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Morinaga Milk Unveils New Research on the Improved Effects of Lactoferrin-fortified Formula on Sleep Quality in Children

TOKYO (JAN2021): Morinaga Milk Industry Co., Ltd. (hereafter, "Morinaga Milk") announced new research titled "Effects of Lactoferrin on Sleep Conditions in Children Aged 12–32 Months: A Preliminary, Randomized, Double-Blind, Placebo-Controlled Trial," in collaboration with Shinshu University in Japan. This research, published in the peer-reviewed journal "*Nature and Science of Sleep*" in September 2020, is the first randomized controlled trial (RCT) that demonstrated the positive effects of lactoferrin-supplemented formula on sleep quality in preschool children.

Lactoferrin is present in the milk of most mammals. Since its discovery in 1939, more than 8,000 articles have been published worldwide. The effects of lactoferrin have been extensively investigated especially in the field of pediatrics. Morinaga Milk started research on lactoferrin in the 1960s to develop a more breastmilk-like infant formula, and recently has conducted advanced research in collaboration with universities and research institutes worldwide to explore the functional benefits of lactoferrin and its application in humans. Among the manufacturers, Morinaga Milk is the largest contributor to the number of academic papers on lactoferrin*. Morinaga Milk has also focused on the production of lactoferrin; its German subsidiary company, MILEI GmbH, has the largest share** of the global market in terms of production volume of lactoferrin.

* As in-company investigation by SCOPUS as of November, 2020.

** As per a research report by Absolute Reports® in 2019.

Background

Lactoferrin (LF) plays an important role in healthy growth and development of children. LF exhibits antimicrobial/antiviral and immunomodulatory activities, and clinical research has demonstrated its protective effects against gastrointestinal and respiratory infections. In contrast, recent fundamental studies suggested that LF improves sleep quality in children. In this study, we investigated the effects of LF-fortified formula on sleep conditions in children.

Study outline

Subjects: Healthy children aged 12–32 months attending nursery schools in Japan.
Study design: A randomized, double-blind, placebo-controlled trial.
Method: Subjects were divided into two groups and ingested a placebo or LF (48 mg/day)-fortified formula for 13 weeks. Children's sleep conditions were investigated before and after the intervention using the Japanese Sleep Questionnaire for Preschoolers (JSQ-P). The questionnaire consists of 39 items classified into 10 domains: obstructive sleep apnea syndrome (OSAS), restless legs syndrome (RLS)-sensory, RLS-motor, morning symptoms, sleep habits, parasomnias, insufficient sleep, daytime excessive sleepiness, daytime behaviors, and insomnia or circadian rhythm disorders. Parents answered the questionnaire by rating on a 6-point Likert scale, where a score of 6 was "strongly agree/true/applicable", and a score of 1 was "strongly disagree/false/inapplicable". The JSQ-P T scores were calculated in total and for each domain according to the instructions.

Study results

The change in total T scores tended to improve in the LF group. In particular, the change in morning symptoms (grumpy in the morning, hard to wake up, and hard to get out of bed) showed significant improvement in the LF group compared to the placebo group (Figure 1). Moreover, the T scores of the LF group showed an improved trend in RLS-motor (rubs feet at night and touches feet at night) and insufficient sleep (stays up more than one hour later the day before a holiday and wakes up more than one hour later on a holiday) as compared to the placebo group. Wake-up time, bedtime, and nighttime sleep were comparable between the two groups and were maintained during the intervention period.

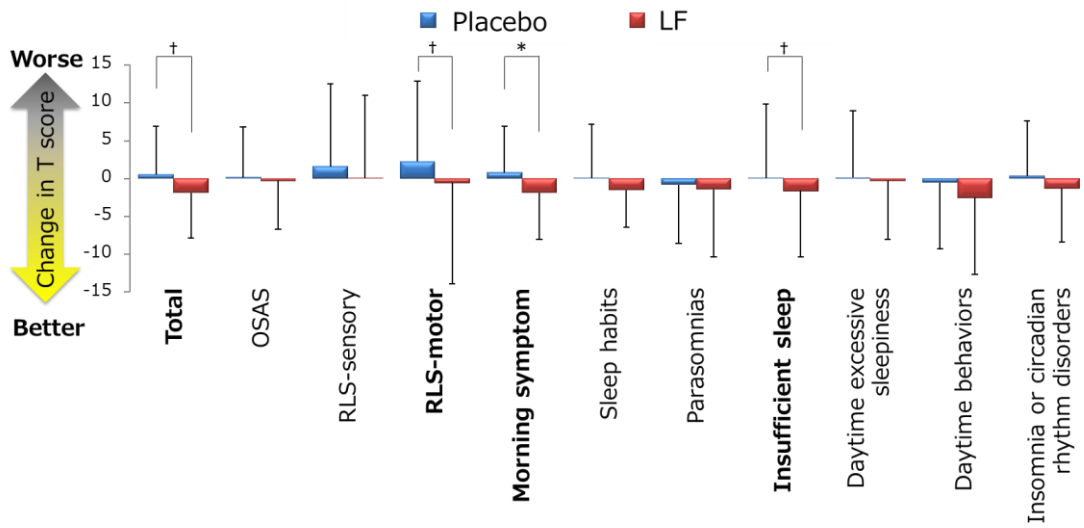

Figure 1. The changes in JSQ-P T scores before and after intervention
(*P < 0.05; significant difference, †P < 0.10; tendency)

Conclusion

This study demonstrated that LF intake could improve sleep quality in children. We will continue to research how LF, which is originally abundant in breast milk, contributes to the healthy growth and development of children.

Reference

Effects of Lactoferrin on Sleep Conditions in Children Aged 12–32 Months: A Preliminary, Randomized, Double-Blind, Placebo-Controlled Trial
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