

Probiotics do not help infants with colic, trial finds

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Credit: CDC.gov

Giving probiotics to infants with colic does not appear to have any benefit, according to a large trial published today.

These findings differ from previous smaller trials and do not support a general recommendation for the use of probiotics to treat colic in infants.

Infant colic (excessive crying of unknown cause) affects up to 20% of infants and is a major burden to families and health services. Although it spontaneously resolves three to four months after birth, its cause remains elusive and no single effective treatment exists.

Previous small trials suggest that the probiotic *Lactobacillus reuteri* effectively treats colic in [breastfed infants](#). These studies, however, had

limitations as they examined only a highly selective group of infants with colic. The effects of *L reuteri* on formula fed infants with colic are unknown.

So researchers based in Australia and Canada set out to determine whether the probiotic *Lactobacillus reuteri* reduces crying or fussing in 167 breastfed and formula fed infants with colic aged less than three months old.

A total of 85 infants were randomised to receive the probiotic and 82 to receive placebo for one month. Outcomes included daily duration of crying or fussing at one month, sleep duration, mother's mental health, family and infant quality of life.

Levels of gut microbial diversity, faecal calprotectin (a marker of gut inflammation) and *E coli* colonisation were also examined.

The results show that the probiotic group fussed significantly more than the placebo group at all time points from day seven to one month. At one month, the probiotic group cried or fussed 49 minutes more than the placebo group. This increased fussing occurred only in formula fed infants. *L reuteri* did not affect crying or fussing time in exclusively breastfed infants.

L reuteri treatment did not lead to changes in infant faecal microbial diversity, *E coli* colonisation, or calprotectin levels.

The researchers point out that this is the largest randomised controlled trial of probiotic intervention in infants with colic to date. They conclude that *L reuteri* treatment "did not reduce crying or fussing in infants with colic, nor was it effective in improving infant sleep, maternal mental health, family or infant functioning, or quality of life" and say "probiotics therefore cannot be routinely recommended for all infants

with colic."

Further research is needed to identify which subgroups of infants with colic may benefit from probiotics, they add.

This represents the most definitive and well designed study to date on this controversial topic, writes William E Bennett Jr, Assistant Professor of Paediatrics at Indiana University School of Medicine, in an accompanying editorial.

With such a dearth of good evidence, should we be treating [infant colic](#) at all, he asks? He points out that children with colic "incur no serious long term effects" from the disorder and symptoms "abate with time," whereas the potential harm associated with diagnostic testing and treatment of [infants](#) "is likely to surpass the harm from [colic](#) itself."

As the old adage goes "babies cry," he concludes. Parents and their babies "may be better served if we devote more resources to studying the interventions recommended long before the discovery of [probiotics](#): reassurance, family social support, and the tincture of time."

More information: www.bmj.com/cgi/doi/10.1136/bmj.g2107
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