

## Title

Measuring the Effectiveness of Craniosacral Therapy in sleep initiation patterns versus daily doses of Melatonin in Children Aged 8-14.

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### **CLINICAL SCENARIO:**

Pediatric insomnia is an increasing health concern given its negative impact on synaptic plasticity, learning, memory consolidation, mood regulation, hormonal development and growth.(Rolling et al., 2022). Approximately 70% of children with ADHD experience sleep problems, with 42.6% exhibiting excessive daytime sleepiness and 29.7% facing insomnia, leading to more severe ADHD symptoms, comorbid internalizing issues, and impaired daily functioning (Sung et al., 2008; van der Heijden et al., 2018; Craig et al., 2020; Accardo et al., 2012). Primary treatments for ADHD can result in worsening sleep. Psychostimulants, such as Ritalin, can exacerbate sleep disturbances such as, sleep latency, worse sleep efficiency, and shorter sleep duration (Kidwell et al., 2015; Konofal et al., 2010).

Although pharmacological alternatives exist, melatonin has been increasingly used off-label in pediatric insomnia due to its benign safety profile to treat pediatric insomnia (Rolling et al, 2022).

The purpose of this Critically Appraised Topic (CAT) is to evaluate recent literature on the effectiveness of CST in decreasing sleep initiation times in children with ADHD.

### **FOCUSED CLINICAL QUESTION:**

To what degree can weekly craniosacral therapy (CST) improve the average duration of time it takes for a child, ages 8-14, diagnosed with ADHD to fall asleep at 1 week, 2 weeks, 4 weeks, 3- and 6-month intervals post treatment as compared to daily doses of melatonin?

### **SUMMARY of Search, 'Best' Evidence' Appraised, and Key Findings**

A literature search aimed at assessing the efficacy of craniosacral therapy (CST) for ADHD yielded no studies within the specified criteria. Expanding the search revealed a European study on Manual Osteopathic Therapy (OMTh) that concluded OMTh could enhance selective and sustained attention in children with ADHD (Accorisi et al., 2014).

Two additional papers focused on melatonin and sleep disturbances in children with ADHD. A systematic review (Parvataneni et al., 2020) and a controlled trial (Checa-Ross et al., 2023) both found that low-dose melatonin improved sleep.

In a study by Ughreja et al. (2023), Craniosacral Therapy (CST) effectively reduced sleep disturbances in patients with fibromyalgia, providing evidence of cranial therapies' effectiveness in neurological treatment and sleep improvement, although this is not directly related to ADHD.

### **CLINICAL BOTTOM LINE:**

Limited data exists on the effectiveness of CST for sleep initiation. Although CST has demonstrated efficacy in addressing sleep disturbances in individuals with neurological disorders and improving attention in children with ADHD, research specifically on its impact on sleep initiation is scarce. While melatonin is commonly used to enhance sleep quality in children with ADHD, its associated risks remain unclear. Given the limited research on manual therapy and sleep initiation, further studies are essential to explore promising non-pharmacological options for children with ADHD.

**Limitation of this CAT:** This critically appraised paper (or topic) was prepared for a graduate course assignment and has /has not been peer-reviewed by one other independent person/an instructor.

### **SEARCH STRATEGY:**

#### **Terms used to guide Search Strategy:**

- **P**atient/Client Group: – Children between the ages of 8-14 with diagnosed ADHD
- **I**ntervention (or Assessment): Manual CST at intervals of 1x/week for 4 weeks.

- **C**omparison: Daily dose of Melatonin prescribed by patients' physician
- **O**utcome(s): Measured duration of time it takes for patient to fall asleep. Monitored and recorded by parents.

