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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.





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





- 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







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.







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)







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







- 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







Intervention:

Manual therapy - hands on delivered with therapeutic intent

 Manual therapist - a trained and regulated health care professional / therapist







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







- Selection by two reviewers independently
- Data extraction by two reviewers independently
- Quality appraised

Meta analysis where possible





Grade of evidence (all studies by outcome)

- High, moderate, low
- Favourable, unfavourable, inconclusive



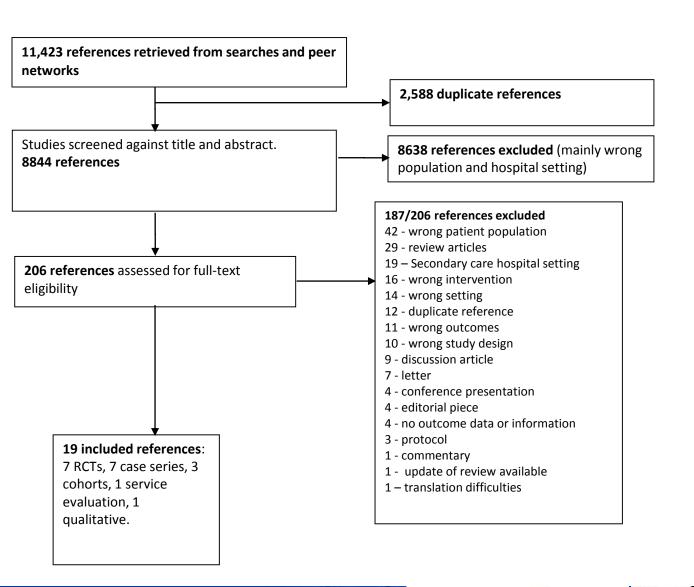


















#### 19 studies:

- 7 RCTs
- 7 case series
- 3 cohort studies
- 1 service evaluation
- 1 qualitative study







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

15 chiropractic, 3 osteopathic, 1 massage







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







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

	Experimental			Control				Mean Difference	Mean Difference				
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Random, 95% CI			
Hayden 2006	-1.5	1.1973	14	0.5	1.0046	12	28.0%	-2.00 [-2.85, -1.15]		-			
Wiberg 1999	-2.7	1.5	25	-1	1.55	16	26.2%	-1.70 [-2.66, -0.74]		_	-		
Miller 2012a	-2.4	2.5	30	-1	1.6	22	23.8%	-1.40 [-2.52, -0.28]			_		
Olafsdottir 2001	-2	2.6	41	-2.3	2.7	31	22.0%	0.30 [-0.94, 1.54]		-	<del> </del>		
Total (95% CI)			110			81	100.0%	-1.27 [-2.19, -0.36]			<b>&gt;</b>		
Heterogeneity: $Tau^2 = 0.59$ ; $Chi^2 = 9.53$ , $df = 3$ (P = 0.02); $I^2 = 69\%$										<del>                                     </del>	<del>                                     </del>	<del>                                     </del>	
Test for overall effect: $Z = 2.72$ (P = 0.006)									-4 -2 0 2 4 Favours [experimental] Favours [control]				







# 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 study9, 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

	Manual therapy		Control			Risk Ratio	Risk Ratio					
Study or Subgroup	Events	Events	Total	Weight	M-H, Random, 95% C	I M-H, Random, 95% CI						
Wiberg 1999	0	25	7	25	36.3%	0.07 [0.00, 1.11]	<del></del>					
Miller 2012a	0	30	1	22	28.8%	0.25 [0.01, 5.80]				_		
Herzhaft-Le Roy 2017	0	47	0	38		Not estimable						
Hayden 2006	0	14	3	12	34.9%	0.12 [0.01, 2.18]	<b>—</b>	•				
Total (95% CI)		116		97	100.0%	0.12 [0.02, 0.66]	•		-			
Total events	0		11									
Heterogeneity: Tau <sup>2</sup> = 0.	0.01	0.1	1	10	100							
Test for overall effect: Z = 2.45 (P = 0.01)								0.1 ours [experime	ntal] Favou	10 rs [control]	100	







#### **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









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