

ABSTRACT

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Title: Sleep Improvement in Autism Spectrum Disorder and Osteopathic Manipulative Treatment (**SIASDA OMT**): A Pilot Randomized Control Trial Using Osteopathic Manipulative Treatment to Treat Sleep Problems in Children with an Autism Spectrum Disorder

Background:

Compared with typically developing children, children with Autism Spectrum Disorder (ASD) are known to experience significantly more sleep problems, including sleep onset delay, poor sleep maintenance, OSA, insomnia, and parasomnias. The severity of these sleep problems are significantly correlated with behavioral problems, such as self-injury, aggression, and mood instability. Families struggle to find ways to improve sleep in their children with ASD, in hopes of also improving their behaviors throughout the day. Many families turn to complementary alternative medicine (CAM) techniques, including osteopathic manipulative treatment (OMT).

OMT uses a patient-centered approach incorporating complete medical care with craniosacral therapy, massage, physical therapy, and chiropractic techniques. Although evidence of effectiveness of OMT as a treatment of pediatric conditions remains preliminary, a systematic review of OMT has shown improvements in hyperactivity in children with ADHD, decrease in the number of apneas in children with OSA, and decreased crying and less irritability in children with colic thus improving time spent sleeping.

Past randomized control trials using OMT were criticized for not having a sham treatment group to determine the difference of OMT versus the placebo effect of human touch. OMT protocols can be administered with no serious adverse effects and have been anecdotally shown to work in children with ASD and sleep disturbances. But to date there has been no evidence for OMT improving sleep and behavioral problems in children with ASD.

Objectives: To compare Standard of Care versus OMT in treating sleep disturbances in children with ASD.

Methods: Randomized Control Trial Study in all Children aged 3-8 years old who have clinically diagnosed ASD (as previously proven by ADOS) and sleep difficulties, recruited from children's hospital clinics. Sleep difficulties will be measured using the Child Sleep Habits Questionnaire pre and post a 6-week treatment cycle. Behavioral symptoms, as a secondary outcome, will be measured using the ABC. I will use the ASRS for measuring Autism severity for confounding. Patients will be randomized into 2 groups: Control Sham Treatment vs OMT, and give them the same sleep hygiene talk and handouts per the ATN sleep toolkit, then monitor over a 6 week treatment course with actigraphy.

Questions for group: What is the right outcome? Are there better tools to use (i.e. ABC, CBCL, EYBERG, CBI)? Are these tools available in other languages? Is there a better way to measure sleep? Do I need to include a sleep diary? What do I include in my control (i.e. children on medication like clonidine/guanfacine/melatonin/iron)? Are there other CAM studies that I should be aware of?