<b>Databases and Sites Searched</b>	<b>Search Terms</b>	<b>Limits Used</b>
Medline (Ovid)	<p>"adhd.mp." or "Attention Deficit Disorder with Hyperactivity"</p> <p>AND</p> <p>"Manipulation, Osteopathic/" or "osteopathic therapy.mp." or "Manipulation, Orthopedic"</p> <p>-</p> <p>"Manipulation, Osteopathic/" or "osteopathic therapy.mp." or "Manipulation, Orthopedic"</p> <p>OR</p> <p>"craniosacral therapy.mp."</p> <p>AND</p> <p>"Sleep/ or Sleep Disorders," "Circadian Rhythm"/ or "sleep.mp." or "Sleep Initiation and Maintenance Disorders"/</p>	<p>Child</p> <p>Last 10 years</p>

CINAHL	<p>"adhd" or "attention deficit hyperactivity disorder" or "attention deficit-hyperactivity disorder"</p> <p>AND</p> <p>"Crani* therapy" or ("osteopathic manipulation or orthopedic manual treatment")</p> <p>AND</p> <p>"sleep deprivation" or "sleep disturbance" or "reduced sleep" or "sleep loss" or "lack of sleep"</p>	<p>Children</p> <p>Last 5 years</p>
Pubmed	<p>"adhd" or "attention deficit hyperactivity disorder" or "attention deficit-hyperactivity disorder"</p> <p>AND</p> <p>"Sleep*" or "wind-down"</p> <p>AND</p> <p>"Treat*" or "Correct*"</p> <p>AND</p> <p>"Child*"</p>	

EMBASE	<p>"ADHD.mp." or "attention deficit hyperactivity Disorder"</p> <p>AND</p> <p>"osteopathic manipulation"/ or "orthopedic manipulation"/ or "osteopathic therapy.mp."</p> <p>AND</p> <p>"sleep initiation.mp." or "sleep disorder" or "sleep*"</p>	<p>Last 10 years</p> <p>Pediatric and Children</p>
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## INCLUSION and EXCLUSION CRITERIA

- Inclusion:
  - Children with ADHD between the ages of 8-14.
  - Orthopedic manipulation.
  - Studies performed outside of North America.
- Exclusion:
  - Adults diagnosed with ADHD ages 18 years and older.
  - Additional comorbidities such as sleep initiation disorder.
  - Incomplete trials or poor study protocols.
  - Studies with more than one method to improve sleep initiation.

## RESULTS OF SEARCH

5 relevant studies were located and categorised as shown in Table 1.

**Table 1:** Summary of Study Designs of Articles Retrieved

Study Design/ Methodology of Articles Retrieved	Level*	Number Located	Author (Year)
Randomized Control Trial (RTC)	1b	1	Accorisi et al. (2014)
Controlled Trial	3b	2	Checa-Ross et al.(2023) Ughreja et al, (2023)
Systematic Review of Randomized Control Trial	1a	1	Parvataneni et al.(2020)
Individual cohort study	2b	1	Qu. X et al. (2023)

\* Oxford Centre for Evidence-Based Medicine: Levels of Evidence (March 2009)

## BEST EVIDENCE

The following study/paper was identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting this study were:

- An RTC was the best type of study to address an intervention type question.
- It was the most closely related study to the PICO even though it did not directly address sleep.
- It is the only research paper that includes craniosacral therapy and ADHD.

## SUMMARY OF BEST EVIDENCE

**Table 2:** Description and appraisal of the *Effect of Osteopathic Manipulative Therapy in the Attentive Performance of Children With Attention-Deficit/Hyperactivity Disorder* by Accorsi et al. (2014).

### Aim/Objective of the Study/Systematic Review:

**Study Design:** This randomized control trial involved two conditions: 1. Manual Osteopathic Therapy (OMTh) and 2. Control Group (conventional care). Participants were recruited from the Center for Pediatric Neuropsychiatry between November 2008 and September 2009. A neuropsychiatrist (M.P.) confirmed the ADHD diagnosis, and a psychologist examined each participant at enrolment. The baseline was determined at week 0, and OMTh was administered once a week for the first 2 weeks, then once bi-weekly for 4 weeks, totalling a 10-week trial.

Participants underwent the Biancardi-Stroppa Modified Bell Cancellation Test at enrolment and the trial's conclusion. Both the neuropsychiatrist and psychologist were blinded to participant allocation. Participants and parents were not blinded to group placement but were not informed about the study's outcomes.

**Setting:** The study took place at the Macerta Public Hospital in Italy through the Center for Pediatric Neuropsychiatry.

