

INSIGHTS FOR
HEALTHCARE
PROFESSIONALS

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Danone Nutricia
Campus



The burden of Cow's Milk Allergy (CMA) in early childhood



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Kate Grimshaw specializes in paediatric food and adult food allergy. The majority of her research work and clinical practice to date has been in pediatric food allergy.

Prevalence and symptoms

Food allergy is an increasing healthcare concern, especially in children.¹ One of the most common food allergies is CMA, affecting up to 5% of infants across Europe.²

Symptoms of CMA usually present within the first year of life, and can affect multiple organ systems [Figure 1].³

Classification of CMA

CMA can be classified according to the different immune responses it elicits, which can be IgE-mediated or

non-IgE-mediated.² IgE-mediated CMA accounts for ~44% of cases and triggers immediate onset of symptoms which can be more acute than non-IgE-mediated CMA and may lead to anaphylaxis in rare cases.²

Health and economic burden of CMA

A real-world retrospective cohort study investigated the clinical burden of CMA by reviewing anonymized case records of 3,499 children with CMA and comparing allergic symptoms and infections with 3,499 matched children without CMA.³

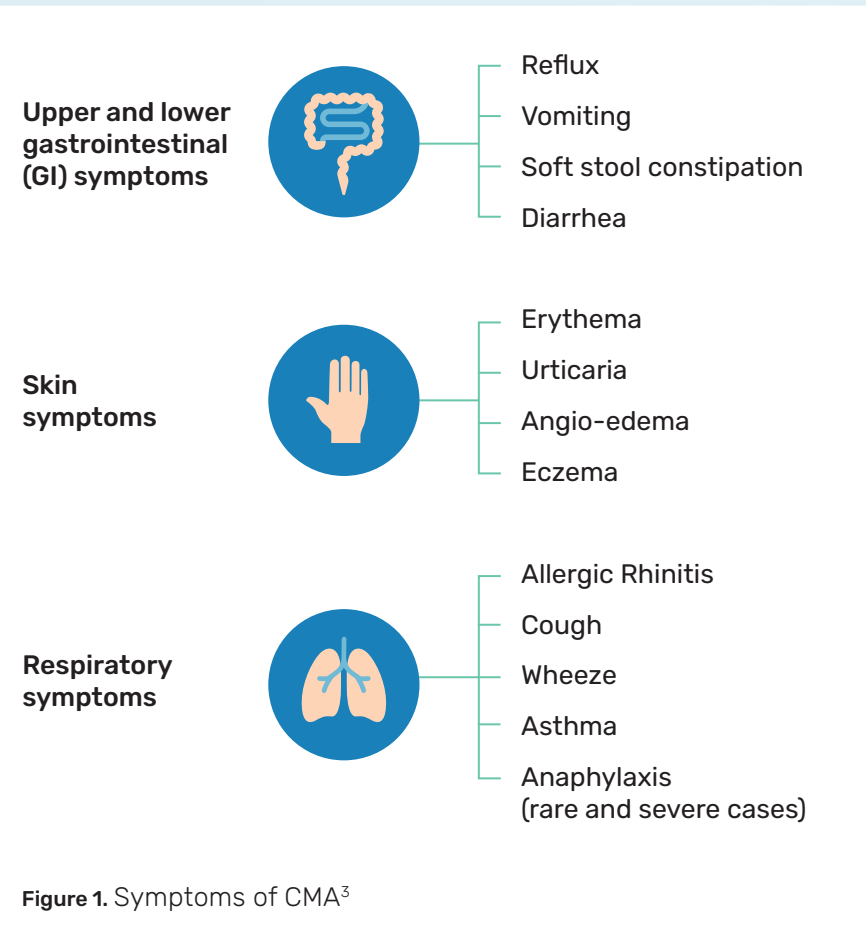
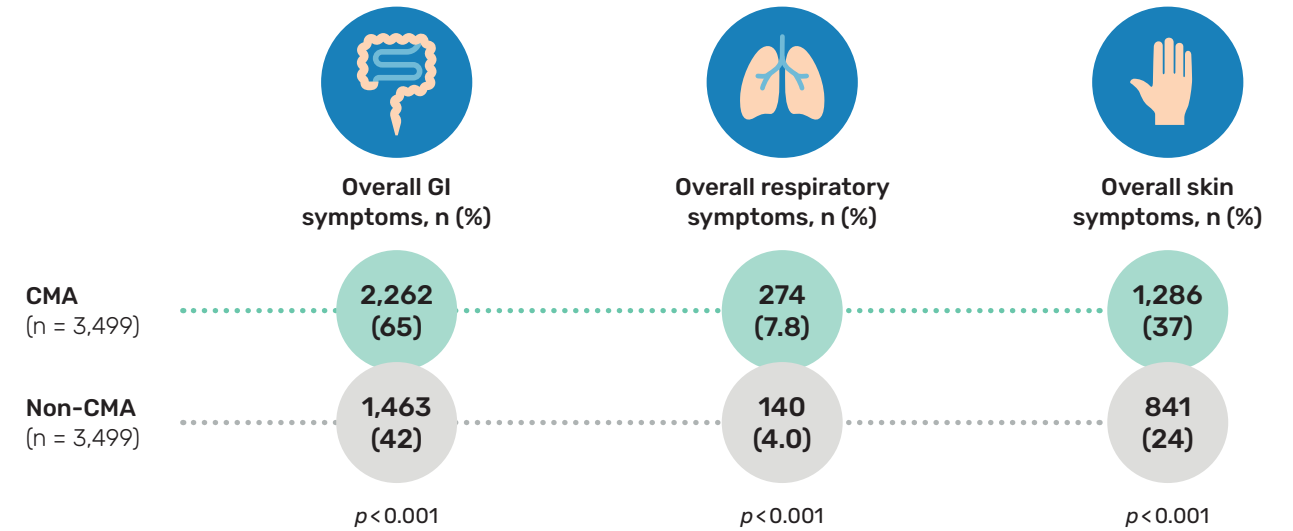
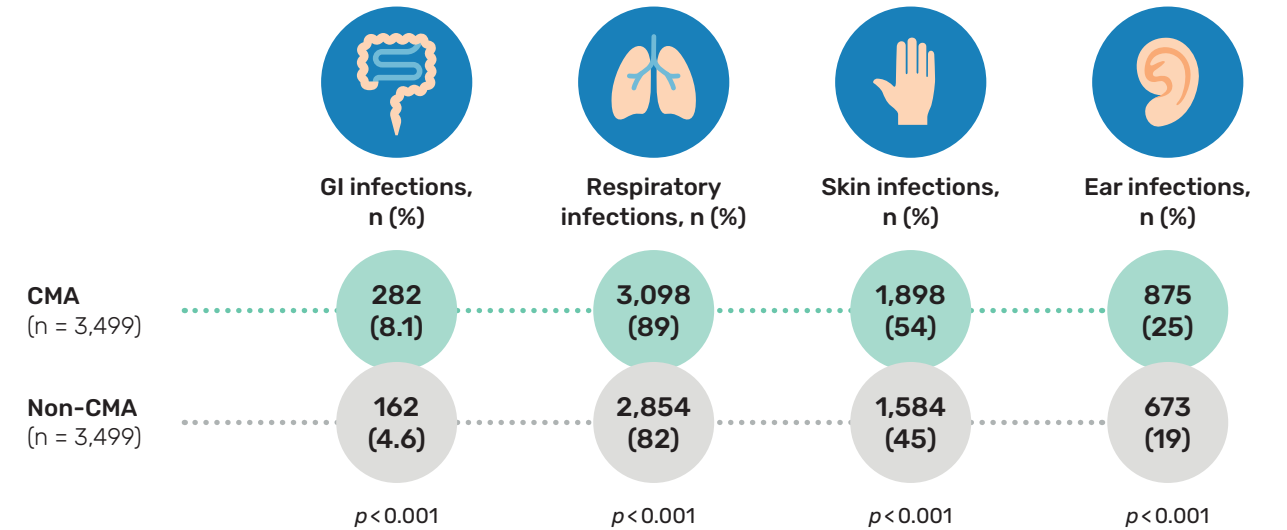


