

Application for re-authorisation of MAIF Agreement: Infant Nutrition Council's response to ACCC Draft Determination

Overview

- 1 The Infant Nutrition Council (**INC**) thanks the ACCC for the opportunity to respond to the draft determination (**Draft Determination**)¹ on its application for re-authorisation of the MAIF Agreement and associated guidelines (**INC Application**).
- 2 In the Draft Determination, the ACCC states that it is considering whether to grant authorisation subject to a condition that would extend the advertising restrictions in clause 5(a) of the MAIF Agreement to what the ACCC refers to as 'all breast milk substitutes', which the ACCC asserts includes Toddler Milk (the **Proposed Condition**).²
- 3 The INC does not consider that the imposition of the Proposed Condition would be appropriate, having regard to the scope of the ACCC's powers and the factual circumstances underpinning the INC Application.
- 4 The arguments in support of the INC's position are set out in this submission. In summary:
 - (a) The Proposed Condition is beyond the scope of the ACCC's power to impose a condition under section 88(3) of the CCA. The INC considers that imposing the Proposed Condition would in effect amount to the ACCC seeking to implement legislative reform and redraft the MAIF Agreement to create what the ACCC considers to be an 'ideal' industry code. Further, those changes would take effect without the usual regulatory assessment and consultation processes that ordinarily accompany the consideration of such reforms.
 - (b) The regulation of Toddler Milk marketing is a matter of public health policy, which should be addressed by the Federal Government rather than be implemented through the ACCC authorisation process. Any extension of the scope of the MAIF Agreement should be considered by appropriate public health departments, including through the upcoming Federal Government review of the MAIF Agreement.
 - (c) As the ACCC acknowledges in the Draft Determination, the restrictions in the MAIF Agreement are likely to promote and protect breastfeeding, and result in significant public benefits compared to the counterfactual.³ The INC considers that the Proposed Condition may erode those public benefits, as: (i) existing signatories may be unwilling to remain signatories going forward; (ii) new signatories may be deterred from signing up to the MAIF Agreement; and/or (iii) the Proposed Condition may have a chilling effect on new entry more broadly.
 - (d) The ACCC's consideration of whether the Proposed Condition may be appropriate in this case appears to be predicated on a number of matters (put forward by interested third parties) that, in the INC's view, do not have a proper factual basis. In particular, the INC's position is that:
 - (i) Based on the relevant Federal Government policies and publications, Toddler Milk should not be regarded as a breast milk substitute.
 - (ii) There is no evidence that marketing of Toddler Milk has resulted in reduced breastfeeding rates in Australia.

¹ <https://www.accc.gov.au/system/files/public-registers/documents/Draft%20Determination%20-%20001.03.21%20-%20PR%20-%20AA1000534%20INC.pdf>

² Draft Determination, [4.87].

³ Draft Determination, [4.15] – [4.18].

- (iii) The MAIF Complaints Committee is effective in addressing issues arising out of infrequent instances of cross-promotion of Infant Formula.
- 5 This response by the INC to the Draft Determination is structured as follows:
- (a) **Part A** sets out why the INC considers that the Proposed Condition is not an appropriate exercise of the ACCC's power to impose a condition to authorisation; and
- (b) **Part B** explains why there is no proper basis to support a number of the factual assertions relied on by the ACCC to justify the imposition of the Proposed Condition.
- 6 Where a term used in this submission is defined, the definitions in: (i) the INC Application; and (ii) the INC's response to third party submissions dated 18 January 2021, are to be adopted.

Part A: Exercise of ACCC's power to impose the Proposed Condition is not appropriate

The Proposed Condition is beyond the scope of the ACCC's statutory powers

- 7 The INC submits that the Proposed Condition is beyond the scope of the ACCC's power to impose a condition under section 88(3) of the CCA for the reasons set out below.

