



## **Morinaga Milk Unveils New Research on the Protective Effects of Lactoferrin-fortified Formula on Acute Gastrointestinal Symptoms in Children**

TOKYO (JUN, 2020): Morinaga Milk Industry Co., Ltd. (TOKYO:2264), a leading Japanese dairy product company, announced new research titled “Effects of Lactoferrin-Fortified Formula on Acute Gastrointestinal Symptoms in Children Aged 12–32 Months: A Randomized, Double-Blind, Placebo-Controlled Trial,” in collaboration with Shinshu University of Japan. This report published in the peer-reviewed journal “Frontiers in Pediatrics” in May 2020 is the first randomized controlled trial (RCT), the gold standard of research, that demonstrated the protective effects of a lactoferrin-supplemented formula on acute respiratory and gastrointestinal symptoms in preschool children.

Since the discovery of lactoferrin in 1939, more than 8,000 articles have been published on its diverse functions. In the field of pediatrics, lactoferrin has been demonstrated to have several physiological functions. Morinaga Milk Industry started research on lactoferrin in the 1960s to develop a more breast milk-like infant formula. Morinaga Milk Industry Co., Ltd. has also focused on the production of lactoferrin; the German subsidiary company, MILEI GmbH, is the largest lactoferrin manufacturer in the world\*. Over the past decades, Morinaga Milk Industry Co. Ltd. has conducted advanced research in collaboration with universities and research institutes worldwide to explore the functional benefits of lactoferrin and its application in humans.

\*As per a research report by Absolute Reports® in 2018

### ***Background***

Lactoferrin (LF) is one of the components of the immune system of the body that is widely expressed in various secretory fluids such as milk, saliva, tears, and nasal secretions. LF is thought to play a role in host defense via its antimicrobial/antiviral and immunomodulatory activities. Due to its high safety profile, the intake of LF as a possible preventive measure against infections has been widely proposed. In this study, we investigated the effects of LF-fortified formula on acute gastrointestinal and respiratory symptoms in nursery school children, who are at high risk of infections because of group living.

### ***Study outline***

**Study period:** November 2017 to April 2018, including the intervention (13 weeks) and post-intervention (2 weeks) periods.

**Subjects:** Healthy children aged 12–32 months attending nursery schools in Japan.

**Study design:** Randomized, double-blind, placebo-controlled trial.

**Intervention:** Placebo (placebo group, 0 mg/day, n = 48) or LF-fortified formula (LF group, 48 mg/day, n = 53) for 13 weeks.

**Outcomes:** Acute gastrointestinal and respiratory symptoms were recorded in diaries by the parents.

### ***Study Results***

#### ***1. Prevalence of acute gastrointestinal symptoms during the 13-week intervention period***

The prevalence of acute gastrointestinal symptoms during the intervention period was significantly lower in the LF group (22/53 [41.5%]) than in the placebo group (30/48 [62.5%]) (Figure 1).

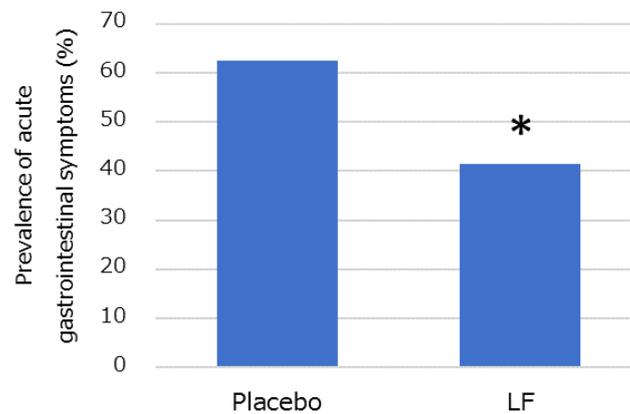


Figure 1. The prevalence of acute gastrointestinal symptoms during the intervention period

(\* Significant difference between the groups,  $P < 0.05$ )

## 2. Total number of days of acute respiratory symptoms during the 13-week intervention period

The total number of days of acute respiratory symptoms during the intervention period was significantly lower in the LF group (9.0) than in the placebo group (15.0) (Figure 2).

