Safety and Feasibility of Osteopathic Manipulative Treatment (OMT) in Addressing Plagiocephaly

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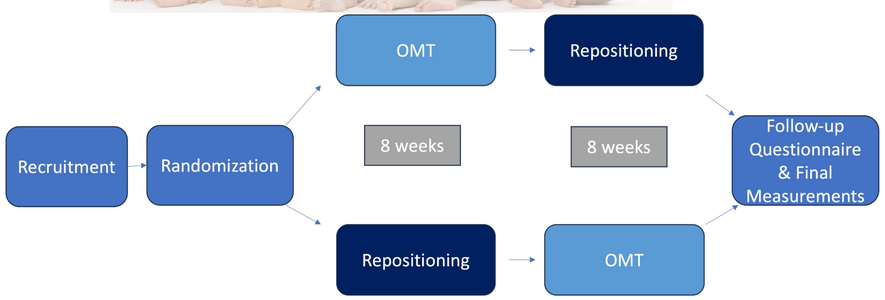
Background

- Positional plagiocephaly (PP) = asymmetrical flattening of the cranium due to sustained pressure
- The unique cranial anatomy of an infant leaves them vulnerable to PP and creates asymmetric flattening, usually of the occiput which leads to compensatory shifts of other cranial structures (1)
- There is a variable incidence but plagiocephaly in infants between 7 to 12 weeks of age may be as high as 46.6% (2-4)
- Since the initiation of the AAP's "Back to Sleep" campaign the incidence of plagiocephaly has risen 600% (5-6)
- Safety = no report of significant adverse events attributed to OMT
- Feasibility = assess the degree to which a patient and their family could easily complete the entire treatment protocol
- OMT & other similar manual therapies share low-risk profiles, primarily causing mild fussiness or irritability
- **Objective: Examine how safe & feasible OMT is for PP treatment in infants enrolled between 0-4 months old**

Methods

- Safety & feasibility assessed through a feedback survey, focus groups, and concurrent symptoms/significant adverse events tracked through a weekly survey & monitored monthly by an internal data and safety committee
- 107 participants recruited; 63 met eligibility criteria and enrolled. Of those, 21 completed study, 24 completed 16-week intervention, 10 are active, and 8 withdrew
  - **29** parents completed feedback survey on experience with OMT
  - **7** parents participated in focus group to share feedback on the treatment received and what they learned about OMT
  - **52** parents have provided feedback on concurrent symptoms





Results

- Safety was considered evaluable if the weekly survey was completed and a family had a least one visit in which safety was assessed. Concurrent symptoms were selected for 53 visits out of 373 (14%)
- 29 families out of 52 (56%) had a least one visit in which a concurrent symptom was identified. The majority (66%) only identified a concurrent symptom for one of their visits. All concurrent symptoms were resolved, typically within a few hours (43%) and not bothersome to family (94%)
- No significant adverse events have occurred, showing OMT is safe and well-tolerated by infants. The most frequent concurrent symptoms were fussiness/irritability (51%), followed by "other" (18%), did not sleep well (16%), and discomfort/pain (7%) & "unsure" (7%)
- Among 45 participants who have completed the 16-week intervention, there is 100% compliance (10 visits/participant: 8 OMT & 2 measurement)
- Preliminary results suggest that OMT has a favorable safety profile and is a feasible option for families in management of PP

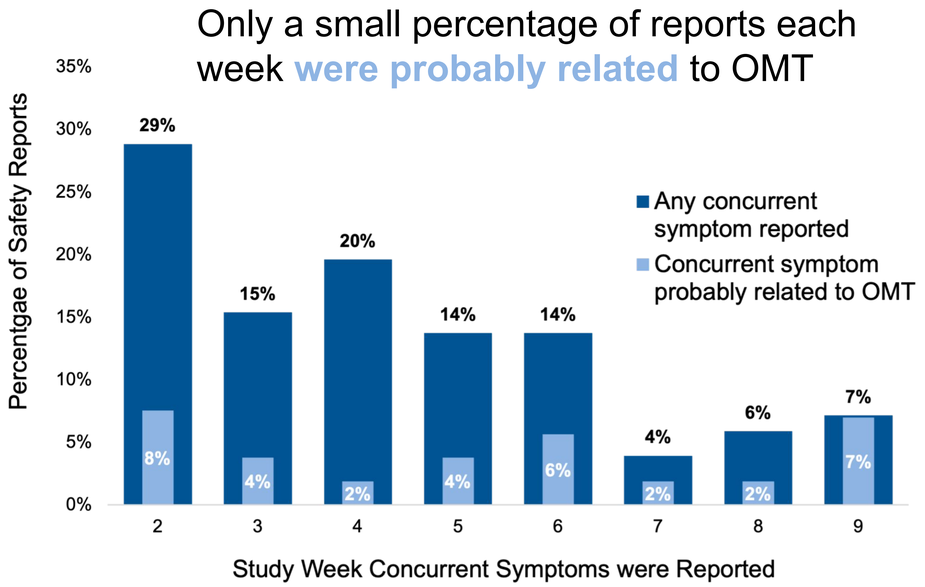


Figure 1: Reports of concurrent symptoms and those probably related to OMT by study week



Figure 3: Words describing OMT as shared by parents

Concurrent Symptoms	Percentage
Resolution of concurrent symptoms	
Yes	100%
No	--
Relationship of concurrent symptoms to OMT	
Definitely related	--
Probable	28%
Possible	43%
Unlikely	15%
Not related	13%
Timeline of resolution	
Within a few hours	43%
Within 1 day	25%
1+ days	17%
Unknown	15%
Bothersome to family	
No	94%
Yes	4%

Figure 2: Outcomes of observed concurrent symptoms versus explanation

> **"Safe. I feel like that was my biggest concern. I am not a huge fan of chiropractors. I wasn't sure how closely related the manipulation would be to that. I felt comfortable while doing OMM. I forgot she was even really treating my son. She just made me feel comfortable too. It was effective and I could see improvements relatively quick. It was not as scary as I thought it might be."**

Conclusion

OMT is a favorable, non-invasive treatment for infants with PP, and there have been no significant adverse events in this study. Concurrent symptoms that were reported were mild, not bothersome to the family, and resolved quickly. Parental feedback revealed that OMT was "gentle, effective, and awesome."

References