Imposing the Proposed Condition is tantamount to introducing legislative reforms

- 8 The MAIF Agreement was developed in consultation with the Federal Government, the Infant Formula industry and other stakeholders. The aim of the MAIF Agreement is to promote and protect breastfeeding, while also ensuring that appropriate information is provided to those who are unable to (or make an informed choice not to) breastfeed.
- 9 Extending the scope of the MAIF Agreement to 'all breast milk substitutes' (which the ACCC asserts includes Toddler Milk) would involve fundamental changes to the MAIF Agreement as it currently operates. Those changes would result in significant additional restrictions being imposed on the business activities of the signatories.
- 10 The INC submits that if the ACCC were to impose the Proposed Condition, the outcome would be tantamount to the ACCC seeking to (in effect) implement de-facto legislative reforms. Further, the measures put in place would not be accompanied by the policy development processes that ordinarily accompany the introduction of reforms. Those processes would usually involve a detailed review of the available empirical evidence and research, conducting a regulatory impact assessment and undertaking extensive consultation with relevant stakeholders.

The ACCC does not have the power to redraft the MAIF Agreement

- 11 The ACCC acknowledges in its Guidelines that it is not for the ACCC to use its power to impose conditions in order to redraft substantially or redesign proposed conduct, simply to make the conduct better.⁴ This principle was first articulated by the Australian Competition Tribunal (the **Tribunal**) in *Re Medicines Australia (Medicines Australia)*,⁵ and was recently upheld by the Tribunal in *Application by Flexigroup Limited (No 2)*.⁶
- 12 In *Medicines Australia*, the Tribunal found that the imposition of a condition designed to enhance or increase the likelihood of public benefits; or to reduce or limit the likelihood of public detriments did not constitute a redrafting of a code.⁷

⁴ ACCC Guidelines for Authorisation of conduct (non-merger) (**Guidelines**), [9.5].

⁵ *Re Medicines Australia Inc* [2007] ACompT 4.

⁶ *Application by Flexigroup Limited (No 2)* [2020] A CompT 2.

⁷ Guidelines, [9.5] reflecting the principle laid out by the Australian Competition Tribunal in *Re Medicines Australia Inc* [2007] ACompT 4, [134] and later affirmed in *Application by Flexigroup Limited (No 2)* [2020] A CompT 2, [141].

- 13 The INC submits that in the present scenario, the nature of the condition proposed and underlying factual circumstances are fundamentally different to those in *Medicines Australia*. The condition considered in *Medicines Australia* was limited in scope and did not involve a substantial variation to the conduct that was the subject of the authorisation application. In contrast, the Proposed Condition seeks to expand the restrictions in the MAIF Agreement to encompass a broad range of conduct (ie, the advertising and promotion of what the ACCC refers to as 'all breastmilk substitutes', including Toddler Milks) that is entirely outside the current scope of the agreement.
- 14 If the Proposed Condition were imposed, the INC submits that extensive variations to the MAIF Agreement (and the conduct of the signatories seeking to comply with the MAIF Agreement) would be required. The result is that the ACCC is, in effect, seeking to redraft substantial parts of the MAIF Agreement.
- 15 At a minimum, to extend the limitations on advertising set out in Clause 5(a) to apply to Toddler Milk as envisaged by the Proposed Condition:
- (a) The MAIF Agreement would need to be redrafted to update clause 2 (scope); clause 3 (definitions), clause 5(a) (the general public and mothers) and clause 10 (implementation and monitoring) to include Toddler Milks and manufacturers and importers of Toddler Milks.
 - (b) The Committee's *Interpretation of the MAIF Agreement related to Clause 5(a): The general public and parents and/or carers* and *Interpretation of Clauses 5(a) & 9(b) of the MAIF Agreement relating to information on appropriate age range on infant formula labels* would need to be redrafted.
- 16 However, in practice, further and extensive variations would be required. This is because clause 5(a) includes a general prohibition in the following terms: '*Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public.*'
- 17 At the same time, other clauses in the MAIF Agreement provide prohibitions on specific forms of conduct which amount to the 'promotion of infant formula to the general public'. For example, the prohibitions in clause 6 restrict the promotion of infant formula to the general public through the health care system while the prohibitions in clauses 5(b)-(d) restrict the provision of samples, distribution of gifts and direct contact respectively.
- 18 To avoid uncertainty for signatories in relation to these targeted prohibitions and to ensure there are no internal inconsistencies within the MAIF Agreement many, if not all, other clauses, as well as any associated guidelines, would need to be considered and potentially redrafted to implement the Proposed Condition.⁸