**Participants:** Out of the initial 40 recruits, 28 participants (N=28) met the inclusion criteria. Inclusion criteria consisted of male and female children aged 5-15 with a primary diagnosis of ADHD. Exclusion criteria included a secondary diagnosis of ADHD, mental retardation, anxiety disorder, pervasive development disorder, diphasic disorder, childhood

schizophrenia, manic episode, underdevelopment of a special learning skill, overactive symptoms caused by organic disorders, or adverse drug reactions. Informed consent from a parent or legal guardian was required for participation. The trial and control groups had similar mean ages at baseline and study conclusion, as well as gender distribution.

**Intervention/Phenomenon Investigated:** Participants were randomly assigned to either an intervention group (OMTh + conventional care) or a control group (conventional care). Randomization used the R statistical program (v.2.12.0, R Foundation for Statistical Computing). The OMTh + conventional care group were assigned one of four osteopaths who received standardized education and pre-research training (8 hours). They had six 40-minute sessions over 10 weeks, initially weekly for 2 weeks, then bi-weekly for 4 weeks. Sessions were on the same day each week to minimize bias. The sequence of techniques was left to the discretion of the practitioner.

The conventional care group continued psychostimulant drug therapy and psychosocial intervention (CBT). Participants had weekly group and individual sessions to enhance self-control strategies, conducted separately from OMTh sessions and led by the same psychologist.

**Outcome Measures/Qualitative Methods:** The Biancardi-Stroppa Modified Bell Cancellation Test was administered both initially and after the last Osteopathic Manual Therapy (OMTh) session to both control and experimental groups, assessing visual-spatial attention abilities. Participants located and marked bells in a specified time frame on four sheets, with accuracy and rapidity scores measured. Continuous data were analysed using mean, median, and standard deviation, while categorical data used frequency and percentage. Shapiro-Wilk test assessed normality, and univariate tests examined group discrepancies at baseline and at the end of the study.

Multivariate linear regression, considering age, gender, medication usage, psychosocial interventions, OMTh treatment, and counterpart Biancardi-Stroppa Test score, analysed variations in accuracy and rapidity scores. The study also reported a reduction in cranial findings for the OMTh group after the 10-week trial, though specific tests were not detailed.

**Main Findings:** The researchers employed chi-square tests, t-tests, and one-way analyses of variance for baseline characteristics, supported by a table of mean differences across conditions. Point estimates and confidence intervals were used in a multivariate linear regression, but potential bias in the testing was not identified.

Although the psychologist (F.F.) conducted baseline testing, it remains unclear whether the same psychologist performed the end-trial testing, raising questions about result consistency.

Table 1

Baseline and Outcome Measures of Children with AD/HD (N=28), Control vs OMTh

	B	SG	P value
Psychosocial Intervention			.05
Bell Cancellation test			
Rapidity	44.1	42.9	.81
Accuracy	104.1	112.7	.24

Researchers noted no change for any characteristic between the control group and the OMTh group except for psychosocial interventions.

Table 2

Multivariate Linear Regression for Biancardi-Stroppa Modified Bell Cancellation Test - Accuracy

	B	95% CI	P value
Drug Therapy	-0.861	-5.794 to 0.538	.72
Psychosocial Intervention	-0.090	-5.860 to 5.680	.97
OMTh	7.948	0.181 to 15.714	.04
BSMBCT	0.387	0.006 to 0.769	.04

Statistical significance in improving accuracy ( $p < .05$ )

Table 3

Multivariate Linear Regression for Biancardi-Stroppa Modified Bell Cancellation Test - Rapidity

	B	95% CI	P value
Drug Therapy	-0.176	-5.516 to 5.163	.95
Psychosocial Intervention	-0.992	-7.202 to 5.218	.74
OMTh	9.090	0.821 to 17.358	.03
BSMBCT	0.452	0.007 to 0.896	.05

Statistical significance in improving rapidity ( $p < .05$ )

Table 4

Cranial area with SD	Baseline (+)	End Point (+)
Sphenobasilar synchondrosis	7	2



Occipitomastoid suture	1	1
Lambdoid suture	0	1
Sphenoparietal suture	1	1
Frontal suture	2	0
Intersquamous occiput	1	0
Left occipital condyle	3	0
Right occipital condyle	2	0

Data from the study shows that OMTh could improve selective and sustained attention in children with ADHD. It also shows the efficacy of craniosacral treatment and correcting somatic dysfunction.

