



May 11, 2026

## ***Bifidobacterium infantis* M-63 May Support Bowel Habits and the Gut Environment in Infants and Toddlers During the Weaning Period**

**Joint Research with Matsumoto City Hospital Published in Scientific Journal  
*Pediatric Research***

Morinaga Milk Industry Co., Ltd. has been conducting basic research on bifidobacteria for over 50 years, studying these beneficial bacteria that colonize the human intestine and provide various health benefits. Under a comprehensive partnership agreement with the government of Matsumoto City, Nagano Prefecture\*<sup>1</sup>, we have carried out clinical research on functional ingredients for many years, applying the results to support citizens' health and develop our proprietary ingredients.

Joint research with Matsumoto City Hospital\*<sup>2</sup> found that supplementation with *Bifidobacterium infantis* M-63 (hereafter, *B. infantis* M-63) was associated with improvements in bowel habits and gut environment measures in infants and toddlers during and after the weaning period. Furthermore, the findings suggest that in groups with a relatively higher risk of infection, supplementation with *B. infantis* M-63 may be associated with a reduction in the number of days with cold-like symptoms and other related outcomes. These research findings were published in the scientific journal *Pediatric Research* on April 29, 2026\*<sup>3</sup>.

### **1. Research Background**

Infancy and toddlerhood are periods of rapid physical growth and development, during which the gut environment also changes and matures rapidly, influenced by breast milk and weaning foods. It is also a period during which health challenges may arise: as weaning progresses, bowel irregularities and an increased risk of infections become more common. Against this background, regulating the gut environment has attracted attention as a promising approach to addressing these challenges. In this study, we conducted an exploratory evaluation in healthy infants and toddlers during and after the weaning period to assess the effects of *B. infantis* M-63 supplementation on the gut environment and health status.

### **2. Research Methods**

- Participants: 100 healthy infants and toddlers aged 5 months to under 3 years
- Study Design: Randomized, double-blind, placebo-controlled, parallel-group comparative study
- Test Product: Daily intake of powder containing 5 billion CFU of *B. infantis* M-63 or a placebo powder without *B. infantis* M-63, for 8 weeks
- Evaluation Parameters: Stool habits, gut microbiota, SCFAs\*<sup>4</sup>, and general health status

### *Bifidobacterium infantis* M-63

*B. infantis* M-63 is a proprietary bifidobacterial strain of the species *Bifidobacterium longum* subsp. *infantis*, originally isolated from the intestine of a human infant. Among the bifidobacteria found in the intestines of human infants, *B. infantis* is particularly well-adapted to breast milk and is thought to contribute to immune development and reduce infection risk through the production of beneficial metabolites in the gut.



*B. infantis* M-63 has been reported to have a high capacity to utilize human milk oligosaccharides present in breast milk, and early-life supplementation has been shown to promote a favorable gut environment and to exert beneficial effects on immune function and bowel habits<sup>5, 6</sup>.

### 3. Research Results

- In the *B. infantis* M-63 group, the number of days with diarrhea decreased compared to the placebo group (Figure 1), and the number of days with normal stools increased (Figure 2). These results suggest that *B. infantis* M-63 has a bowel-regulating effect in infants and toddlers during and after the weaning period.
- In subgroup analyses stratified by breastfeeding status, children who were continuously breastfed showed a marked increase in the relative abundance of *B. infantis* following supplementation with *B. infantis* M-63 (Figure 3). In contrast, non-breastfed children exhibited a significant increase in total fecal SCFA concentrations (Figure 4).
- Furthermore, post hoc exploratory analyses suggested that in groups with a relatively higher risk of infection—such as younger infants and those with siblings—supplementation with *B. infantis* M-63 was associated with a reduction in the number of days of antibiotic and probiotic preparation use as well as the number of days with cold-like symptoms (Figure 5).

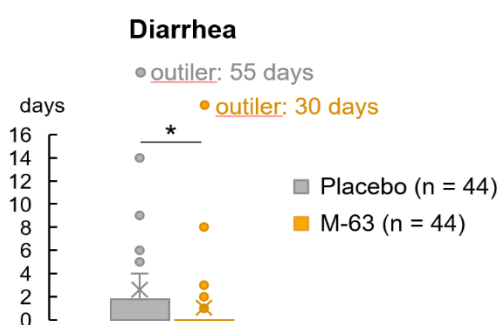


Figure 1. Number of days with diarrhea during the test product intake period

\*Days on which the average daily stool consistency was rated 6 or 7 on the Bristol Stool Scale were counted.

