

The evidence on homeopathy for children with diarrhoea is presented in Chapter 4.5.2 of the Overview Report (p.36-42). This includes:

- Table summarising all systematic reviews (SRs) which include trials on diarrhoea in children
- A brief description of the SRs and the trials within them
- Reviewer comments
- **Evidence statement** – this is NHMRC’s overall findings, including a ‘level of confidence’ in the evidence (see FAQ#7) and a final conclusion as to whether there is evidence for the effectiveness of homeopathy this condition
- Table providing full details of the evidence provided by the SRs.

HRI analysis of NHMRC’s handling of this evidence

Four trials have been carried out to assess the effectiveness of homeopathy for the treatment of diarrhoea in children. The trials tested two different homeopathic approaches:

a) Individualised homeopathic treatment for children with diarrhoea

Three trials have been carried out to assess the effectiveness of **individualised homeopathic treatment (IHT)** for the treatment of diarrhoea in children (see Figure). This approach, involving a consultation and personalised prescription by a qualified homeopathic practitioner, is considered by most experts in the field to be the highest quality homeopathic treatment available.

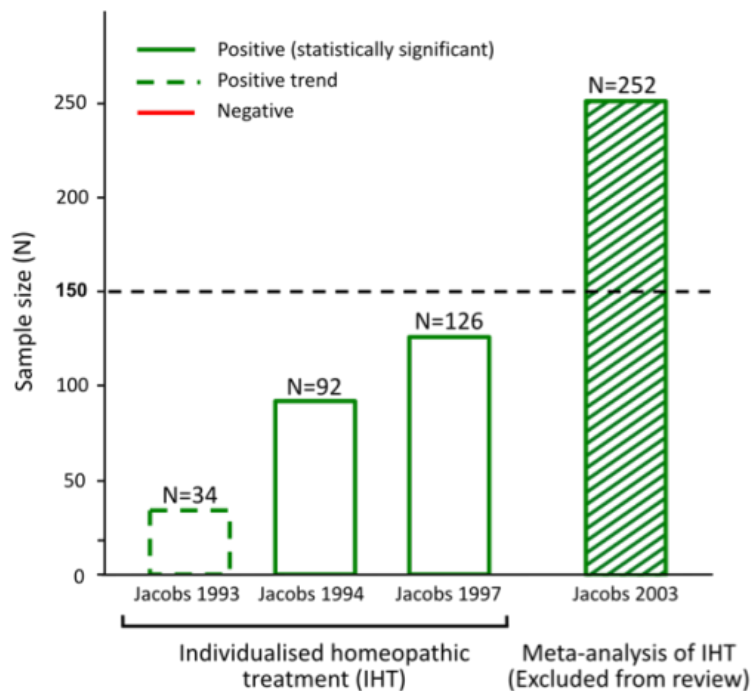


Figure: Evidence base for individualised homeopathic treatment of children with diarrhoea

The initial 'pilot study' (Jacobs 1993, N=34)¹ showed a 'positive trend' i.e. the group receiving homeopathy improved more than the placebo group, but the number of participants was too small to determine whether this was a true clinical effect or due simply to chance.

The two following studies (Jacobs 1994, N=92² and Jacobs 1997, N=126^{3,4}) found that the positive effect of homeopathy was 'statistically significant' i.e. a real clinical effect beyond placebo and not due to chance.

Jacobs then pooled the results of these three trials together and performed a 'meta-analysis' (Jacobs 2003)⁵. This process enables one to draw stronger conclusions from the body of evidence as a whole and is commonly done when multiple trials exist that are sufficiently similar. The meta-analysis (total **N=252**) concluded that **individualised homeopathy is more effective than placebo**, reducing the duration of diarrhoea in children by two thirds of a day. A 'p-value' less than or equal to 0.05 ($p \leq 0.05$) is generally considered to indicate that a result is not due to chance; the p-value for this result was **p=0.008**.

NHMRC's evidence statement, summarising this evidence base, is as follows: *"The studies of individualised homeopathy are of insufficient quality and/or size to warrant further consideration of their findings. LOC: Low – moderate. Based on the body of evidence evaluated in this review [...] there is no reliable evidence that individualised homeopathy is more effective than placebo for the treatment of children with diarrhoea"* (OR, p.38).

This demonstrates how three perfectly acceptable positive trials were inappropriately dismissed due to NHMRC's N>150 filter, despite two of them meeting NHMRC's unusual criteria for 'good quality'. Furthermore, **by excluding the results of the Jacobs 2003 meta-analysis** from the Review (a robust positive study with 252 participants), **NHMRC failed to include all relevant evidence on IHT for treating children with diarrhoea**.

There seems to have been some confusion about what to do with the Jacobs 2003 meta-analysis study – whether it should be included in the Homeopathy Review or not, and if not, what reason should be given for excluding it. Interestingly **Optum identified Jacobs 2003 as being suitable for inclusion in the Review**, listing it as one of the 176 included studies identified from SRs that were considered to be 'in scope' for the Review (*List of considered evidence*, item #73, p.5).