Figure 1. Symptoms of CMA³

GI, skin and respiratory symptoms occurred in both the CMA and non-CMA cohorts, but affected significantly more children in the CMA cohort than those in the non-CMA cohort.³



Infections also occurred in both groups, but the CMA cohort experienced significantly more infections than the non-CMA cohort.³



Compared to those without CMA, significantly more children with CMA were prescribed medications and had contacts with the GP, referrals to the dietitian and other specialists, and hospital admissions.²



Conclusion

The burden of CMA in children is rising and its clinical and economic impact is significant.^{2,3} Further research into management approaches may support strategies to improve the clinical and health outcomes of CMA in children.

CMA, cow's milk allergy; GI, gastrointestinal; GP, general practitioner; IgE, Immunoglobulin E.
References: 1. Vandeplass Y, Greef ED and Devreker T. *Pediatr Gastroenterol Hepatol Nutr* 2014;17(1):1-5. 2. Cawood AL, Meyer R, Grimshaw KE, Sorensen K, Acosta-Mena D and Stratton RJ. *Clin Transl Allergy* 2022;12(8):e12187. 3. Sorensen K, Meyer R, Grimshaw KE, Cawood A, Acosta-Mena D and Stratton RJ. *Immun Inflamm Dis* 2022;10(3):e572.

A clinician's role in CMA: symptom management vs long-term outcomes



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Maeve Hanan is a registered dietitian with a range of experience in clinical nutrition, nutrition communication and nutrition writing. She founded Dietetically Speaking in 2015 to share evidence-based nutrition messages online and on social media.

CMA is defined as “a reproducible adverse reaction of an immunological nature induced by cow’s milk protein”, usually presenting by 6 months of age.¹ This article will explore the balance between managing symptoms and optimizing long-term outcomes for infants with CMA.

Depending on the speed of symptom occurrence and the organs involved in this, CMA is classified as either IgE-mediated or non-IgE-mediated.