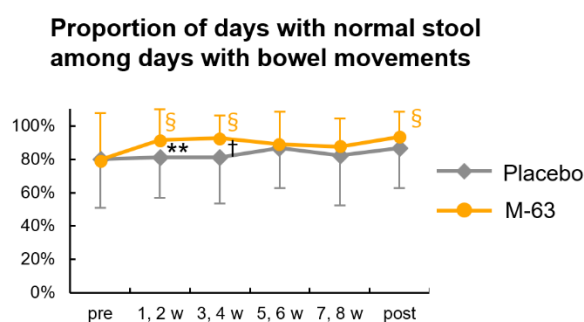


Figure 2. Proportion of days with normal bowel movements

\*The ratio of days with normal bowel movements to total days with bowel movements was calculated every two weeks.

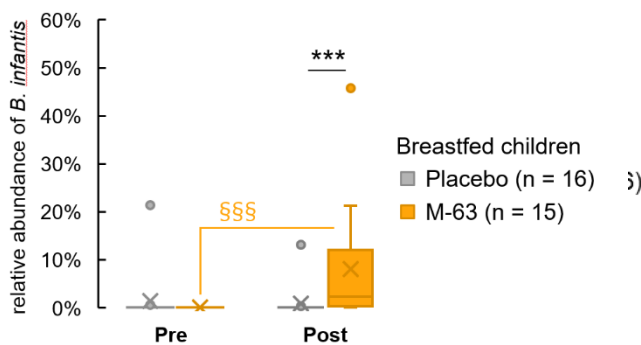


Figure 3. Relative abundance of *B. infantis* in the gut microbiota in the subgroup of breastfed children

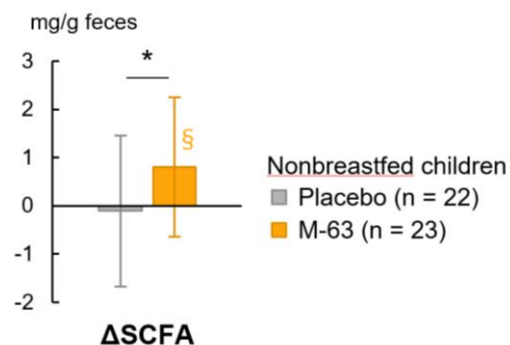


Figure 4. Increase in total fecal SCFA concentrations in the non-breastfed children subgroup (change from pre- to post-intake)

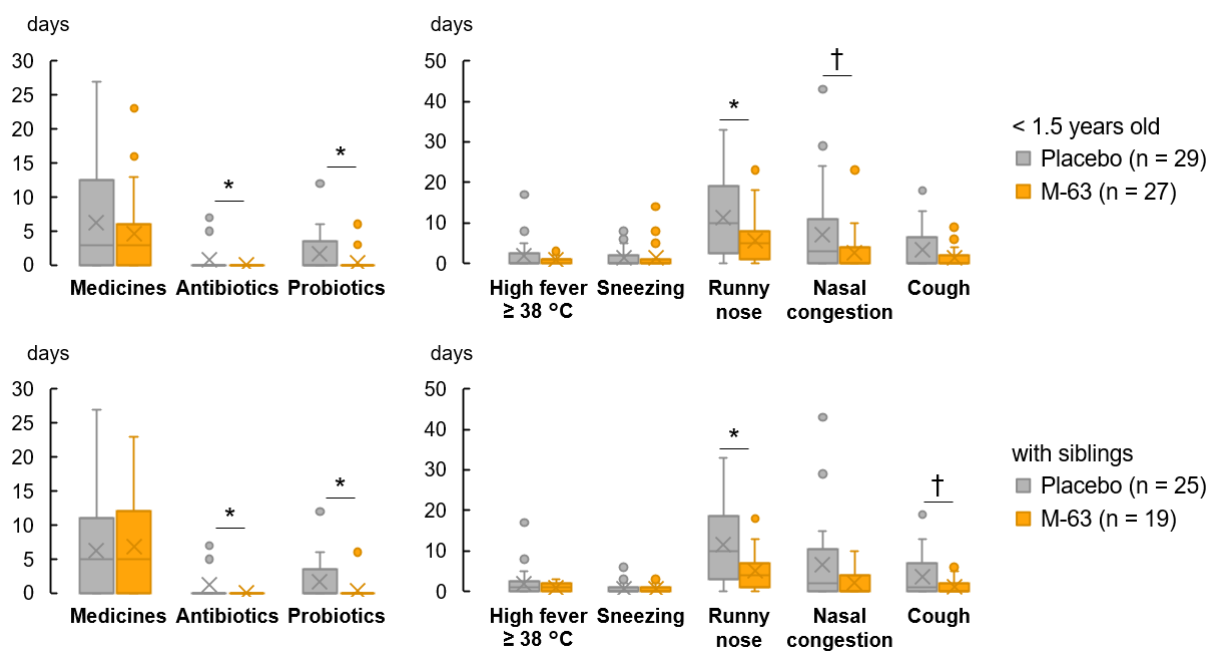


Figure 5. Comparison of the number of days of medication use and cold-like symptoms in groups with a relatively higher risk of infection

\*  $p < 0.05$  and \*\*\*  $p < 0.001$  indicate statistically significant differences compared to the placebo group. (†  $p < 0.1$  indicates a trend toward significance.)