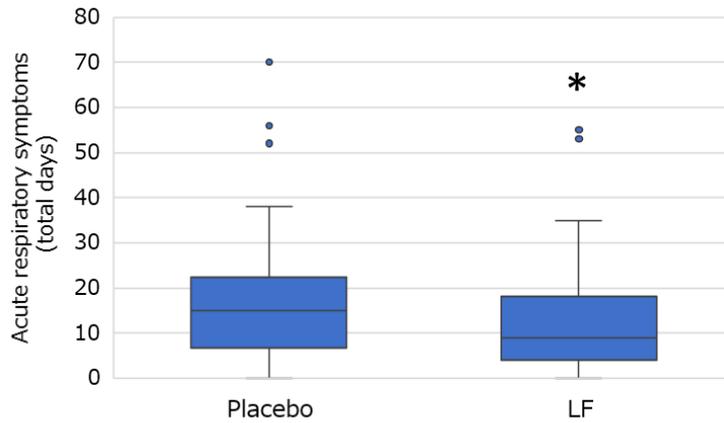


Figure 2. Total number of days of acute respiratory symptoms during the intervention period (days)

(\* Significant difference between the groups,  $P < 0.05$ )

## 3. Prevalence and total number of days of acute respiratory symptoms in the 2-week post-intervention period

The prevalence of acute respiratory symptoms in the post-intervention period was significantly lower in the LF group (16/53 [30.2%]) than in the placebo group (25/48 [52.1%]) (Figure 3). In addition, the total number of days of acute respiratory symptoms in the post-intervention period was significantly shorter in the LF group (0) than in the placebo group (1.0) (Figure 4).

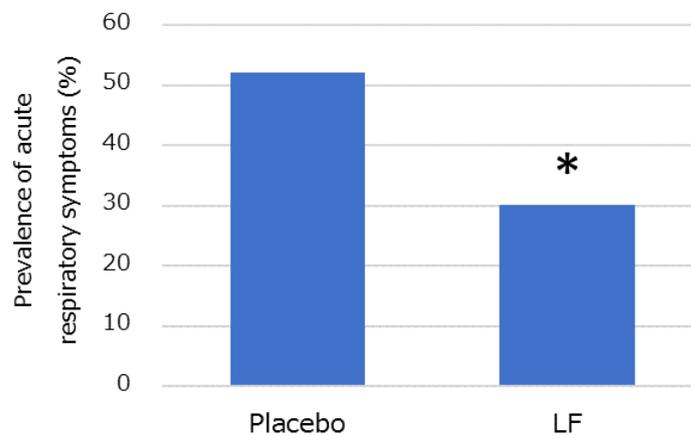


Figure 3. Prevalence of acute respiratory symptoms in the post-intervention period (%)

(\* Significant difference between the groups,  $P < 0.05$ )

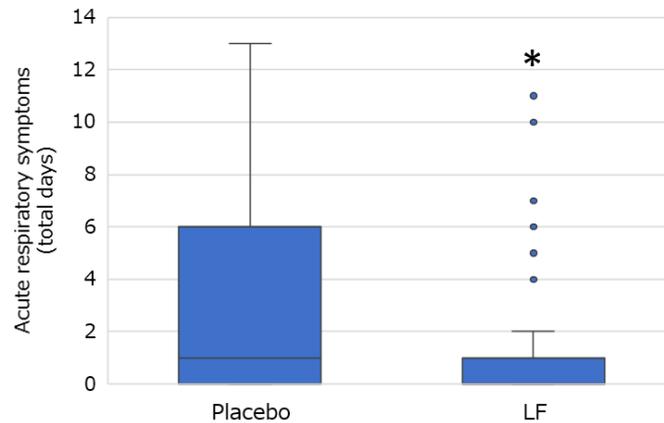


Figure 4. Total number of days of acute respiratory symptoms in the post-intervention period (days)

(\* Significant difference between the groups,  $P < 0.05$ )

### **Conclusion**

This study demonstrated that ingestion of LF could decrease the prevalence of acute gastrointestinal symptoms and lower the total number of days of acute respiratory symptoms in children. Furthermore, a reduction in the prevalence and total number of days of acute respiratory symptoms was observed even after LF intake. According to previous fundamental studies, LF has been reported to exhibit a direct inhibitory activity against a wide range of viruses that cause acute gastrointestinal and respiratory infections by preventing the entry and replication of the viruses in the host cells. Moreover, LF enhances the systemic immune function and inhibits excessive inflammation caused by infection. Therefore, in this study, the ingestion of LF might have provided protection against acute gastrointestinal and respiratory symptoms via the abovementioned mechanisms.

### **Reference**

Effects of Lactoferrin-Fortified Formula on Acute Gastrointestinal Symptoms in Children Aged 12–32 Months: A Randomized, Double-Blind, Placebo-Controlled Trial  
 Front Pediatr. 2020 May 19;8:233. doi: 10.3389/fped.2020.00233.

### **CONTACT INFORMATION**

International Division

Morinaga Milk Industry Co., Ltd.

+81-3-3798-0152

[interntl@morinagamilk.co.jp](mailto:interntl@morinagamilk.co.jp)

<http://www.morinagamilk.co.jp/english/>