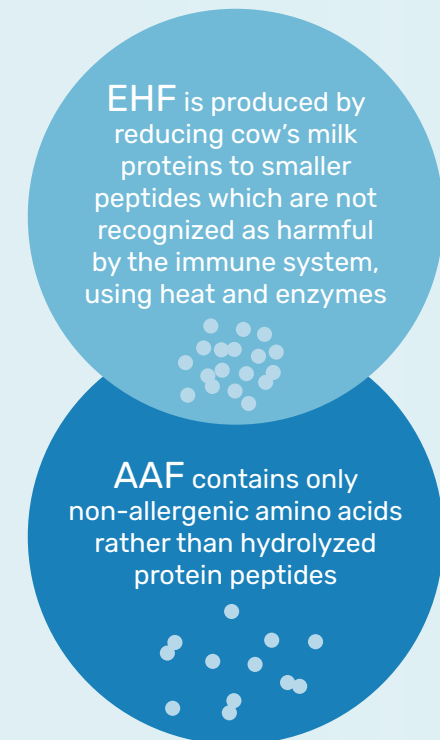
<p>IgE-mediated CMA</p> <p>Antibodies form in response to cow’s milk protein^{1,2}</p> <p>Symptoms occur within minutes of ingestion, but may take up to 2 hours^{1,2}</p>
<p>Non-IgE-mediated CMA</p> <p>More common; cell-mediated mechanism³</p> <p>Slower onset of symptoms (up to 2 and 72 hours²)</p>

Both forms of CMA can involve reactions occurring in the skin, gastrointestinal tract and respiratory system, although IgE-mediated CMA symptoms can be more acute and rare cases can lead to anaphylaxis.^{1,2}

CMA resolves within 2-4 years of diagnosis in most children, with non-IgE mediated CMA generally resolving earlier than IgE-mediated CMA.⁴ Therefore, it is advised to reassess tolerance every 6-12 months from one year of age.

Managing this condition involves medical diagnosis followed by elimination of cow’s milk protein from the diet.^{1,2} Where infants are breastfed, this involves supporting the mother in eliminating cow’s milk protein from her diet, without compromising her nutritional status. Infants of weaning age will also require a nutritious cow’s milk protein-free diet.

If a baby is formula-fed, clinicians are faced with a few options. Extensively hydrolyzed formula (EHF) and amino acid formula (AAF) both meet the criteria for hypoallergenic formula suitable for use in the management of CMA.^{1,2}



EHF has been found to be effective for the majority of infants with a diagnosis of CMA, and is also more cost effective than AAF.^{5,6} However, AAF is recommended when symptoms continue while on EHF, or if severe symptoms or anaphylaxis occur.^{2,6}

Another consideration is the use of prebiotics, probiotics and synbiotics.

Emerging research suggests that gut bacteria may influence immune and inflammatory responses related to food sensitization and allergy.^{7,8} Furthermore, infants with CMA have been found to have low levels of Lactobacilli and Bifidobacteria in their gut as compared with healthy infants.^{9,10}

There is growing evidence that dysbiosis precedes the development of food allergy,¹¹ with changes observed in the proportion and diversity of the microbiota in children with CMA.¹²

Although ongoing research is needed in this area, the World Allergy Organization guideline panel reported in 2015 that “there is a likely net benefit from using probiotics resulting primarily from prevention of eczema” in relation to allergic disease prevention. The panel also suggested using probiotics in infants and women who breastfeed infants and are “at high risk of developing allergy”.⁷

What are prebiotics?

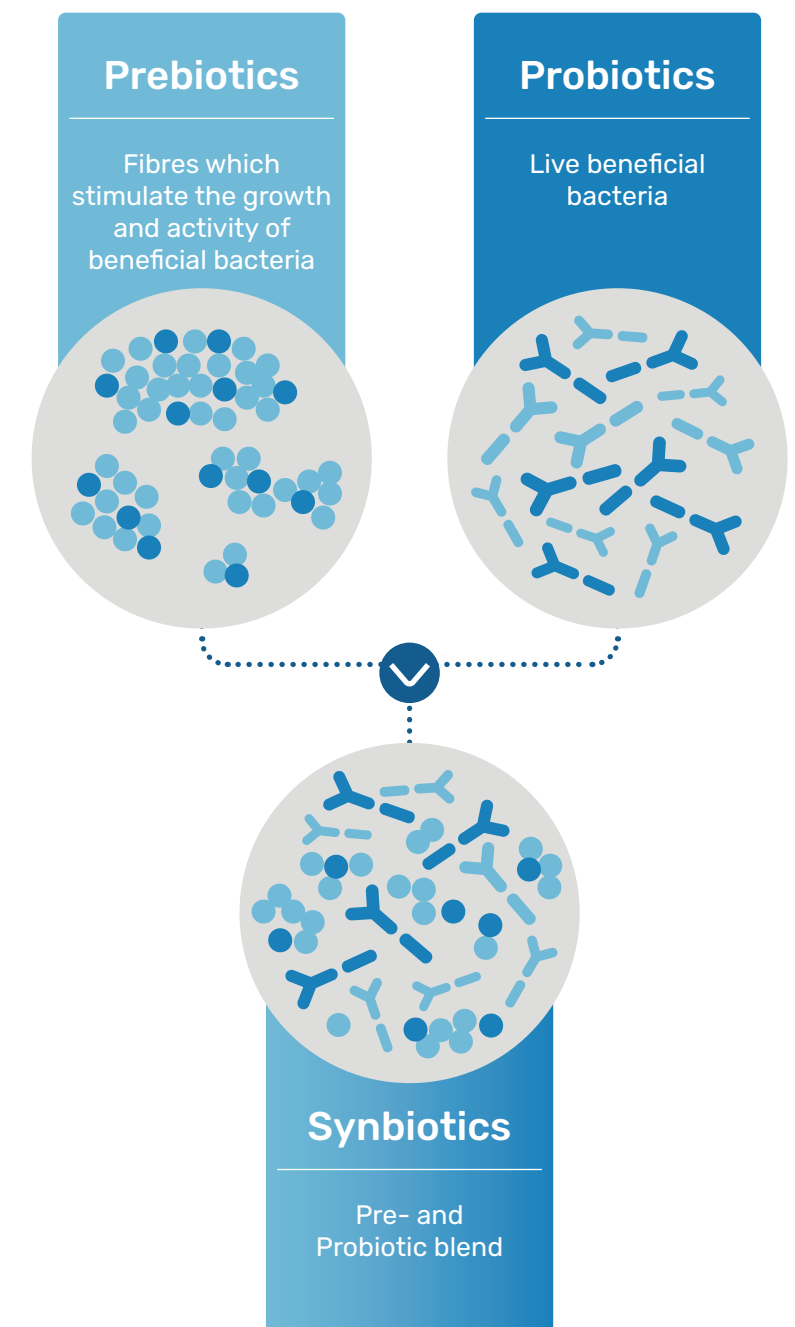
A substrate that is selectively utilized by host micro-organisms conferring a health benefit.¹³