§  $p < 0.05$  and §§§  $p < 0.001$  indicate statistically significant differences compared to baseline (pre-intake).

#### **4. Future Outlook**

These results suggest that *B. infantis* M-63 may help regulate the gut environment and support overall health in infants and toddlers during and after the weaning period.

Morinaga Milk Industry will continue to communicate the distinctive characteristics and scientific evidence for bifidobacteria in an accessible manner and will contribute to the health of more people worldwide through product applications and global business expansion.

#### **<Reference Information>**

##### **Human-Residential Bifidobacteria (HRB)**

More than 100 species of bifidobacteria have been discovered to date. However, the species of bifidobacteria that colonize the human intestine are fundamentally different from those that live in other organisms. Morinaga Milk Industry Co., Ltd. is particularly focused on research and development of bifidobacteria that colonize the human intestine.

Furthermore, we named the species of bifidobacteria that uniquely colonizes the human intestinal tract "Human-Residential Bifidobacteria (HRB)." Research suggests that bifidobacteria that colonize the human intestine have evolved together with human ancestors for over 15 million years. We believe that this long process of co-evolution is one piece of evidence that HRB has played an extremely important role in human health.

##### **\*1 Comprehensive Partnership Agreement with Matsumoto City, Nagano Prefecture**

We signed a Comprehensive Partnership Agreement with the Matsumoto City government in 2021. We are working on initiatives to support the health of local residents through clinical trials of functional ingredients and collaboration with the local community.

<https://www.morinagamilk.co.jp/release/newsentry-3776.html>

##### **\*2 Joint Research with Matsumoto City Hospital, Nagano Prefecture**

In 2019, we launched the "Survey on Infant Health and Support for Childbirth and Childcare for Matsumoto Citizens" in collaboration with Matsumoto City Hospital and the Matsumoto City government.

<https://www.morinagamilk.co.jp/release/newsentry-3239.html>

##### **\*3 Article Title and Authors**

Arai S, Hiraku A, Nakata S, et al. Effects of *Bifidobacterium infantis* M-63 on Gut Environment and Bowel Function during Weaning: RCT. *Pediatr Res*. Published online April 29, 2026.

DOI: <https://doi.org/10.1038/s41390-026-04960-2>

##### **\*4 Short-chain fatty acid (SCFA)**

SCFAs are metabolites produced in the large intestine by gut bacteria, including bifidobacteria, through the fermentation of oligosaccharides and dietary fiber. They include acetic acid, propionic acid, butyric acid, and others. SCFAs serve as a primary energy source for colonic epithelial cells and have been reported to play beneficial roles in maintaining the gut environment and supporting immune function, attracting growing attention as health-promoting substances.

**\*5 Reference**

Hiraku A, Nakata S, Murata M, et al. Early Probiotic Supplementation of Healthy Term Infants with *Bifidobacterium longum* subsp. *infantis* M-63 Is Safe and Leads to the Development of *Bifidobacterium*-Predominant Gut Microbiota: A Double-Blind, Placebo-Controlled Trial. *Nutrients*. 2023;15(6):1402. Published 2023 Mar 14. doi:10.3390/nu15061402

**\*6 Reference**

Xu C, Odamaki T, Hiraku A, et al. Anti-inflammatory effects of *Bifidobacterium infantis* M-63 during the early postnatal period in term infants. *Pediatr Res*. Published online July 18, 2025. doi:10.1038/s41390-025-04263-y

**\*7 GRAS (Generally Recognized as Safe)**

When introducing new food ingredients in the United States, experts assess their safety as food ingredients. They review factors such as ingredient characteristics, manufacturing process, quality control, product specifications, usage history, and clinical trial results. GRAS status is required when marketing a substance as a food ingredient in the United States. *B. infantis* M-63 obtained GRAS status in 2022 for both general food use and infant applications.

**\*8 New Food Ingredient system**

The New Food Ingredient system allows the sales in China of food ingredients that are not part of the traditional Chinese diet. Ingredients that may be used in foods for infants and toddlers under the age of three, in particular, must possess food properties and satisfy stringent nutrition, health, and safety standards. *B. infantis* M-63 was registered as a New Food Ingredient in China in 2024.

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