

# Research Study

## THE BACKGROUND: WHAT IS INFANTILE COLIC?

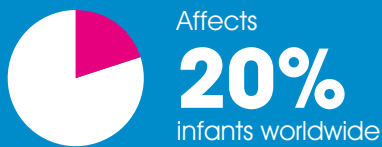
**Over 3 hours**

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



Reduced quality of life of the whole family / household

## THE STUDY:

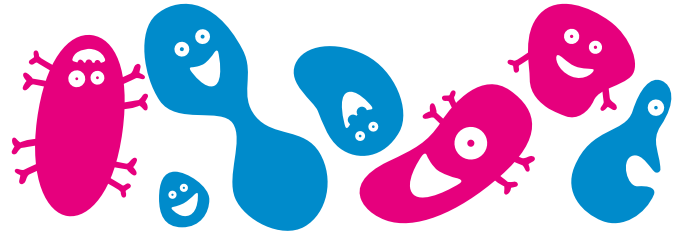
Randomised, double blind, placebo controlled prospective parallel study

PLACEBO GROUP

INTERVENTION GROUP GIVEN SYNBIOTIC

### Synbiotic contained:

- 7 probiotic strains
- prebiotics



Infants aged

**2 weeks**

**4 months**

Diagnosed with colic

## THE RESULTS:

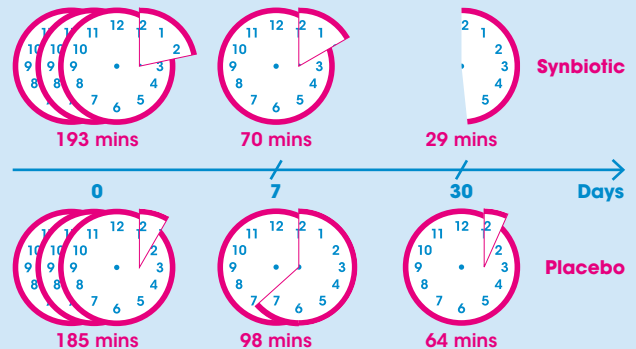
In less than 7 days...



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.

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.

Formulation used - *Lactobacillus casei* PXN® 37™, *Lactobacillus rhamnosus* PXN® 54™, *Streptococcus thermophilus* PXN® 66™, *Bifidobacterium breve* PXN® 25™, *Lactobacillus acidophilus* PXN® 35™, *Bifidobacterium infantis* PXN® 27™, *Lactobacillus bulgaricus* PXN® 39™, FOS (Fructooligosaccharide)

Formulation found in both Bio-Kult Infantis and Protexin Restore.

M0258-02

# A synbiotic in the management of infantile colic:

## A randomised controlled trial

### Question:

Is a multi-strain synbiotic 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, 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.

Formulation used - *Lactobacillus casei* PXN® 37™, *Lactobacillus rhamnosus* PXN® 54™, *Streptococcus thermophilus* PXN® 66™, *Bifidobacterium breve* PXN® 25™, *Lactobacillus acidophilus* PXN® 35™, *Bifidobacterium infantis* PXN® 27™, *Lactobacillus bulgaricus* PXN® 39™, FOS (Fructooligosaccharide)  
Formulation found in both Bio-Kult Infantis and Protexin Restore.