National Council for
Osteopathic Research

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Effectiveness of manual therapy for unsettled, distressed and excessively crying infants: a systematic review.
Parents caring for healthy but unsettled, distressed and excessively crying infants often seek help and support during the first 12 weeks of their infant’s life from manual therapists.
Background:

- Prevalence ~20%
- 6 weeks peak in crying time.
- Peak abusive harm to infants
- Association between maternal depression and unsettled infant behaviour
Background:

- Aetiology unknown
- Manual therapy based on premise that musculoskeletal strains and or limitations can cause distress

- Controversial as condition is self-limiting
- Controversy over effectiveness and safety
Background:

- Cochrane review (Dobson et al 2012)

- RCTs: Found small statistically non significant outcomes

- We wanted to update this study and look at a greater variety of research
Aim:

To assess the effect of manual therapy interventions on parent- and patient-centred outcomes to provide information to help inform decisions about care.
Method:

- Systematic review of literature
- Last 26 years
- 9 databases
  (Medline, EMBASE, Web of Science, PEDro, OSTMED.DR, Cochrane, Index of Chiropractic Literature, Open Access Theses and Dissertations (OATD) and CINAHL)
Method:

• Inclusion criteria:
  – Infants 0-12 months
  – Unsettled, distressed or excessively crying, but otherwise healthy
  – Treated in primary care
  – Original research
Method:

• Exclusion criteria:
  - Conditions requiring specialist care such as: Respiratory disorders, developmental disorders, cystic fibrosis, otitis media, neuralgia, congenital torticolis or MSK trauma.
  - Plagiocephaly and brachiocephaly
  - Mixed therapies
Method:

• Intervention:

  – Manual therapy - hands on delivered with therapeutic intent

  – Manual therapist - a trained and regulated health care professional / therapist
Method:

• Outcomes:
  – Crying
  – Sleep
  – Displays of distress, discomfort
  – Difficulties feeding
  – Parental confidence, satisfaction, experience
  – Adverse events
Method:

- Selection by two reviewers independently
- Data extraction by two reviewers independently
- Quality appraised
- Meta analysis where possible
Method:

Grade of evidence (all studies by outcome)

- High, moderate, low
- Favourable, unfavourable, inconclusive
Results:
Studies screened against title and abstract. 8844 references

206 references assessed for full-text eligibility

187/206 references excluded
- 42 - wrong patient population
- 29 - review articles
- 19 – Secondary care hospital setting
- 16 - wrong intervention
- 14 - wrong setting
- 12 - duplicate reference
- 11 - wrong outcomes
- 10 - wrong study design
- 9 - discussion article
- 7 - letter
- 4 - conference presentation
- 4 - editorial piece
- 4 - no outcome data or information
- 3 - protocol
- 1 - commentary
- 1 - update of review available
- 1 – translation difficulties

19 included references:
- 7 RCTs, 7 case series, 3 cohorts, 1 service evaluation, 1 qualitative.

11,423 references retrieved from searches and peer networks

2,588 duplicate references

8638 references excluded (mainly wrong population and hospital setting)
Results:

19 studies:
• 7 RCTs
• 7 case series
• 3 cohort studies
• 1 service evaluation
• 1 qualitative study
Results:

- 9 studies UK
- 3 USA
- 3 Australia
- 2 Denmark
- 1 Canada
- 1 Norway

- 15 chiropractic, 3 osteopathic, 1 massage
Results:

- Conditions using diagnosis of unsettled, distressed and excessively crying infants:
  - 11 ‘Colic’
  - 2 Gastroesophageal ‘reflux’
  - 5 Breastfeeding difficulty
  - 1 Infant ‘headache’
Results:

• Quality:

  – RCTs 7:
    • 4 High quality
    • 2 Moderate quality
    • 1 Low quality

  – Qualitative study 1: High quality

  – Remainder: 11 Moderate to Low quality
Results: Effectiveness - crying

- **Outcome: Crying time** - 4 studies suitable for meta-analysis

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hayden 2006</td>
<td>-1.5 1.1973</td>
<td>0.5 1.0046</td>
<td>-2.00 [-2.85, -1.15]</td>
</tr>
<tr>
<td>Wiberg 1999</td>
<td>-2.7 1.5</td>
<td>-1 1.55</td>
<td>-1.70 [-2.66, -0.74]</td>
</tr>
<tr>
<td>Miller 2012a</td>
<td>-2.4 2.5</td>
<td>-1 1.6</td>
<td>-1.40 [-2.52, -0.28]</td>
</tr>
<tr>
<td>Olafsdottir 2001</td>
<td>-2 2.6</td>
<td>-2.3 2.7</td>
<td>0.30 [-0.94, 1.54]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>14 110</td>
<td>12 81</td>
<td><strong>-1.27 [-2.19, -0.36]</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: $\text{ Tau}^2 = 0.59$; $\text{ Chi}^2 = 9.53$, df = 3 ($P = 0.02$); $I^2 = 69$

Test for overall effect: $Z = 2.72$ ($P = 0.006$)
Results: Effectiveness - sleeping

Moderate strength evidence: inconclusive

Not possible to meta-analyse
4 studies of varying quality reporting mixed outcomes

2 studies: Hours of sleep
2 studies: Parent report on an impression scale
Results: Effectiveness – parent child relations

Moderate strength evidence: inconclusive

Not possible to meta-analyse

3 studies of varying quality

Outcomes studied: social cues, contact time and impression scale
Results: Effectiveness – global improvement

Moderate strength evidence: no effect

Not possible to meta-analyse
5 studies of varying quality
Outcomes reported: impression scales for ‘overall improvement of symptoms’ (2 studies) and ‘complete resolution’ (1 study, practitioner reported improvement (2 studies)
Results: Effectiveness

Low strength evidence:

- Improvement in feeding: (6 studies)
- Resolution of gastric symptoms: (1 study)
- Maternal satisfaction: (1 study)
- Nipple pain: (1 study)
- Temper tantrum frequency: (1 study)
- Improvement in headache associated behaviours: (1 study)
### Results: Adverse events

Comparison - exposed to manual therapy vs other

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Manual therapy</th>
<th>Control</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wiberg 1999</td>
<td>0 Events</td>
<td>25 Total</td>
<td>36.3%</td>
<td>0.07 [0.00, 1.11]</td>
</tr>
<tr>
<td>Miller 2012a</td>
<td>0 Events</td>
<td>30 Total</td>
<td>28.8%</td>
<td>0.25 [0.01, 5.80]</td>
</tr>
<tr>
<td>Herzhaft-Le Roy 2017</td>
<td>0 Events</td>
<td>47 Total</td>
<td>34.9%</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Hayden 2006</td>
<td>0 Events</td>
<td>14 Total</td>
<td>34.9%</td>
<td>0.12 [0.01, 2.18]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>116 Events</strong></td>
<td><strong>97 Total</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>0.12 [0.02, 0.66]</strong></td>
</tr>
</tbody>
</table>

Total events: 0 Events, 11 Total

Heterogeneity: $\text{Tau}^2 = 0.00$; $\text{Chi}^2 = 0.39$, df = 2 ($P = 0.82$); $I^2 = 0$

Test for overall effect: $Z = 2.45$ ($P = 0.01$)
Results: Adverse events

- 1308 infants exposed to manual therapy
- 9 non-serious adverse events
- 7 non serious events per 1000 infants exposed
Conclusions:

Positive effect for crying time: Is it patient and clinically important?

Cost and cost effectiveness not evaluated

Findings could change with more research

Relatively safe
Crowd funded

With thanks to all those who donated and made this work possible

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