

# Baby-Led Introduction to SolidS (BLISS) study

## 1. Specific aims

In 2002, the World Health Organization recommended that the age for starting complementary feeding should be changed from 4-6 months of age to 6 months (1, 2). Although this change in age has generated substantial debate, surprisingly little attention has been paid to whether advice on *how* to introduce complementary foods should also be changed. It has been proposed that by 6 months of age most infants will have developed sufficient motor skills to be able to feed themselves rather than needing to be spoon-fed by an adult (3). This has the potential to predispose infants to better growth by fostering better energy self-regulation, however no randomised controlled trials have been conducted to determine the benefits and risks of such a “baby-led” approach to complementary feeding. This is of particular interest given the widespread use of “Baby-Led Weaning” by parents internationally.

The **aim** of the BLISS study is to determine whether a novel approach to complementary feeding using foods that an infant can feed themselves - ‘Baby-Led Introduction to SolidS’ (BLISS) - prevents overweight in young children by improving energy self-regulation, without increasing the risk of iron deficiency, choking and growth faltering.

The **primary objective** of the BLISS study is to determine whether BLISS improves weight status (BMI-for-age z-score) at 12 months of age.

**Secondary objectives** are to determine whether BLISS:

- (i) improves energy self-regulation at 12 months
- (ii) improves iron and zinc intake and status at 12 months
- (iii) improves diet quality at 7 and 12 months
- (iv) impacts favourably on parental feeding behaviours at 12 months
- (v) results in more highly developed motor skills at 6, 8 and 12 months
- (vi) is an acceptable option for parents (mess, overall acceptability, adherence) at 7 to 9 months; or
- (vii) is not an acceptable approach to infant feeding because it increases the risk of choking or growth faltering between 6 and 12 months of age
- (viii) improves weight status, energy self-regulation, diet quality, parental feeding behaviours and infant motor skills at follow up at 24 months of age.

## 2. Research design and methods

### Study design

The Baby-Led Introduction to SolidS (BLISS) Study is a 2-arm randomised controlled trial commencing in late pregnancy. Expectant mothers in their third trimester of pregnancy will be randomised into one of two groups: control group - accessing standard care; or the BLISS (intervention) group - offered BLISS advice in addition to accessing standard care. The study consists of a 12-month intervention phase with the main outcomes at 12 months of age and a follow up at two years of age.

The study was approved by the Lower South Regional Ethics Committee (LRS/11/09/037) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612001133820). Written informed consent will be obtained from all participants before randomisation.

### **Participants and recruitment**

All pregnant women booked into the Queen Mary Maternity Unit, Dunedin Hospital (Dunedin, New Zealand), will be invited to participate in the BLISS study during the third trimester of pregnancy. There are no other birthing facilities in Dunedin (population 120,000) and the number of home births is < 3%. Each woman will receive a letter that acknowledges their booking into the maternity unit and provides them with initial information about the study. Women requesting home births will be given similar information regarding the study from their Lead Maternity Carer (LMC; all mothers in New Zealand choose a LMC, usually a midwife, who is responsible for their pregnancy-related health care from pregnancy to approximately 6 weeks after birth). Just before 28 weeks gestation, the prospective participant's LMC will be contacted to ensure that invitation letters are not sent to women who have miscarried. At 28 weeks gestation, the prospective participant will receive a letter inviting them to take part in the study. This letter will contain an opt-out phone number for an answerphone where the woman can leave a message advising if they do not wish to participate. Research staff will then contact women who do not opt-out within two weeks to establish eligibility, explain the purpose of the study, answer any questions and if they were interested in participating, and organise a time for an individual meeting so that the woman can give written informed consent to participate.

#### *Inclusion criteria*

Women are eligible to participate if they: book into the birthing unit at Queen Mary Maternity Hospital before 34 weeks gestation (those women who choose a home birth are considered eligible if their midwife notifies the study before 34 weeks gestation); speak English or Te Reo Māori (the official language of the indigenous people of New Zealand); plan to live in the Dunedin area until their child is at least two years of age; and are 16 years of age or older.

