

Supplementary Table S1. Demographic characteristics of the intervention groups¹ in the ITT population

| | Statistic | Control w/o prebiotics IMF ² (n = 155) | Control IMF (n = 146) | Concept IMF (n = 152) |
|-------------------------------------|-----------|---|-----------------------|-----------------------|
| Infant characteristics | | | | |
| <i>Sex</i> | | | | |
| Male | n (%) | 81 (52%) | 77 (53%) | 80 (53%) |
| Female | n (%) | 74 (48%) | 69 (47%) | 72 (47%) |
| <i>Ethnicity</i> | | | | |
| Chinese | n (%) | 92 (59%) | 83 (57%) | 98 (65%) |
| Malay | n (%) | 50 (32%) | 50 (34%) | 44 (29%) |
| Indian | n (%) | 9 (6%) | 5 (3%) | 5 (3%) |
| Other | n (%) | 4 (3%) | 8 (6%) | 5 (3%) |
| <i>Birth characteristics</i> | | | | |
| Weight (g) | Mean (SD) | 3135 (348) | 3174 (355) | 3158 (361) |
| Length(cm) | Mean (SD) | 48.9 (1.9) | 49.0 (1.8) | 49.3 (2.0) |
| Head circumference (cm) | Mean (SD) | 33.6 (1.2) | 33.8 (1.3) | 33.6 (1.2) |
| Caesarean section | n (%) | 44 (28%) | 39 (27%) | 33 (22%) |
| Gestational age (wk) | Mean (SD) | 38.9 (1.0) | 39.0 (1.0) | 39.0 (1.0) |
| Maternal characteristics | | | | |
| Maternal age (y) | Mean (SD) | 30.8 (5.4) | 30.0 (5.2) | 30.0 (4.8) |
| Maternal university education (yes) | n (%) | 41 (27%) | 49 (35%) | 40 (28%) |
| <i>Weight status²</i> | | | | |
| Underweight | n (%) | 19 (13%) | 21 (15%) | 20 (14%) |
| Normal | n (%) | 69 (45%) | 69 (50%) | 73 (51%) |
| Overweight | n (%) | 35 (23%) | 26 (19%) | 26 (18%) |
| Obese | n (%) | 29 (19%) | 23 (17%) | 25 (17%) |
| <i>Smoking status</i> | | | | |
| Before pregnancy (no) | n (%) | 130 (86%) | 113 (81%) | 115 (80%) |
| During pregnancy (no) | n (%) | 144 (95%) | 129 (93%) | 125 (87%) |

¹ Infants randomized to intervention formula before 4 months of age; ²IMF; infant milk formula; ²Weight status was based on pre-pregnancy BMI: Underweight BMI <18.5 kg/m², Normal weight BMI 18.5 kg/m² to < 23 kg/m², Overweight BMI 23 kg/m² to < 27.5 kg/m², Obese BMI ≥ 27.5 kg/m².

Supplementary Table S2. Mean (SD) daily formula intake per intervention group of the PP population fully formula fed before 28 days of age (ml/kg/d)

| Age (months) | Control w/o prebiotics IMF ¹ (n = 28) | Control IMF (n = 29) | Concept IMF (n = 35) |
|---------------------|--|-------------------------|-------------------------|
| 1 | 174 (44) | 169 (42) | 183 (38) |
| 2 | 165 (25) | 172 (42) | 161 (34) |
| 3 | 145 (28) | 145 (38) | 144 (30) |
| 4 | 149 (26) | 134 (34) | 136 (29) |

¹IMF; infant milk formula

Supplementary Table S3. Tolerance parameters of the AST population of infants on study product or being fully breastfed

| Parameter | Statistic | Age | Severity | Control w/o prebiotics IMF ² | Control IMF | Concept IMF | Breastfed ³ |
|---------------------------------|-----------|-------------------|----------|---|---------------|----------------|------------------------|
| Diarrhea incidence ³ | n (%; N) | 1 mo | -- | 6 (4.4%; 136) | 6 (5.2%; 115) | 7 (5.6%; 126) | 13 (11.4%; 114) |
| | n (%; N) | 2 mo | -- | 10 (8.2%; 122) | 5 (4.8%; 104) | 3 (2.5%; 119) | 2 (11.8%; 17) |
| | n (%; N) | 3 mo | -- | 7 (4.8%; 147) | 4 (3.0%; 132) | 8 (5.7%; 140) | 7 (9.3%; 75) |
| | n (%; N) | 4 mo | -- | 3 (2.0%; 147)** | 9 (6.7%; 134) | 10 (7.0%; 143) | 4 (6%; 67) |
| Regurgitation ⁴ | n (%) | 1 mo* | Absent | 63 (46%) | 52 (45%) | 66 (52%) | 37 (33%) |
| | | | Mild | 56 (41%) | 45 (39%) | 49 (39%) | 68 (60%) |
| | | | Moderate | 17 (13%) | 17 (15%) | 10 (8%) | 9 (8%) |
| | | | Severe | 0 (0%) | 1 (1%) | 1 (1%) | 0 (0%) |
| | | 2 mo [#] | Absent | 56 (46%) | 48 (46%) | 63 (53%) | 4 (24%) |
| | | | Mild | 59 (48%) | 44 (42%) | 40 (34%) | 11 (65%) |
| | | | Moderate | 7 (6%) | 12 (12%) | 15 (13%) | 2 (12%) |
| | | | Severe | 0 (0%) | 0 (0%) | 1 (1%) | 0 (0%) |
| | | 3 mo [§] | Absent | 85 (58%) | 75 (57%) | 95 (68%) | 34 (45%) |
| | | | Mild | 53 (36%) | 46 (35%) | 40 (29%) | 36 (48%) |
| | | | Moderate | 24 (6%) | 11 (8%) | 4 (3%) | 5 (7%) |
| | | | Severe | 1 (0%) | 0 (0%) | 1 (1%) | 0 (0%) |
| | | 4 mo [§] | Absent | 97 (66%) | 86 (64%) | 101 (71%) | 35 (52%) |
| | | | Mild | 46 (31%) | 43 (32%) | 37 (26%) | 30 (45%) |
| | | | Moderate | 4 (3%) | 4 (3%) | 4 (3%) | 2 (3%) |
| | | | Severe | 0 (0%) | 1 (1%) | 1 (1%) | 0 (0%) |

¹ The timing of randomisation was flexible and to evaluate the intervention products most stringently, the diary data of randomized infants before their first formula consumption (when still being breastfed) was not considered in the statistical analysis comparing intervention groups. This data was allocated to the group of breastfed infants instead. ²IMF, infant milk formula. ³The visit at 2 months of age was optional for breastfed infants, resulting in a limited number of diaries (n=17). ³Applying the WHO definition of having ≥ 3 watery stools on 1 day; incidences were tested using the MN test. ⁴Based on worst score reported during 7-d period prior to visit, total number of infants per visit similar as reported for the diarrhea incidence. *BF reference significantly different (distribution) compared to formula intervention groups ($P < 0.05$). **Statistically significant difference between Control w/o prebiotic and Concept IMF group

($P < 0.05$; MN approach). [#]Statistically significant different distribution between Control w/o prebiotic and Concept IMF group ($P = 0.032$). [§] BF reference significantly different (distribution) compared to Concept IMF intervention group ($P < 0.05$).