What are probiotics?

Live micro-organisms which when administered in adequate amounts confer a health benefit on the host.¹⁴

What are synbiotics?

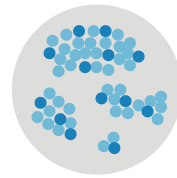
A mixture of pre- and probiotics that affects the host by improving the survival and implantation of live microbial dietary supplements in the gastrointestinal tract, by selectively stimulating the growth and/or activating the metabolism of one or a limited number of health-promoting bacteria, and thus improving welfare.¹⁵



A clinician's role in CMA: symptom management vs long-term outcomes

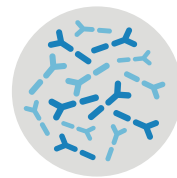


Clinical studies on probiotics, prebiotics and synbiotics have shown that:



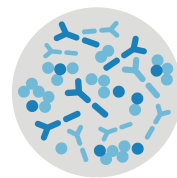
Probiotics

The addition of the probiotic *Lactobacillus rhamnosus* GG (LGG) safely promoted improved tolerance to cow's milk protein as well as improvements in longer-term outcomes such as a reduced risk of atopic dermatitis (i.e. eczema) and asthma.¹⁶⁻¹⁹



Prebiotics

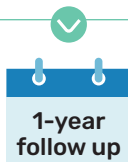
Infant formula containing long-chain fructo-oligosaccharides (FOS) and short-chain galacto-oligosaccharides (GOS) has been found to promote a similar gut microbiota to that of breastfed infants.²⁰



Synbiotics

The addition of synbiotics (a mixture of FOS and *Bifidobacterium breve* M-16 V) to AAF that was consumed for eight weeks resulted in improvements in fecal microbiota in infants with CMA, which was in line with fecal microbiota levels of healthy breastfed infants.²¹

EHF containing a mixture of FOS, GOS and *Bifidobacterium breve* M-16 V provided improvements in the severity of atopic dermatitis in infants; although these improvements only occurred in infants who had raised serum IgE at baseline.²²



Asthma-like symptoms such as wheezing and noisy breathing were reduced in those taking the synbiotic-containing EHF, and less children in this group had started taking asthma medication by the end of the study.²³

A study by Browne et al. from 2019 also reported significant improvement in atopic dermatitis in infants with non-IgE CMA who were switched from a standard EHF to an EHF containing synbiotics (FOS, GOS and *Bifidobacterium breve* M-16 V) for 4 weeks.²⁴ Importantly, this study identified

significant improvement in parental quality of life as well.²⁴ This finding is highly relevant, as the management of this condition can have a significant impact on the quality of life of the entire family.

For example, a study by Meyer et al. found that parental

quality of life and family functioning was worse in families who had a child in the early stages of managing non-IgE mediated food allergies in comparison with families who were taking care of a child with sickle cell disease or intestinal failure.²⁵

Roughly half of the parents of children with CMA surveyed in a study in 2015 reported that having a child with ongoing symptoms led to **exhaustion, stress and anxiety.**²⁶

And

Roughly a third stated that this **negatively impacted** their ability to **work or enjoy family-time.**²⁶



Another study from 2014 found that mothers of children with food allergies displayed **higher levels of stress and anxiety.**²⁷

In conclusion, clinicians play a vital role in supporting patients and their families with the management of CMA.

There is emerging exciting research related to improving both the symptom management and longer-term allergenic outcomes of infants with CMA, including through the use of prebiotics, probiotics and synbiotics.

AAF, amino acid formula; CMA, cow's milk allergy; EHF, extensively hydrolyzed formula; FOS, fructo-oligosaccharides; GOS, galacto-oligosaccharides; IgE, Immunoglobulin E; LGG, *Lactobacillus rhamnosus* GG.

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Clinical and economic benefits of Amino Acid Formula containing pre and probiotics (AAF-Syn) in infants with CMA



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Lisa has worked in tertiary level pediatric dietetics for many years and has led the specialist team in Bristol for over years. She has extensive experience and has covered most clinical areas. She is currently the clinical lead for the unique APP masters in Paediatric Dietetics at Plymouth University.

