# Candy DCA, Van Ampting MTJ, Oude Nijhuis MM, et al. A synbiotic-containing amino acid-based formula improves gut microbiota in non-IgE-mediated allergic infants. Pediatr Res. 2018;83:677-86.

## The ASSIGN Trial

### Background:

Research has shown that infants and children with cow milk allergy have an imbalanced gut microbiota associated with their allergic condition. Prebiotics and probiotics (synbiotics) can modify gut microbiota and have potential in allergy management when combined with amino acid-based formula (AAF) for infants with cow milk allergy (CMA).

### Methods:

This multicenter, double-blind, randomized, controlled trial investigated the effects of an AAF containing a synbiotic blend on percentages of bifidobacteria and *Eubacterium rectale/Clostridium coccoides* group (ER/CC) in feces from infants with suspected non-IgE-mediated CMA. Feces from age-matched healthy, breastfed infants were used as reference (healthy breastfed reference (HBR)) for primary outcomes. The CMA subjects were randomized and received test or control formula for 8 weeks. Test formula was a hypoallergenic, nutritionally complete AAF containing a prebiotic blend of fructooligosaccharides and the probiotic strain *Bifidobacterium breve* M-16V. Control formula was AAF without synbiotics.

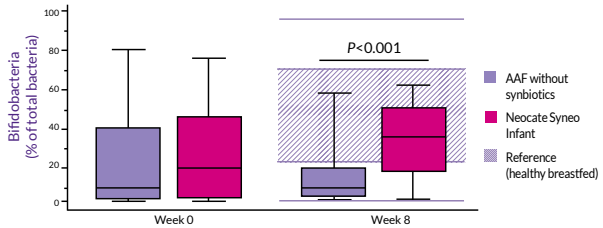
### Results:

A total of 35 (test) and 36 (control) subjects were randomized; HBR included 51 infants. At week 8, the median percentage of bifidobacteria was higher in the test group than in the control group (35.4% vs. 9.7%, respectively; $P<0.001$), whereas ER/CC was lower (9.5% vs. 24.2%, respectively; $P<0.001$). HBR levels of bifidobacteria and ER/CC were 55% and 6.5%, respectively.

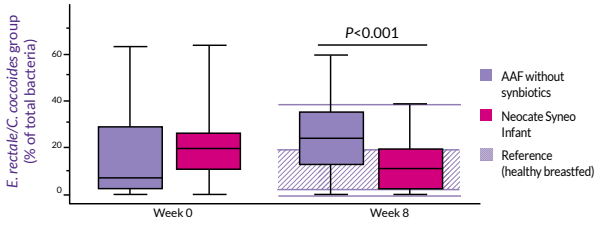
### Conclusion:

AAF containing specific synbiotics, which results in levels of bifidobacteria and ER/CC approximating levels in the HBR group, improves the fecal microbiota of infants with suspected non-IgE-mediated CMA.

Increased levels of infant-like bifidobacteria*




Decrease of adult-like *E. rectale/C. coccoides* group*




**Neocate® Syneo® Infant is an amino acid-based formula with prebiotics and probiotics (synbiotics) that has been clinically shown to help address the hidden, underlying gut dysbiosis in infants with CMA by bringing the gut microbiota closer to that of healthy, breastfed infants.**

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ASSIGN = Amino acid-based formula with Synbiotics – Study in Infants with Gastrointestinal Non-IgE-mediated cow's milk allergy

*The grey shaded area represents the sample 25th to 75th percentile of the reference group (healthy subjects) and the grey horizontal lines represent the minimum and maximum values of this reference group. The bottom and top edges of the box are located at the sample 25th and 75th percentiles. The center horizontal line is drawn at the 50th percentile (median). The whiskers of the box plots show the minimum and maximum values.

Nutricia North America supports the use of breast milk wherever possible. Neocate® Syneo® is a hypoallergenic, amino acid-based medical food for use under medical supervision. Neocate® Syneo® Infant is indicated for the dietary management of cow milk allergy, multiple food allergies and related GI and allergic conditions, including food protein-induced enterocolitis syndrome, eosinophilic esophagitis and gastroesophageal reflux.