The Proposed Condition is not incidental to the conduct sought to be authorised

- 19 In circumstances where the Tribunal has previously endorsed the imposition of a condition to authorisation, that condition has (as a factual matter) been incidental or ancillary to the conduct sought to be authorised. The INC submits that the ACCC does not have the power to impose conditions that are extraneous to the conduct sought to be authorised and cannot be regarded as incidental to that conduct.
- 20 The Tribunal's decision in *Medicines Australia* illustrates this point.⁹ In that case, Medicines Australia applied for authorisation by the ACCC of its industry code, which sought to regulate

⁸ These include: MAIF Complaints Committee's interpretation of the MAIF Agreement related to electronic media marketing; MAIF Complaints Committee's interpretation of Clause 7(a) of the MAIF Agreement relating to scientific and factual information provided to health care professionals; MAIF Complaints Committee's interpretation of the MAIF Agreement related to information and education.

⁹ Medicines Australia (a national association representing the prescription medicines industry) applied for authorisation by the ACCC of its Code of Conduct (the **Code**), which sought to regulate certain activities including the advertising and promotion of prescription

(among other things) the advertising and promotion of prescription medicines to doctors. The ACCC authorised the code subject to a condition requiring Medicines Australia to publicly report details about all functions attended by healthcare professionals sponsored by pharmaceutical companies to increase the likelihood that public benefits claimed would be realised. That condition was upheld by the Tribunal on appeal.

- 21 The INC submits that in *Medicines Australia*, the relevant condition was clearly incidental to the conduct sought to be authorised. That is because it was directed towards enhancing public benefits by maximising the prospects of the signatories complying with the code. There was no suggestion that the conduct that was the subject of the authorisation application itself should be expanded.
- 22 Here, the Proposed Condition cannot be regarded as incidental or ancillary to the MAIF Agreement. The Proposed Condition expands the scope of the conduct that is to be restricted under the MAIF Agreement to additional products, rather than promoting or monitoring compliance with the agreement.

The regulation of Toddler Milk marketing is a matter for Federal Government policy

The regulation of Toddler Milk marketing is a matter for public health policy

- 23 The regulation of Toddler Milk marketing is a matter of public health policy, which should be addressed by the Federal Government rather than being implemented through the ACCC authorisation process.
- 24 The INC considers that effective evidence-based health policy is best developed by government bodies with relevant subject matter expertise and experience, rather than the ACCC. Government stakeholders, such as the Department of Health, the National Health and Medical Research Council (**NHMRC**) and the Australian Institute for Health and Welfare, are better placed to evaluate the available evidence regarding the impact of Toddler Milk marketing on breastfeeding rates, and consider the application of that evidence to the Australian context.
- 25 The ACCC itself acknowledged in the 2016 Determination that whether marketing restrictions in the MAIF Agreement should be extended to Toddler Milk is a policy decision for the Federal Government.¹⁰

The MAIF Agreement should align with Federal Government policy

- 26 The INC considers that the manner in which the WHO Code is implemented in Australia is properly a matter for Federal Government policy. The WHO Code is not legislation in Australia and itself notes that governments should give effect to the principles and aims of the Code as appropriate to their own social and legislative framework.¹¹
- 27 It is current Federal Government policy that the WHO Code is implemented in Australia through the combination of the MAIF Agreement, the FSANZ Standard, the NHMRC *Infant Feeding Guidelines: Information for Health Workers (Infant Feeding Guidelines)* and the Australian Consumer Law.¹²
- 28 Current Government policy allows the marketing of Toddler Milks under FSANZ Standard 2.9.3 and there is good reason for that. There is considerable evidence that Toddler Milks are supplementary foods which assist parents and caregivers to meet nutritional needs of young children (avoiding nutrient deficiencies and undernutrition), particularly during the transition period

medicines to doctors. The ACCC authorised the Code subject to a condition requiring Medicines Australia to publicly report details about all functions sponsored by pharmaceutical companies.