The gut microbiota is essential in maintaining immune function, influencing the development and responses of the immune system.¹ Gut dysbiosis can disrupt immunological tolerance and play a role in the clinical course of allergic diseases such as CMA.¹ Infants with CMA have been found to have divergent gut microbiota composition and lower levels of some beneficial bacteria that can promote a proper immune system function.²

Accumulating clinical evidence indicates that pre- and probiotics can have beneficial effects on infants at risk of, or living with allergies, leading to an earlier resolution of CMA, thus reducing in infections, hospital admissions and medication usage.¹ As such, AAFs containing synbiotics (a mixture of

pre- and probiotics that stimulates the proliferation of beneficial bacteria in the gut) could benefit children with CMA and potentially reduce healthcare costs.¹

However, real-world evidence investigating the benefits of AAF-Syn in the clinical setting is lacking.¹

A retrospective matched cohort study examining clinical and healthcare data from The Health Improvement Network database compared a group of infants managed with an amino acid formula containing synbiotics (AAF-Syn; 74 infants) with another group of infants who were fed standard amino acid formula without pre or probiotics (AAF; 74 infants).¹

Study population¹

74 infants with CMA prescribed with AAF-Syn

74 infants with CMA prescribed with AAF without pre- or probiotics

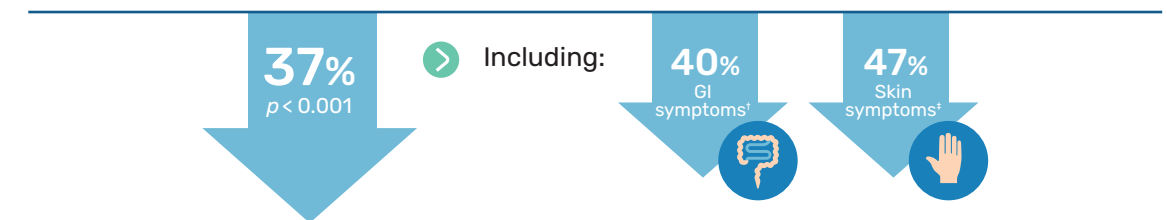


Infants first presented with symptoms at a mean age of **0.52 months** and were prescribed hypoallergenic formula (HAF) at a mean age of **4.69 months**

Results

Compared to AAF, infants prescribed AAF-syn had:¹

Significantly fewer allergic symptoms



Significantly fewer infections

35%
 $p < 0.001$

Significantly fewer medication prescriptions

19%
 $p < 0.001$

Fewer healthcare contacts

18%
 $p = 0.15$

Infants prescribed AAF-syn had a

3.7 times higher probability

of achieving asymptomatic management without the need to continue on an HAF, compared to AAF.¹

The clinical course of symptoms for infants prescribed AAF-Syn was also shorter, with the AAF-Syn group achieving asymptomatic management without the need to continue on an HAF at a median age of 1.35 years vs 1.95 years for the AAF group.¹

Cost savings were associated with the early discontinuation of AAF-Syn compared to AAF, and reduced medication prescriptions and healthcare usage.¹

While it is not possible to attribute causation of the observed benefits to AAF-Syn usage from this observational study, the findings presented above are consistent with available literature and suggest that the use of AAF-Syn in infants with CMA may provide clinical benefits as well as potential cost-savings pertaining to allergy management.

Further research is now needed looking at the comparison of peptide-based pre- and probiotic containing HAFs compared to AAF-Syn as peptide-based HAF is the recommended first line treatment in non-complex CMA.^{3,4}

AAF-Syn was associated with potential cost-savings of £452.18 (approximately €527) per infant over the clinical course of symptoms¹

¹Values shown denote the difference in rates per person-year; ²Significantly fewer infants in the AAF-Syn group experienced GI symptoms compared with the AAF group (23% vs 46%); ³Significantly fewer infants in the AAF-Syn group experienced skin symptoms compared with the AAF group (11% vs 26%).

AAF, amino acid formula; AAF-Syn, amino acid formula containing synbiotics; CMA, cow's milk allergy; GI, gastrointestinal; HAF, hypoallergenic formula.

References: 1. Sorensen K, Cawood AL, Cooke LH, Acosta-Mena D and Stratton RJ. *Nutrients* 2021;13(7):2205. 2. Kirjavainen PV, Salminen SJ and Isolauri E. *Gut* 2002;51:51-5. 3. Flocchi A, Brozek J, Schünemann H, Bahna SL, Berg AV, Beyer K, Bozzola M, Bradsher J, Compalati E, Ebisawa M, Guzman MA, Li H, Heine RG, Keith P, Lack G, Landi M, Martelli A, Rancé F, Sampson H, Stein A, Terracciano L and Vieths S. *World Allergy Organ J* 2010;3(4):57-161. 4. Luyt D, Ball H, Makwana N, Green MR, Bravin K, Nasser SM and Clark AT. *Clin Exp Allergy* 2014;44(5):642-72.

Benefits of AAF-Syn for infants with CMA: a review of the evidence



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Dr. Abbie Cawood is a registered nutritionist who has been working in clinical nutrition research for nearly 25 years at the University of Southampton and as part of her medical role at Nutricia in the UK. With over 40 publications in the field of clinical nutrition across adults and pediatrics, she continues to work on several projects including systematic reviews, service evaluations and randomized controlled trials across a variety of patient groups.

