and had some mild-moderate snoring at night. He was referred to the Sleep Center and diagnosed with moderate OSA and had a T&A with subsequent improved sleep.

Conclusions: Preliminary results suggest that the sleep protocol was acceptable to families and was feasible to implement by the multi-disciplinary team. TAB and SC group decreased sleep latency and wake minutes and significantly increased sleep minutes.

Actigraph Measure	TAB (N=13)		Control (N=11)		TAB-SC P-values
	Baseline-Week 8	Difference (P-value)	Baseline-Week 8	Difference (P-value)	
Start time (Child is put to bed)	9:13PM-9:29PM	+16 min (NS)	8:00PM-8:54PM	+54 min (NS)	NS
End time (Parent reports child wakes up)	7:09AM-6:55AM	-14 min (NS)	6:58AM-6:46AM	-12 min (NS)	NS
Duration (min) (Time in bed)	596.41-569.30	-27.11 (0.005)	597.13-594.37	-2.75 (NS)	0.023
Activity mean (Nighttime movements)	32.32-21.91	-10.41 (0.003)	28.09-24.97	-2.75 (NS)	0.042
Wake minutes (Time awake during night)	162.36-106.45	-55.91 (0.005)	125.95-116.10	-9.85 (NS)	0.036
Sleep minutes (Time asleep)	434.04-466.93	+32.88 (0.048)	470.36-478.27	+7.91 (NS)	NS
Sleep latency (min) (Time to fall asleep)	34.23-18.91	-15.32 (0.002)	36.11-31.61	-4.50 (0.084)	0.076

Funded by the Department of Defense GRANT AR120166