¹⁰ 2016 Determination, [108].

¹¹ WHO Code, p7.

¹² INC Submission, pp 9-10.

from breastfeeding (or Infant Formula) to family foods.¹³ In these circumstances, it is important that parents and caregivers have access to accurate information about their child's nutritional needs and understand the options available. The marketing of Toddler Milk is an important and reliable source of information in this decision-making process.

- 29 As outlined in the Nous Effectiveness Review, many of the WHO Code recommendations are most relevant to developing countries, where issues such as poverty, illiteracy and hygiene present specific challenges to infant feeding.¹⁴ Australia is not under any obligation to implement the WHO Code in its entirety, nor does the MAIF Agreement need to be aligned in its entirety to the WHO Code in order to deliver successful outcomes.¹⁵
- 30 In May 2016, the WHO Secretariat presented *Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children* to the WHA (**WHO Guidance**).¹⁶ The guidance included recommendations for restricting the marketing of foods and beverages for children under the age of 36 months, including Toddler Milk. On 28 May 2016, the WHA 'welcomed with appreciation' (but did not formally endorse) the WHO Guidance.¹⁷ As such, the WHO Guidance does not form part of the WHO Code to which the Federal Government is a signatory, rather, it is a guidance document.
- 31 The Federal Government has not given any indication that it considers the MAIF Agreement should be extended in accordance with the WHO Guidance. A review of the MAIF Agreement may conclude that an extension of the agreement to include Toddler Milks is not warranted. It is not for the ACCC to pre-empt any policy decisions made by the Federal Government in this regard.
- 32 In addition, the INC notes that the ACCC has itself stated on the subject of industry coverage, which also relates to the scope of the MAIF Agreement, '*these arrangements are voluntary, and the extent to which additional coverage or mandatory regulation is required is a policy issue beyond the ACCC's role in this assessment*'.¹⁸ The INC submits that the same principles apply to an extension of the scope of the MAIF Agreement to Toddler Milks.

The upcoming Government Review is the proper forum for considering Toddler Milk marketing

- 33 As stated in the Draft Determination, the Department of Health is currently developing an implementation plan for the Breastfeeding Strategy.¹⁹ The Department of Health has stated that the issue of whether restrictions should be imposed on Toddler Milk marketing requires further consideration and should be explored in detail as part of the Federal Government's proposed review of the MAIF Agreement this year (**Government Review**).²⁰
- 34 The INC submits that the Government Review is the proper forum for considering Toddler Milk marketing, as this will better support the development of effective evidence-based public health policy which is appropriate for the Australian social and legislative framework.

¹³ Lovell AL, Davies PSW et al. 'Compared with cow milk, a growing-up milk increased vitamin D and iron status in healthy children at 2 years of age: the growing-up milk-lite (GUMLi) randomized controlled trial' *The Journal of Nutrition* (2018) 148,1570-9; Lovell AL, Davies PSW et al 'A comparison of the effect of Growing Up Milk – Lite (GUMLi) vs cows' milk on longitudinal dietary patterns and nutrient intakes in children aged 12-23 months: the GUMLi randomised controlled trial' *British Journal of Nutrition* (2019) 121, 678-687; Hojsak I, Bronsky J et al. 'Young child formula: a position paper by the ESPGHAN Committee on Nutrition' *Journal of Pediatric Gastroenterology and Nutrition* (2018) 66,177-85.

¹⁴ Nous Effectiveness Review, p39.

¹⁵ Nous Effectiveness Review, p39.

¹⁶ WHO, 'Maternal, infant and young child nutrition: Guidance on ending the inappropriate promotion of foods for infants and young children' (13 May 2016) available at https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf?ua=1

¹⁷ WHA, WHA69.9 Agenda item 12.1 'Ending inappropriate promotion of foods for infants and young children' (28 May 2016) available at https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf?ua=1, Resolution 1.

¹⁸ Draft Determination, [4.55].

¹⁹ Draft Determination, [2.19].

²⁰ Department of Health Submission, p3.