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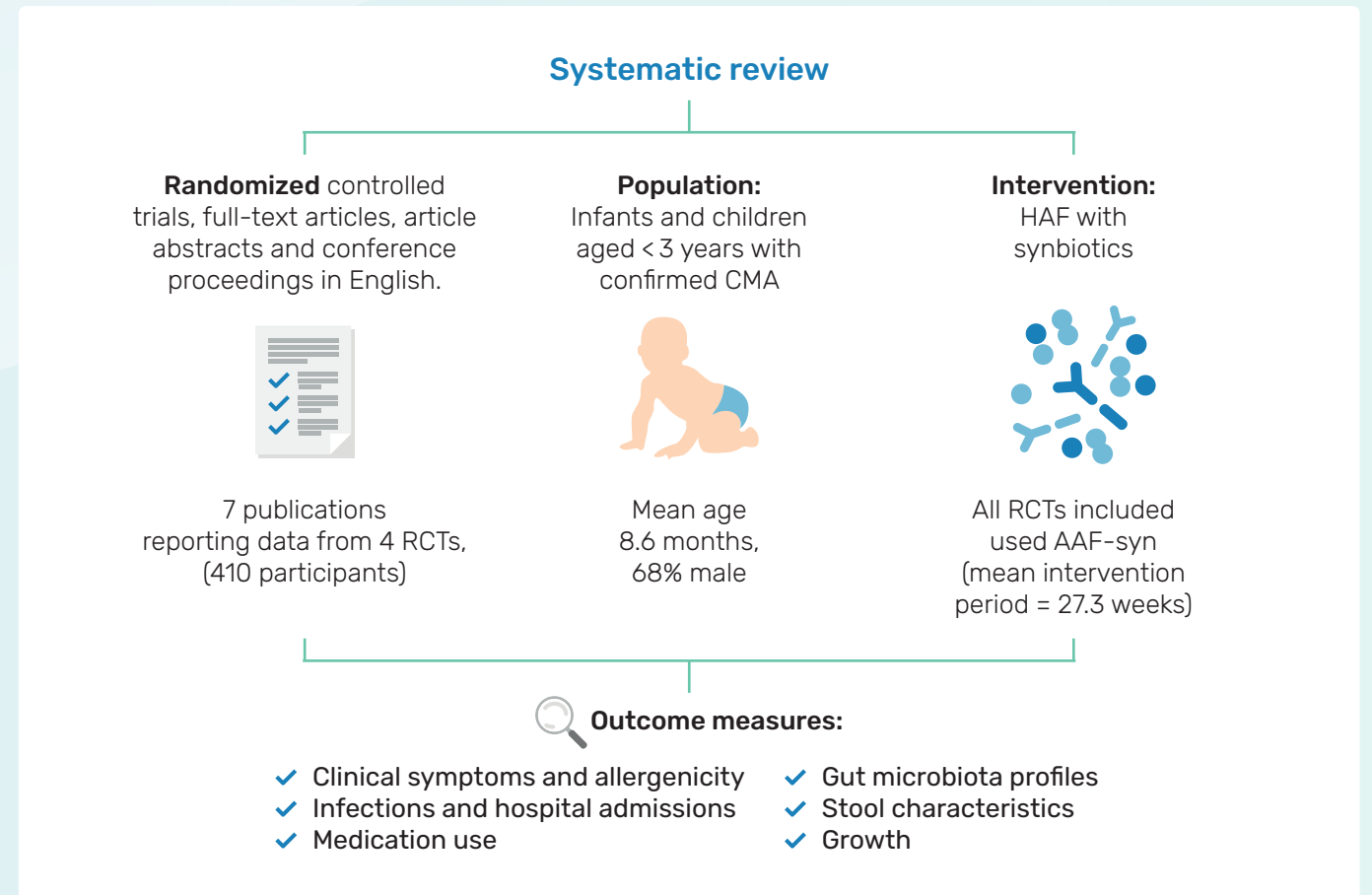
Dr. Rebecca Stratton, a dietitian and nutritional scientist, has been working in medical nutrition research for over 25 years at the Universities of Cambridge, Southampton and at Danone Nutricia. She is a leading researcher in the use of medical nutrition across the ages, diseases and conditions, managing a large clinical trial portfolio and with over 270 publications.



Breastfeeding can avoid exposure to cows' milk protein, and remains the best strategy for managing CMA, although it may not always be possible.¹ HAF, such as EHF or AAF, may be needed to meet nutritional needs in partially or fully formula-fed infants with CMA.¹ Guidelines recommend the use of EHF in majority of infants with CMA, while AAF is recommended in severe or complex CMA, or when symptoms do not resolve with EHF.^{2,3}

While HAF are guideline-recommended, their impact on gut microbiota is an important consideration.¹ Gut dysbiosis is common in CMA and has implications for immune and allergic development.¹ It has been suggested that gut dysbiosis in early life disrupts immune regulation and triggers pro-allergic responses.¹ Thus, modification of the gut microbiome should be investigated as a potential strategy in CMA management.¹

One approach in this strategy is the use of formula supplemented with pre- and probiotics ('synbiotics', when used together). Emerging evidence from RCTs suggest a benefit of synbiotic supplementation, but there has not been a comprehensive review of these findings.¹ Thus, this systematic review was conducted to examine the effect of HAF containing synbiotics on clinical outcomes in infants with CMA.¹



