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# A study on probiotics in infants transitioning from partially hydrolyzed formula to standard formula

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| **Submission date**<br>04/07/2026 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>09/07/2026 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>06/07/2026 | **Condition category**<br>Other | |

**Plain English summary of protocol**
Not provided at time of registration

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# Additional identifiers

# Study information

### Scientific Title
A real-world minimal intervention randomized controlled trial on the effects and health impacts of probiotics on infants switching from partially hydrolyzed formula to regular formula

### Study objectives
To evaluate whether supplementation with Bifidobacterium infantis R0033, Bifidobacterium bifidum R0071 and Bifidobacterium helveticus R0052 improves the success rate of transitioning to standard infant formula among infants fed partially hydrolyzed formula under real-world clinical conditions.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 04/07/2026, Baoxing Center for Disease Control and Prevention (No.1 Zhongling Avenue, Lingguan Town, Baoxing County, Ya'an City, Sichuan Province, 625700, China; +86 0835-6822027; 263662086@qq.com), ref: Research Ethics Approval No. 2026(02)

### Primary study design
Interventional

### Allocation
Randomized controlled trial

### Masking
Blinded (masking used)

### Control
Placebo

### Assignment
Parallel

### Purpose
Supportive care

### Study type(s)

## Health condition(s) or problem(s) studied
Infants fed partially hydrolyzed formula (pHF) for functional dyspepsia syndrome, mild atopic dermatitis (eczema), or step-down treatment of cow's milk protein allergy

## Interventions
The intervention group receives compound probiotic powder sachets weighing 1.5 g each, containing Bifidobacterium infantis R0033 ($1.425 \times 10^8$ CFU), Bifidobacterium bifidum R0071 ($1.425 \times 10^8$ CFU), Bifidobacterium helveticus R0052 ($9.6 \times 10^9$ CFU), 0.75 g fructooligosaccharides (FOS) and 0.56 g maltodextrin. The dosage is one sachet taken twice daily; the powder can be dissolved in an adequate volume of warm water (≤40°C) or mixed with infant formula or complementary foods for oral administration.

The control group is given matching placebo powder sachets that only contain 1.5 g maltodextrin without any test probiotic strains, with identical appearance, odor and packaging to the probiotic product; the placebo is administered at the same twice-daily dosage and via the same administration methods as the intervention product.

The treatment course commences on the first day of supplementation with either the probiotic or placebo, continues for one full month after the infant achieves successful formula transition, and shall not exceed a maximum total duration of six months.

## Intervention Type
Supplement

## Primary outcome(s)
1. Success rate of transitioning to standard infant formula within the 180-day intervention period measured using a comprehensive clinical assessment including review of feeding logs, evaluation of gastrointestinal symptoms and mental status, together with regular weight measurement using calibrated infant weighing scales. Assessment will be conducted continuously during the 180-day intervention period. The final judgment of transition success is confirmed at 1 month after full conversion to standard formula, and no later than day 180.

## Key secondary outcome(s)
1. Final overall formula transition success rate measured using a review of standardized feeding records at the end of the 180-day intervention period

2. One-time formula transition success rate measured using a review of standardized feeding records at the end of the 180-day intervention period

3. Duration of pHF exposure measured using data extracted from subject feeding diaries continuously recorded throughout the 180-day intervention period at the end of the 180-day intervention period

4. Time to stable feeding on standard formula measured using data extracted from subject feeding diaries at immediately once stable formula transition is achieved

5. Proportion of infants reverting back to pHF measured using statistical calculation based on feeding records at the end of the 180-day intervention period

6. Gastrointestinal symptom frequency, duration and severity measured using an assessment using standardized symptom diary cards at all scheduled follow-up visits during the 180-day intervention

7. Atopic symptom frequency, duration and severity measured using standardized symptom diary cards at all scheduled follow-up visits during the 180-day intervention

8. Respiratory symptom frequency, duration and severity measured using standardized symptom diary cards at all scheduled follow-up visits during the 180-day intervention

9. Growth parameters (weight, length, head circumference) measured using calibrated infant anthropometric instruments at all scheduled follow-up visits within 180 days

### Completion date
02/06/2028

## Eligibility

### Key inclusion criteria
1. Infants aged ≤12 months stably fed partially hydrolyzed formula (pHF) for functional dyspepsia, mild atopic dermatitis (eczema) or step-down cow's milk protein allergy therapy, with no initiation of transition to standard intact-protein formula
2. Written informed consent signed by legal guardians ≥18 years old, who agree to fully comply with the trial feeding regimen
3. No contraindications to home-based standard formula oral challenge; no history of severe cow's milk protein allergy or comorbidities endangering formula transition safety
4. pHF use independently decided by guardians before enrolment; infants achieve stable tolerance to pHF without clinical need to switch to extensively hydrolyzed or amino acid formula
5. Guardians shall refrain from self-administering probiotics, antibiotics, prebiotics, synbiotics, postbiotics or other gut flora-modulating agents throughout the trial

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
0 Days

### Upper age limit
12 Months

### Sex
All

### Total final enrolment
0

### Key exclusion criteria

1. Infants with congenital malformations, hereditary/metabolic/infectious diseases, gastrointestinal surgery history or other conditions that may interfere with study outcomes
2. Any intake of probiotic strains contained in the study intervention within 1 month prior to enrolment
3. Infants requiring special feeding, including extensively hydrolyzed formula, amino acid formula, metabolic special formula or tube feeding
4. Current or previous participation in other clinical trials
5. Guardians unable to complete scheduled visits and comply with trial procedures
6. Other conditions deemed ineligible for enrolment by the investigator’s clinical judgment

### Date of first enrolment
20/07/2026

### Date of final enrolment
20/01/2028

## Locations

### Countries of recruitment
China

## Sponsor information

### Organisation
H&H (China) Co., Limited

## Funder(s)

### Funder type

### Funder Name
H&H (China) Co., Limited

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. Kechen, kechen@uestc.edu.cn.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | in Chinese version 1.0 | 23/05/2026 | 06/07/2026 | No | Yes |