**Original Authors' Conclusions** The authors identified that the OMTh worked as an adjunct to conventional treatment in improving attention in children with ADHD. They noted that "it is possible to speculate that OMTh might have positive effects on short- and long-term attention (p.379)" They also indicated that OMTh could have more than immediate positive effects, but further testing was required. The authors highlighted the significance of their findings, especially given that fewer participants in the intervention group underwent psychosocial intervention compared to the control group. This suggests that the intervention group may have started in less favourable conditions at baseline. Importantly, drug therapy did not show any association with changes in Biancardi-Stropps Test scores (p.379).

**Critical Appraisal: Critical Appraisal:** Based on Guidelines for Critical Review Form – Quantitative Studies by Law et al. (1998)

**Validity** The PedPro score for this RCT is 10/11. The study lost points for no blinding of subjects.

**Study Purpose:** The purpose was clearly identified, and justification was provided by a lack of research in this field of study.

**Literature:** The researchers reviewed relevant background literature on ADHD and OMTh however most papers reviewed were 9 years old. Only one recent paper in 2014 was included.

**Study Design:** A RCT was used to compare a control group receiving standard treatment and the therapeutic group. Assessment was standardised with a modified online test.

**Sample:** The researchers identified that the sample size was too small which was due to a lack of ADHD studies and were unable to estimate an appropriate size. Key and demographical characteristics were equally distributed at baseline and patients were randomized using an R statistical program. They were not blind to the study but were blind to the results. Researchers obtained both patient and parent consent and received ethical approval from institutional review boards.

**Outcomes:** Outcome measures, averaged across multiple tests, were presented in tables without indications of recall bias. Assessors were blinded to groups, enhancing study integrity. Pre and post-treatment measurements were conducted, but long-term effects were not assessed. The reliable outcome measures were administered by four therapists, and testing was standardized with a blind assessor. Results seem valid as they were compared against a control group receiving standardized treatment.

**Intervention:** The intervention involved OMTh and nontherapy groups, specifying session frequency and duration, but lacked sufficient detail for study replication. While therapists received standardized education, the discretion in treatment execution was not detailed for individual participants. Treatment specifics for trial participants were not provided, but therapists remained consistent throughout the study. The treatment frequency was appropriately spaced for recovery and response to OMTh therapy. Bias control was effective, with researchers and assessors blinded to allocation, while only participants were aware of their group placement, rendering therapist knowledge inconsequential.

**Interpretation of Results:** The researchers presented participant results with a 100% retention rate, without indicating compliance issues. Statistical significance was appropriately reported, and the analysis method aligned with the measured outcomes. Standardized testing and assessor blinding enhanced result validity. While the OMTh group showed statistically significant improvement in selective and sustained attention in children with ADHD ( $P < .05$ ), the sample size was too small for clinical significance. Lack of control for additional psychosocial drug treatments and inconsistent OMTh treatment plans diminishes overall result reliability. Nevertheless, the study suggests transferability due to favourable OMTh outcomes for children with ADHD, irrespective of concurrent drug therapies.

**Drop-outs:** There was no participant drop-out identified. All 28 participants completed the study.

**Summary/Conclusion:** Although the study showed statistical significance in OMTh as a possible treatment to improve selective and sustained attention in children with ADHD, it is not clinically significant. The study failed to remove significant bias in the testing and controlling the trial group for outside confounding factors. The therapy was not standardized, and the participants could have been receiving additional pharmacological assistance. The researchers were limited to very little resources with respect to their topic of interest and noted that this should be a stepping stone for further research.

### **IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH:**

Accorsi et al. (2014) identified OMTh as a potential treatment for ADHD symptoms in children but couldn't demonstrate results transferable or replicable in other clinical settings. Further research with larger sample sizes, controlled conditions, and standardized treatment protocols is crucial. An ideal randomized controlled trial would exclude pharmacological involvement to assess the true efficacy of OMTh.

While OMTh is widely used for neurological and cognitive disorders, research and validity are limited. It's uncommon in Canada, limited in the USA, and more accepted in Europe. Additional research is needed to support treating neurodevelopmental disorders, enabling OMTh practitioners to offer valuable resources. Increased education in this field could uncover unexplored methodologies and initiate new areas of study.

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