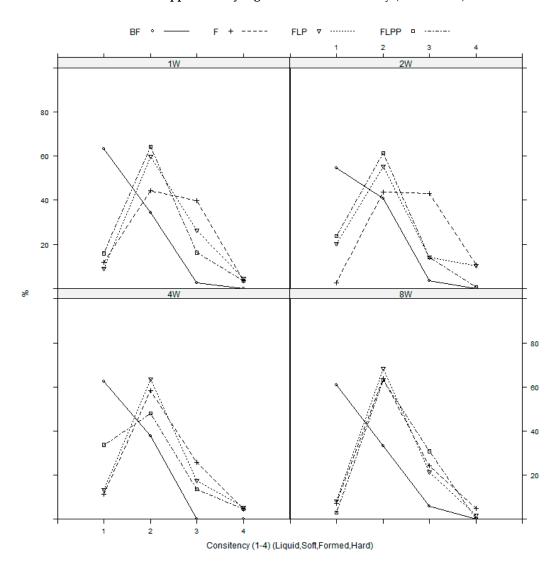


Supplementary Figure S2. Stool consistency (ITT data set).





Supplemental Table S1: CONSORT 2010 checklist of information to include when reporting a randomised trial*.

Section/Topic	Item No	Checklist item	Reported on page No
		Title and abstract	
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Dealeround and	2a	Introduction Scientific background and explanation of rationale	2
Background and objectives	2a 2b	Specific objectives or hypotheses	<u>2</u> 2
objectives	20	Methods	
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
Trial design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
D (1.1.)	4a	Eligibility criteria for participants	3
Participants	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3-4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4-5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Cample size	7a	How sample size was determined	6
Sample size	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	4
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	to conceal the seguence until interventions were assigned		4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6-7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses Results	7
Participant flow (a		For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the	_
diagram is strongly		primary outcome	7
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	7
Recruitment	14a 14b	Dates defining the periods of recruitment and follow-up Why the trial ended or was stopped	<u>'</u>
Baseline data	146	A table showing baseline demographic and clinical characteristics for each group	N/A 8
Dascillic data	13	A table showing baseline demographic and diffical characteristics for each group	U

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7-8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
		Discussion	
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	eralisability 21 Generalisability (external validity, applicability) of the trial findings		18-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17-19
		Other information	
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	Funding 25 Sources of funding and other support (such as supply of drugs), role of funders		19

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplemental Table S2: Starter Formula (control formula-first month of trial).

Nutrients	per 100kcal	per litre
Energy (kcal)	100	650
Protein (g)	2.26	14.7
Total Fat (g)	5.61	36.5
Milk fat (g)	2.8	18.3
Lecithin (g)	2.8	18.3
Lactose (g)	10.12	65.9
Minerals (g)	0.38	2.5
Na (mg)	37	240
K (mg)	95	620
CI (mg)	80	520
Ca (mg)	60	390
P (mg)	33	210
Mg (mg)	6.9	45
Mn (μg)	5	30
Se (µg)	4	26
Vitamin A (IU/μg RE)	380	2400
Vitamin D (IU/μg CE)	60	390
Vitamin E (IU/mg TE)	2	13
Vitamin K1 (μg)	8	52
Vitamin C (mg)	15	98
Vitamin B1 (mg)	0.07	0.45
Vitamin B2 (mg)	0.1	0.65
Niacin (mg)	0.5	3.3
Vitamin B6 (mg)	0.051	0.33
Folic acid (µg)	16	100
Pantothenic acid (mg)	0.7	4.6
Vitamin B12 ((μg)	0.2	1.3
Biotin (μg)	2	13
Choline (mg)	20	130
Inositol (mg)	25	160
Taurine (mg)	8.1	52
Carnitine (mg)	2	13
Fe (mg)	0.69	4.5
I (μg)	20	130
Cu (mg)	0.08	0.51
Zn (mg)	1.2	7.8
UMP (mg)	0.81	5.3
CMP (mg)	1.2	7.8
AMP (mg)	0.76	5
GMP (mg)	0.23	1.5

Standard Reconstitution clause 122 g + 900 mL water per litre; Scoop delivery weight 4.07 g Energy 30 scoops 650 kcal.