

Colic study



THE BACKGROUND: WHAT IS INFANTILE COLIC?

Over 3 hours

of unexplained cry and fuss per day



Over 3 days per week

Persists longer than 3 weeks

but resolves naturally by 3 to 5 months of age



Affects

20%

infants worldwide

Reduced quality of life of the whole family / household

THE STUDY:

Randomised, double blind, placebo controlled prospective parallel study



Placebo



Sample group given synbiotic

Synbiotic contained:

- 7 probiotic strains
- prebiotics



Infants aged

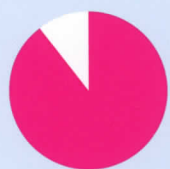
2 weeks

4 months

Diagnosed with colic

THE RESULTS:

In less than 7 days...



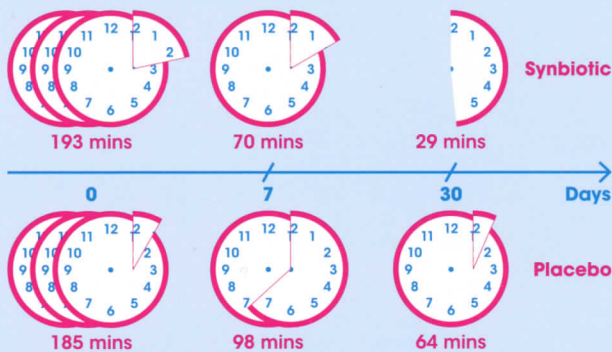
Crying time was reduced by at least half for

82.6% of infants in the probiotic group.



39% of infants in the probiotic group experienced a resolution of symptoms.

Cry & fuss time



No side effects reported by parents.

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Bio-Kult Infantis in the management of infantile colic:

A randomised controlled trial

Question:

Is a multi-strain synbiotic (used in Bio-Kult Infantis) more effective than placebo at reducing crying time in infants with infantile colic?

Methods:

50 breastfed infants aged 15 – 120 days diagnosed with infantile colic according to Wessel's criteria, but otherwise healthy, were randomly assigned to receive either the synbiotic sachet (7 bacteria strains + prebiotic; 1 billion CFU per day), or placebo, daily for 30 days. Parents were asked to record details of crying times in a symptoms diary. The primary outcome measure was the treatment success (reduction in the daily crying time >50%) and the secondary outcome measure was *symptom resolution* (reduction in the daily crying time >90%). No other medications were used.

Results:

Out of the initial 50 infants, 25 from synbiotic and 20 from placebo arm completed the study. At baseline, infants in both groups were crying approximate 190 minutes a day and had 4-5 colic episodes per day. Both groups had a similar proportion of vaginal and caesarean deliveries (respectively 40 and 60%), and 75% of the infants in both groups had familial history of allergy.

The treatment success at day 7 was significantly higher in the synbiotic group compared with placebo (82.6% vs 35.7%; $p < 0.005$), which remained significantly different at day 30 (87% vs 46%; $p < 0.01$). Symptom resolution was also higher in the synbiotic group compared with placebo at

day 7 (39% vs 7%; $p < 0.03$), and at day 30 (56% vs 36% $p = 0.24$).

At both day 7 and day 30, infants in the synbiotic group cried on average over 30 minutes less than infants in the placebo group. No adverse events were reported.

Conclusions:

The multi-strain synbiotic, used in Bio-Kult Infantis achieved a statistically significant reduction in cry and fuss time, evident within the first 7 days, without adverse effects.

Key findings:

1. 8 in 10 infants reduced their cry and fuss time by at least 50% within the first 7 days of synbiotic supplementation.
2. The synbiotic group cried an average 30 minutes less per day than infants in the placebo group.

Kianifar H, Ahanchian H, Grover Z, et al. Synbiotic in the management of infantile colic: a randomised controlled trial. *J Paediatr Child Health* 2014;**50**(10):801-5.

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