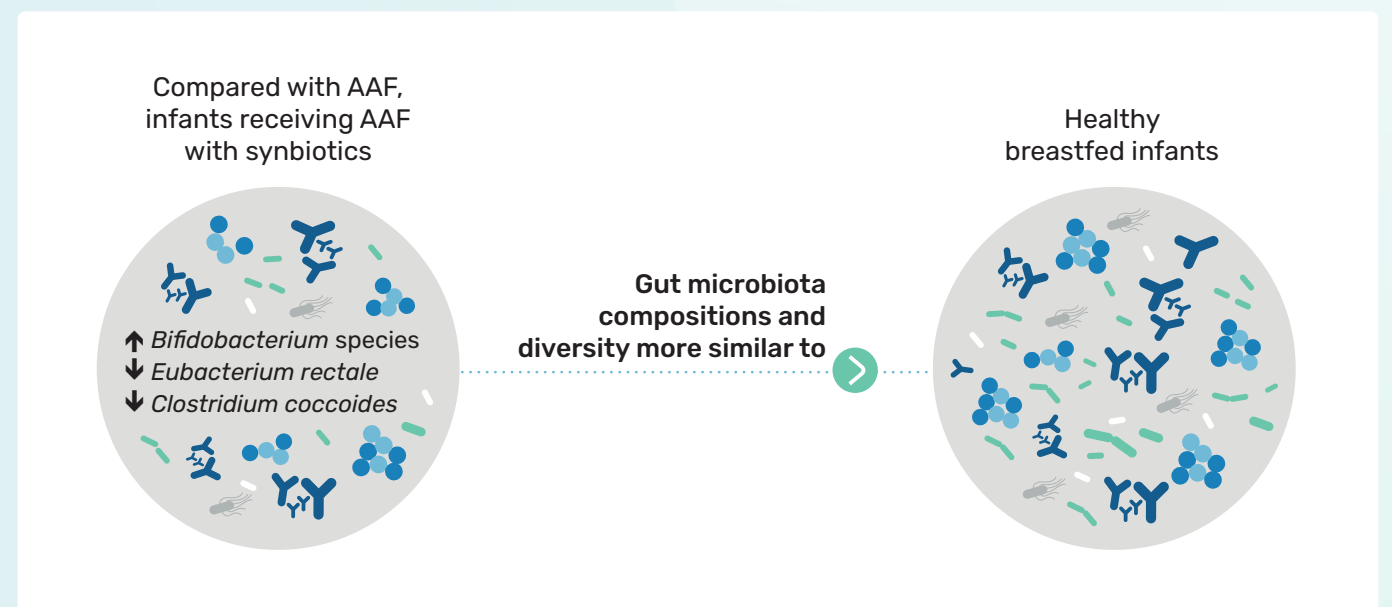
AAF-Syn was associated with gut microbiota closer to that of healthy breastfed infants, along with normal growth.

Five publications examined gut microbiota from fecal samples.¹

AAF-Syn resulted in significantly greater percentages of *Bifidobacterium* species and significantly lower percentages of *Eubacterium rectale* and *Clostridium coccoides* species compared with the AAF group.¹ Compared to the AAF group, the composition of the gut microbiome in the AAF-Syn group was more

similar to that of healthy breastfed infants.¹ Additionally, the AAF-Syn group also had bacterial diversity closer to that of the healthy breastfed infants.¹

All three publications that reported growth found it to be in accordance with the expected ranges for age with no significant differences between groups.



Benefits of AAF-Syn for infants with CMA: a review of the evidence



Infants receiving AAF-Syn had fewer infections and hospital admissions.

Analysis of infections data from three publications showed that the proportion of infants who had infections was significantly lower with AAF-syn than AAF [Figure 1].¹

Hospital admissions arising from infections reported in one publication showed significantly fewer infants had admissions with AAF-syn [Figure 1].¹

Based on the cost of hospital admission and cost of the HAF, AAF-Syn was estimated to provide potential annual cost savings of up to £338.77 (approximately €395) per patient.¹

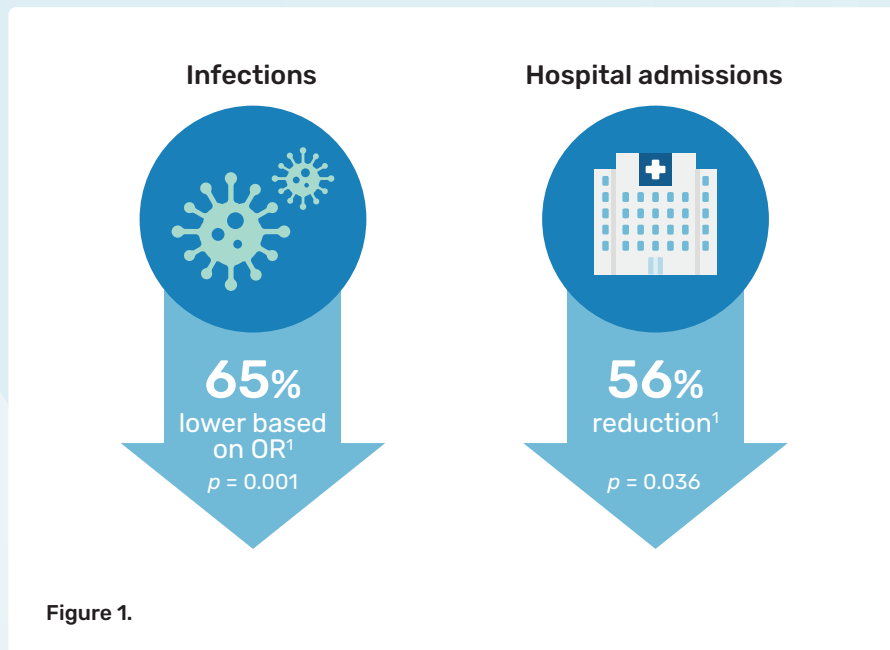


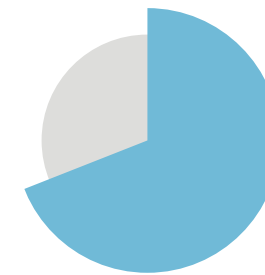
Figure 1.