#### *Exclusion criteria*

After birth, women will be excluded if their infant is born before 37 weeks gestation; or if a congenital abnormality, physical condition, or intellectual disability, which was likely to affect the infant's feeding or growth is identified.

### **Sample size**

Reference data for sample size calculations for our primary aim were obtained from our ongoing Prevention of Overweight in Infancy study for which we had data on growth from 0 to 12 months in 491 participants (4). Using a mean (standard deviation) of 17.3 kg/m<sup>2</sup> (1.4) and a correlation between repeated measures (BMI at 6 and 12 months) of 0.78, our study has 80% power at the 5% level of significance to detect a difference in BMI of 0.40 kg/m<sup>2</sup> (25% of a standard deviation) with 85 infants in each group. Comparable differences have been observed in other obesity prevention initiatives during infancy (5).

Sample sizes for selected secondary objectives for which appropriate data were available (power 80%, significance 5%) range from 63 to 84 as shown in **Table 1**.

**Table 1. Sample size calculations for secondary outcomes**

	<b>Reference data Mean (SD)</b>	<b>Source of reference data</b>	<b>Difference detected<sup>1</sup></b>	<b>Number needed per group</b>
Energy self-regulation scale	3.9 (0.8)	(6)	0.4	63
Plasma ferritin ( $\mu\text{g/L}$ )	16.0 (0.6)	(7)	5.0	84

<sup>1</sup> The difference that could be detected with 80% power and a significance level of 5%.

We aim to recruit 200 participants, which allows for a 15% drop-out for the primary objective and provided sufficient participants for the secondary objectives listed in Table 1.

### **Randomisation**

The participants will be randomised into one of the two study groups using numbers from random length blocks, after stratification for parity (including the current pregnancy: 1 child vs > 1 child) and education (non tertiary vs tertiary), as these may affect responsiveness to the intervention. Research staff will open sequentially numbered opaque, pre-sealed envelopes in the stratum to which the participant belongs and inform the participant which group they have been assigned to. All outcome assessment data will be collected by research staff blinded to group allocation.

### **Study groups**

All participants will receive standard Well Child care (a nationally funded health care programme for children under five years of age (8)) from the LMC and then Well Child agency of their choice. These free home and clinic visits provide advice on feeding, sleep and safety; and assess growth and development, hearing, vision and wellness for all children within New Zealand. Visits are typically scheduled for: birth, 1 week, 2-4 weeks, and 4-6 weeks (provided by an LMC – typically a community-based midwife); and 8-10 weeks, 3-4 months, 5-7 months, 9-12 months, 15-18 months, and 2-3 years (typically provided by a Well Child nurse) (8).

#### *Control group*

Participants randomised to the control group will receive standard Well Child care (as described above) from the providers of their choice and no additional intervention.

#### *BLISS group*

Participants randomised to the BLISS group will receive standard Well Child care (as described above) from the providers of their choice, as well as additional parent contacts for support and education from before birth to 9 months of age delivered by the BLISS study. The intervention will be delivered by an experienced lactation consultant and trained research staff who are supervised by a multidisciplinary team (dietitian, paediatrician, speech-language therapist) throughout the study. The intervention has three key components:

**Professional lactation consultant service** (third trimester of pregnancy to 6 months of age) - There will be at least five contacts with an International Board Certified lactation consultant (IBCLC):

- a) An anticipatory guidance group session before birth (at approximately 34-35 weeks gestation) to discuss breastfeeding (benefits, challenges and developing a “breastfeeding plan”), explain the nature of the free support service on offer until the infant was 6 months of age and introduce the concept of Baby-Led Introduction to SolidS.
- b) A home visit in the first week after the mother returns home from hospital, or during the first week following a planned homebirth; a support phone call and offer of a home visit at 3-4 weeks; a home visit at 3-4 months; and a phone call at 5 months of age, to provide support and education around breastfeeding (or formula feeding if requested), and to assess how the recommended approach of milk only until six months was going. Support includes encouraging: exclusive breastfeeding to 6 months, breastfeeding to at least 12 months and delaying the introduction of complementary foods until 6 months of age.
- c) The lactation consultant will also be available to supply additional support when requested by the participant until her infant is 6 months of age. This involves providing specific individualized advice to address problems with breastfeeding (or formula feeding) via extra home visit(s), phone or email contact. In our earlier Prevention of Overweight in Infancy study (4), this additional support was utilized by 36% of families (Davies, personal communication).