Yet, when external parties later submitted the study to NHMRC it was excluded on the following basis: *'Unable to assign a level of evidence – non-systematic review. Wrong research type or publication type'* (*Review of submitted literature*, p.35; our emphasis).

So, although Optum said the study should be included, NHMRC seem to have excluded it for not being a 'systematic' review, despite the fact that it is not actually a review – it is a meta-analysis.

As NHMRC decided to exclude all meta-analyses from the Homeopathy Review, according to their own 'rules', it is likely that Jacobs 2003 was in fact excluded for that reason, not the reason stated.

We contend that NHMRC further misled the public when explaining why meta-analysis studies were excluded from their Review i.e.:

"In theory, the results of meta-analyses may have also been discussed in this part of the evidence statement. However, it was considered that all of the meta-analyses for specific conditions (i.e. those that had the potential to be included in evidence statements) had included studies that were of poor methodological quality/had a high risk of bias. A decision was made to state the findings of studies that were of good methodological quality and sufficient size in favour of meta-analyses that included poor quality studies" (Information Paper, p.36; our emphasis).

This statement inaccurately implies that the Jacobs 2003 meta-analysis contained poor quality studies. It did not. The three individual trials covered by the meta-analysis met NHMRC's criteria for medium and good quality. We contend that this is deliberately misleading to the public and evidence of inaccurate, biased reporting.

Including Jacobs' 2003 meta-analysis would have meant that a study meeting NHMRC's definition of 'reliable' with 252 participants showed homeopathy to be more effective than placebo; excluding it meant that all three positive studies had less than 150 participants and therefore NHMRC could say, according to their own definition, that there was 'no reliable evidence'. It is our contention that this is biased reporting.

NHMRC state in the Information Paper that for a treatment to be 'considered effective' it must meet several criteria, one of which is that, '*the health improvement occurs consistently in several studies*' (Information Paper, p.10). Jacobs has met this criterion across her three trials and confirmed the validity of her results by conducting the meta-analysis.

The only remaining limitation of this evidence base would be that the same research team carried out all the studies, so the final step is for other independent research teams to attempt to replicate Jacobs' findings.

Diarrhoea in children remains a life-threatening condition amongst certain populations; with this in mind, one might expect NHMRC to understand the importance of accurately presenting data suggesting that there is an effective treatment option for children with this condition.

b) Non-individualised homeopathic treatment for children with diarrhoea

Non-individualised homeopathy a.k.a. 'clinical homeopathy' usually involves the same homeopathic product being given to all patients, without a consultation. This technique can involve either the use of a single homeopathic medicine or a 'complex' homeopathic medicine (containing a specific combination of several remedies).

One trial identified by NHMRC tested a 'complex' homeopathic medicine containing *Arsenicum*, *Calcarea carbonica*, *Chamomilla*, *Podophyllum* and *Sulphur* in 30c potencies⁶. This trial was designed to find out whether children with diarrhoea could be treated easily on a large scale without the need for qualified homeopaths to deliver individualised prescriptions. This study, described by NHMRC as 'medium-sized' (N=292) and 'good quality' did not detect a difference between the complex homeopathic medicine and placebo.

Optum – the external contractor who conducted the evaluation of the evidence – originally suggested that the evidence statement should be: "*There is no evidence that homeopathic combination therapy is effective for the treatment of children with diarrhoea, compared with homeopathy*"; the NHMRC Homeopathy Working Committee (HWC) redrafted this statement to read, "*combined homeopathy is not more effective than placebo for the treatment of children with diarrhoea*". This is a surprisingly definitive statement based on a single trial of one preparation and we contend that HWC's alteration of Optum's recommended evidence statement is evidence of reporting bias.

References

1. Jacobs, J., Jiminez, L. M., *et al.* (1993) Homœopathic treatment of acute childhood diarrhoea: A randomized clinical trial in Nicaragua. *Br. Homeopath. J.* **82**(2): 83–86

2. Jacobs, J., Jiménez, L. M., *et al.* (1994) Treatment of acute childhood diarrhea with homeopathic medicine: a randomized clinical trial in Nicaragua. *Pediatrics* **93**(5): 719–725
3. Jacobs, J., Malthouse, S., *et al.* (1997) Childhood diarrhea: Results from Nepal and combined analysis. *Proc. 52nd Congr. LMHL Seattle WA*
4. Jacobs, J., Jiménez, L. M., *et al.* (2000) Homeopathic treatment of acute childhood diarrhea: results from a clinical trial in Nepal. *J. Altern. Complement. Med. N. Y. N* **6**(2): 131–139
5. Jacobs, J., Jonas, W. B., *et al.* (2003) Homeopathy for childhood diarrhea: combined results and metaanalysis from three randomized, controlled clinical trials. *Pediatr. Infect. Dis. J.* **22**(3): 229–234
6. Jacobs, J., Guthrie, B. L., *et al.* (2006) Homeopathic combination remedy in the treatment of acute childhood diarrhea in Honduras. *J. Altern. Complement. Med. N. Y. N* **12**(8): 723–732