Lower medication usage with AAF-syn

- Medications reported across the publications included
- Overall concomitant medication use (not specified)
- Antibacterials and anti-infectives (which includes antibiotics)
- Dermatologicals
- Antifungals
- Emollients
- Functional GI medications¹



55% reduction in antibacterial, anti-infective or antibiotic usage with AAF-syn from pooled analysis.¹



69% reduction in the usage of emollients, protectives and dermatological medications with AAF-syn from pooled analysis.¹



The findings of this systematic review showed that the use of AAF-Syn results in improvement in dysbiosis, and is associated with reductions in infections, medication usage and hospital admissions, with potential associated cost savings.¹

AAF, amino acid formula; AAF-Syn, amino acid formula containing synbiotics; CMA, cow's milk allergy; EHF, extensively hydrolyzed formula; GI, gastrointestinal; HAF, hypoallergenic formula; RCT, randomized controlled trial.

References: 1. Sorensen K, Cawood AL, Gibson GR, Cooke LH and Stratton RJ. *Nutrients* 2021;13:935. 2. Flocchi A, Brozek J, Schünemann H, Bahna SL, Berg AV, Beyer K, Bozzola M, Bradsher J, Compalati E, Ebisawa M, Guzman MA, Li H, Heine RG, Keith P, Lack G, Landi M, Martelli A, Rancé F, Sampson H, Stein A, Terracciano L and Vieths S. *World Allergy Organ J* 2010;3(4):57-161. 3. Luyt D, Ball H, Makwana N, Green MR, Bravin K, Nasser SM and Clark AT. *Clin Exp Allergy* 2014;44(5):642-72.

Insights into parent and clinician perspectives of AAF-Syn for the management of CMA



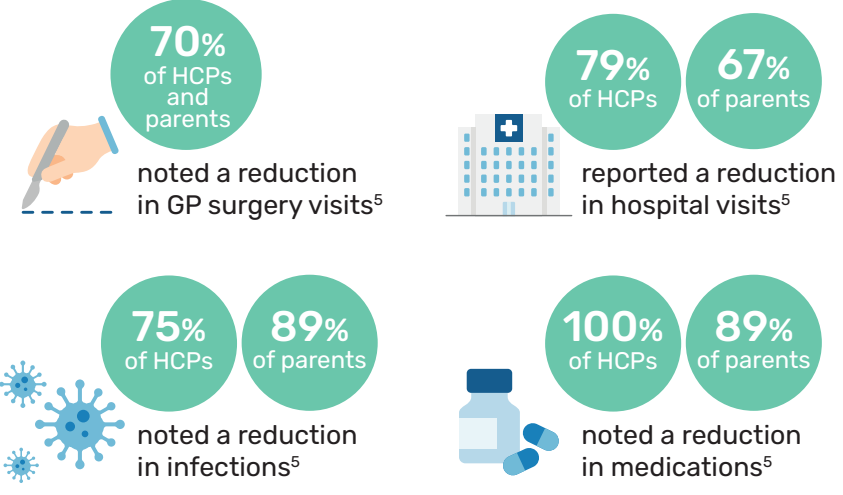
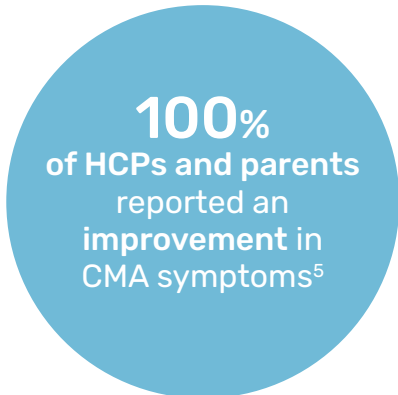
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Dr. Abbie Cawood, is a registered nutritionist who has been working in clinical nutrition research for nearly 25 years at the University of Southampton and as part of her medical role at Nutricia in the UK. With over 40 publications in the field of clinical nutrition across adults and paediatrics, she continues to work on several projects including systematic reviews, service evaluations and randomised controlled trials across a variety of patient groups.

CMA, which is highly common in infants and children, presents a significant health and economic burden.¹⁻³ Beyond that, quality of life of affected families can also be negatively impacted.⁴

To explore the experience of using AAF-Syn in a real-world setting, 10 parents of infants with CMA, as well as 20 healthcare professionals (HCPs) with recent experience of using AAF-Syn in the UK were invited to complete a survey on their perspectives in managing CMA.⁵

HCPs and parents reported benefits of AAF-Syn for infants with CMA



Reductions in healthcare costs associated with the treatment of CMA has potentially important financial implications.

100% of HCPs and parents surveyed reported an **improvement in quality of life of infants and their families**

All HCPs surveyed would recommend the use of AAF-Syn to other HCPs

And

90% would consider this formula as their **first-line choice of AAF** in the future.⁵



The results of this survey demonstrate that the benefits of AAF-Syn observed in clinical trials are also evident in real-world clinical practice.⁵

AAF-Syn provides improvements in symptoms and quality of life of patients and their families, and may be considered in the management of CMA.⁵

AAF-Syn, amino acid formula containing synbiotics; CMA, cow's milk allergy; GI, gastrointestinal; HCP, healthcare professional; HAF, hypoallergenic formula.
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