**BLISS advice** (5.5 to 9 months of age) – There will be at least three contacts with a trained researcher.

- a) A home visit at 5.5, 7 and 9 months of age will provide individualised advice and support for the introduction of complementary foods using the BLISS approach. Parent participants will be advised that they must not start BLISS until their infant was 180 days (i.e. 6 months of age). Research staff will encourage responsive feeding (9), ensuring that: the infant is not distracted while eating, and caregivers pay attention to the infant’s hunger and satiety cues and respond to the infant promptly and supportively. Parents will be encouraged to offer “easy” foods and more frequent milk feeds during both illness and recovery (1). A range of resources will be given to participants explaining how to follow BLISS and providing age-appropriate family recipes (see below).
- b) The research staff are also available to provide additional support when requested by the participant.

**BLISS resources** (third trimester of pregnancy to 9 months of age) - A range of resources developed and pretested for the purposes of this study will be provided to the participants, including information about the BLISS study, recipe books, everyday food lists and safety information (10). These resources follow the philosophy of BLW but also address the three key concerns that some health professionals have expressed about BLW (11): inadequate iron intake, choking and growth faltering. All resources have been developed in conjunction with a paediatric speech-language therapist to address concerns about choking. In particular, the resources encourage parents to:

- a) Test foods before they are offered to ensure they are soft enough to mash with the tongue on the roof of the mouth (or are large and fibrous enough that small pieces do not break off when sucked and chewed, e.g., strips of meat).

- b) Avoid offering foods that form a crumb in the mouth.
- c) Make sure that the foods offered are at least as long as the child's fist, on at least one side of the food.
- d) Make sure the infant is always sitting upright when they are eating – never leaning backwards.
- e) Always have an adult with the child when they are eating.
- f) Never put whole foods into the infant's mouth – the infant must do this at their own pace and under their own control.

Parents will be encouraged to offer three food types at each meal:

1. An iron-rich food (e.g., red meat, iron fortified infant cereal).
2. An energy-rich food.
3. A food such as a fruit or vegetable.

A range of resources were used at the different visits: ante-natal ( $n=1$ ), 3-4 months ( $n=1$ ), 5.5 months ( $n=6$ ), 7 months ( $n=2$ ) and 9 months ( $n=1$ ).

### **Adherence**

Adherence to infant self-feeding will be determined using data provided in the 3-day diet record on who fed the child each food (child, parent, or both) for three days over a period of a month. This provides very detailed data on adherence collected in "real-time". However, it is likely that not all participants will complete all three days of diet recording. For this reason, we will also use a brief (5-10 minute) feeding questionnaire at 2, 4, 6, 7, 8, 9 and 12 months to assess adherence to self-feeding.

Adherence to the recommendation to exclusively breastfeed to 6 months, and to introduce complementary foods at six months, will also be determined using the brief feeding questionnaires at 2, 4, 6, 7, 8, 9 and 12 months.

### **Outcome measures**

The timing of the outcome measures is presented in **Table 2**. The primary outcome measure is BMI-for-age z-score (calculated using body weight and length). Secondary outcome measures included: energy self-regulation, iron and zinc intake and status, diet quality, parental feeding behavior, overall acceptability, choking, and growth faltering.

**Table 2.** Interventions and outcome measures at specified time points

	Time point												
	34-35wk gestation	1wk	3-4wk	2mo	3mo	4mo	5mo	5.5mo	6mo	7mo	8mo	9mo	12mo
<b>Lactation advice</b>	●	●	●		●		●						
<b>BLISS advice</b>								●		●		●	
<b>Feeding Questionnaire (phone)</b>													
Breastfeeding status				●		●			●	●	●	●	●
Extent of spoon and puree feeding				●		●			●	●	●	●	●
<b>Anthropometry</b>													
Weight									●	●	●	●	●
Length									●				●
<b>Calendar</b>													
Gagging and choking									●		●		
<b>Weighed diet record</b>										●			●
<b>Key questionnaires</b>													
Energy self-regulation									●				●
Parental feeding behaviour													●
Motor development									●		●		●
Acceptability and cost										●	●	●	●
Gagging and choking									●	●	●	●	●
<b>Blood collection</b>													
Iron status													●
Zinc status													●

 BLISS participants receive this  
 BLISS and control participants receive this

### *Anthropometric measures*

Birth weight will be accessed from hospital records. Length will be measured at 6 and 12 months and body weight at 6, 7, 8, 9 and 12 months of age by trained anthropometrists, using standard paediatric anthropometric techniques (12). All infant participants will wear a standard nappy of known weight which will be provided to the parent and a singlet top. The weight of both items of clothing will be subtracted from the reported body weight before analysis. Body weight will be measured and recorded to the nearest 0.1kg using digital scales (Seca, Model 334, Hamburg, Germany), which are calibrated (using a 1kg or 5kg calibration weight) prior to each measurement session. Recumbent length will be measured to the nearest 0.1cm using a portable length board (Harlow Healthcare Rollameter, UK) which is calibrated (using a 90cm calibration rod) prior to each measurement session.

Body weight and length measurements will be taken in duplicate and if the second measurement differs by more than 0.1kg for weight and 0.7cm for length, a third measure will be taken (12). An average of the measures will be recorded (where three measurements were taken, the two closest will be averaged; where the three measures are equidistant the median value will be used). The following will be calculated: BMI and BMI-for-age z-score at 6 and 12 months of age, and weight-for-age z-score at 6, 7, 8, 9 and 12 months of age, using the WHO child growth standards (13).

Repeated body weight assessment of infants from 6-12 months (monthly from 6-9 months) will be used to identify growth faltering. Any infant identified as possibly growth faltering was referred to a paediatrician for further assessment.

### *Questionnaires*

A self-administered baseline questionnaire will collect socio-demographic information such as ethnicity, maternal and paternal education, and New Zealand Deprivation Index 2013 score, an indicator of the level of household deprivation (14).

A questionnaire will be completed by adult participants when their infant is 6 and 12 months of age to assess the infant's energy self-regulation using an 8-item scale created by Tan et al. (6).

Infant temperament will be assessed at 6 months of age using the revised infant temperament questionnaire (15). The 'Ages and Stages' questionnaire (16) will be used in questionnaires at 6, 8 and 12 months of age to assess fine and gross motor skills. Parental feeding behaviour and perception of "picky eating" will be assessed when the infant was 12 months of age (17). Eating behaviour will also be assessed at 12 months using the Children's Eating Behaviour Questionnaire by Wardle et al. (18).

Brief feeding questionnaires administered at 7, 8, 9 and 12 months of age will assess a range of issues including the acceptability to parents of the complementary feeding approach used. Acceptability focuses particularly on "mess", convenience, cost and the extent to which the approach "suits you as a parent". At 8 and 9 months, the primary carer will also be asked about their perception of their partner's attitude to the complementary feeding approach used.

### *Choking*

Questions on gagging and choking, including frequency and a description of the cause and outcome of the most serious choking event in the past month, will be asked in questionnaires at 6, 7, 8, 9 and 12 months of age.

Calendars will also be distributed to parents at 6 and 8 months of age and parents asked to indicate on the calendar, each day for a month, whether the infant has gagged or choked that day. Education will be provided on the difference between gagging and choking to help parents distinguish between them. If a choking episode occurs, further information will be requested including the food or drink involved, the form of the food or drink and how the choking episode was resolved.

#### *Dietary assessment*

The parent will be asked to complete a 3-day weighed diet record for the infant at 7 and 12 months of age. Dietary scales accurate to  $\pm 1$ g (Salter Electronic, Salter Housewares Ltd. Tonbridge, UK) will be used to measure all food and drink consumed by the infant on three randomly assigned non-consecutive days of the week (two week days and one weekend day) over a three-week period. Each day of the week will be represented an approximately equal number of times among participants to control for day-of-the-week effects. Parents will receive detailed oral and written instructions from trained research staff on how to complete the 3-day diet record.

The diet record has four key components: (a) the diet record, where information is recorded regarding the time of the day, type and brand of the food or drink, preparation method, weight of the food or drink, consistency of the food or drink (puréed, mashed, diced or whole), who fed the child (parent, child or both) and the total weight and estimated proportions of leftover food or drink; (b) a description of any recipes used, including the raw amounts of ingredients, the cooking method and proportion of the total recipe fed to the child; (c) an “end of day questionnaire”, which determines whether this was a typical eating day for the child and how the meals compared to those consumed by the rest of the family; and (d) whether the child had any iron or zinc containing supplements, including type, brand and amount taken.

On completion of the 3-day diet record, a researcher will check the record for omissions and clarify these with the parent. All diet records will be entered into the dietary analysis software programme Kai-culator (University of Otago, New Zealand) for analysis. Kai-culator uses the New Zealand Food Composition Database, FOODfiles (19); nutrient data for commonly consumed recipes collated in the 2008/09 New Zealand Adult Nutrition Survey (20); and nutrient data for commercial infant foods collated by the research team (21).

#### *Biochemical assessment*

At 12 months of age a non-fasting venous blood sample will be taken from an antecubital vein between 8:30am and 11:30am. A questionnaire will be completed 24 hours before the blood test appointment to determine any recent illness which may affect blood analyses. If the infant is unwell (presence of fever, diarrhoea or vomiting), the blood sample collection will be delayed for 14 days.

Parents will be asked to:

- a) Give their infant a milk feed and stop feeding exactly 90 minutes prior to the blood test appointment (22).

- b) Not give their infant any other food or fluid (except water) until after the blood test appointment.
- c) Apply a local anaesthetic, Ametop gel (Smith & Nephew Ltd., Auckland, New Zealand), 1-4 hours prior to the blood test appointment. The gel is to be applied to the inside elbow crease of both arms to numb the phlebotomy site, and so that if the initial attempt is unsuccessful, the blood sample could be collected from the other arm.

A trained phlebotomist will collect one peripheral venipuncture blood sample (7.5 mL) from each infant participant into a trace element-free lithium heparin anticoagulated tube (Sarstedt S-Monovette, Nümbrecht, Germany). Blood samples will be refrigerated immediately after collection and for no longer than two hours before centrifuging at 2500 x g for 10 minutes. Before centrifuging, 1 mL of whole blood will be removed for analysis of complete blood count and plasma ferritin. Aliquots of plasma will be stored at -80°C until subsequent analysis of soluble transferrin receptor (sTfR), C-reactive protein (CRP),  $\alpha$ -1 acid glycoprotein (AGP) and plasma zinc. A Cobas C311 automatic electronic analyzer (Roche, New Zealand) will be used to determine sTfR, CRP and AGP concentrations in the Department of Human Nutrition Trace Element Laboratory (University of Otago, New Zealand).

Complete blood count will be determined using a Sysmex XE 5000 automatic electronic analyzer (Kobe, Japan) and plasma ferritin concentration using a Cobas 8000 unit e 602 (Roche, United States of America) on the day of blood collection by Southern Community Laboratories Ltd. (Dunedin, New Zealand).

Any infant with iron results that were of concern (haemoglobin  $\leq$  105 g/L and/or plasma ferritin  $\leq$  15  $\mu$ g/L) will be referred to their general practitioner for treatment but remain in the study so they could be included in the intention to treat analysis.

### **Adverse events**

The study will identify and monitor adverse events (defined as any untoward or unfavourable medical occurrence in a participant, including any abnormal sign, symptom, or disease, temporally associated with the participant's participation in the research, whether or not it is considered to be related to the participant's participation in the study) and "serious adverse events" (defined as any adverse event temporally associated with the participant's participation in the BLISS study that results in death, is life-threatening, requires inpatient hospitalization, results in a persistent or significant disability or incapacity, any other adverse event that, based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed) (23).

Specific arrangements will be in place for immediate investigation and referral to the study's paediatric clinicians of choking episodes (reported directly by the participant, or where the involvement of a health professional for a choking incident was reported in the Calendar or in study questionnaires) and growth faltering (identified during the 6, 7, 8, 9 and 12 month anthropometric measurement sessions).

Care will be also taken to identify and investigate: (a) multiple occurrences of the same adverse event in the same participant, (b) occurrence of different adverse events

in the same participant, (c) occurrence of the same adverse event in multiple participants.

### **Quality control**

Measures will be put in place to ensure that the information provided to participants is standardized, that data collected are of high quality and that data collection is as complete as possible.

**Standard operating procedures** – Detailed protocols have been developed and used for all study-related tasks including participant contacts and data management tasks.

**Observed interviews** – Research staff will be observed by the investigators of the study twice yearly to ensure that the standard operating procedures are being followed.

**Data audits** - Every three months a data audit will be conducted to check for completeness of collected data.

**Technical error of measurement** – Inter-evaluator technical error of measurement (TEM) will be determined for all research staff who were responsible for making anthropometric measurements, after initial training and then annually. The TEM will be determined by repeated anthropometric measurements on a separate sample of 5-10 infants (24).

**Checking of weighed diet records** – Diet records are checked when they were received. If any data are missing or unclear the participant will be contacted for clarification. After the diet records have been entered in Kai-culator, a New Zealand Registered Dietitian will check each diet record and correct any errors made in the initial calculation and entry of the record, and ensure consistency in the data entry decisions.

**Biomarkers** – The precision of the biochemical assays will be checked using a pooled plasma sample and their accuracy via the use of certified reference materials or manufacturer’s controls, where appropriate.

### **Follow-up at 24 months of age**

Participants will be followed up when the child participant was 24 months of age. The follow up will consist of anthropometric measurements, a 3-day diet record and a comprehensive questionnaire assessing most of the variables outlined previously (energy self-regulation, parental feeding practices, infant fine and gross motor skills, perception of “picky eating” and acceptability of the complementary feeding approach - all as described above).

### **Statistical analysis**

The primary analysis will determine whether BLISS results in differences in BMI-for-age z-score at 12 months of age (i.e. at the end of the intervention) and 24 months (i.e. at the end of the planned follow up) of age. Data will be analysed according to intention to treat, following CONSORT guidelines (25), based on those that had at least one follow-up BMI measure, using Stata 13 or a later version (StataCorp, College Station, TX).

Linear mixed-effects models with participant-level random intercepts will be used to estimate the difference in BMI z-score (primary outcome) and BMI (secondary outcome) between BLISS and Control groups, adjusting for infant age, infant sex, and the stratification variables parity (first child, subsequent child) and maternal education (tertiary, non-tertiary).

Logistic regression will be used to estimate the relative risk (95% CI) of being overweight (BMI  $\geq$  95<sup>th</sup> from the WHO growth standards (13)), because the prevalence of overweight defined in this way is expected to be low.

Chained equations will be used to estimate missing values using a model which includes age, weight, length and BMI as well as terms for sex, parity, maternal education, household deprivation, marital status, and weeks of exclusive breastfeeding. This type of model assumes the data are missing at random (MAR).

Regression analysis will be used to compare the BLISS and Control groups for energy self-regulation and eating behaviors, adjusting for birth weight, infant age and sex, and the stratification variables parity (first child, subsequent child) and maternal education (tertiary, non-tertiary). Regression analyses will also be used to analyze secondary outcomes including iron and zinc intake and status.

Adherence to a baby-led approach to feeding will be defined as the infant feeding themselves most or all of their food (from the questionnaire data assuming greater completion than the diet record data). Analyses of differences between groups for adherence will be limited to those who are eating solids, and will be presented as relative risks (95% CI).

If numbers allow, we will undertake a per protocol analysis. This will be restricted to those who meet adherence criteria (defined as those in the BLISS group feeding themselves most or all of their food at 7 months of age, defined as those in the control group being mostly or all parent fed at 7 months of age). The difference (95% CI) in BMI z-score between the groups will be estimated using similar methods as the main analysis.

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