- 35 Given this, the INC submits that the ACCC's consideration of the INC Application should be based on the MAIF Agreement as it stands, which aligns with current Federal Government policy. In any event, any significant changes in the applicable policies that arise out of the Government Review are likely to provide a basis for the ACCC to review the authorisation if it wishes to do so.

The Proposed Condition may erode public benefits arising from the MAIF Agreement

- 36 As the ACCC acknowledges in the Draft Determination, the restrictions in the MAIF Agreement are likely to promote and protect breastfeeding, and result in significant public benefits compared to the counterfactual.²¹ The INC wholly supports breastfeeding and recognises that breastfeeding provides the best nutritional start for infants.
- 37 The INC considers that the Proposed Condition may erode those public benefits. If the condition is imposed, current signatories may be unwilling to remain parties to the MAIF Agreement if faced with the implementation of significant additional restrictions on their business activities. Potential new signatories (including new industry entrants) are likely to be deterred from signing up to the MAIF Agreement. Similarly, the Proposed Condition may have a chilling effect on new entry more broadly.
- 38 The INC notes that since the 2016 Determination, there has been a significant increase in the number of signatories to the MAIF Agreement (from 10 signatories in 2016 to 17 signatories in 2021). In the INC's view, the increase in signatories has enhanced the public benefits delivered under the MAIF Agreement.
- 39 If the number of signatories to the MAIF Agreement declines as a result of the Proposed Condition, there is likely to be an erosion of the public benefits associated with the MAIF Agreement. As identified by the ACCC any alternative regulatory response by the Federal Government would likely take a number of years to develop and implement and would likely involve development, implementation and operational costs.²²

Part B: There is no proper factual basis for certain assertions in the Draft Determination

- 40 The ACCC's consideration of whether the Proposed Condition may be appropriate in this case appears to be predicated on a number of matters (put forward by interested third parties) that, in the INC's view, do not have a proper factual basis. The INC sets out its position in relation to those matters below.

Toddler Milk is not a breastmilk substitute

- 41 The ACCC states in the Draft Determination that breast milk substitutes potentially include '*infant formula and toddler milk products*'.²³ It appears that the ACCC's basis for that statement is the WHO Guidance referred to in paragraph 30 above.
- 42 The INC rejects the proposition that Toddler Milk should be regarded or classified as a breast milk substitute. The INC considers that the only food that should properly be regarded as a breast milk substitute is Infant Formula. That is because:
- (a) Toddler Milk is intended as an alternative to cow, sheep, goat and other non-human milks for young children over 12 months of age (unlike Infant Formula, which is a breast milk substitute for children 12 months of age and younger);

²¹ Draft Determination, [4.15] – [4.18].

²² Draft Determination, [4.11].

²³ Draft Determination, [2.6].

- (b) the nutritional composition of Toddler Milk is different to the nutritional composition of Infant Formula;
 - (c) Toddler Milk and Infant Formula are regulated under separate FSANZ standards. Specifically, Infant Formula is regulated under FSANZ standard 2.9.1 as a 'breast-milk substitute' while Toddler Milks are regulated under FSANZ standard 2.9.3 as a 'formulated supplementary food for young children';²⁴
 - (d) the Infant Feeding Guidelines published by NHMRC state that 'infant formulas should be used as an alternative to breastmilk until 12 months of age';²⁵ and
 - (e) the Australian Government, including the Department of Health, has not suggested or put forward a position to the effect that breast milk substitutes include Toddler Milk.
- 43 As noted above, the WHA did not endorse the WHO Guidance, but rather 'welcome[d] it with appreciation'.²⁶ Further, the WHO Code is not a mandate for its signatories, but rather provides guidelines for Member States (who must then interpret and apply the code within their own jurisdictions as they deem appropriate). Guidance documents developed by the WHO are aimed at addressing all populations, some of which report undernutrition as a major factor in up to 45% of childhood deaths.²⁷ The INC acknowledges that breast milk continues to be an important source of nutritional needs for toddlers in countries affected by such issues. This is not, however, the experience in Australia and the WHO Guidance must be considered in that context.
- 44 The ACCC has expressed concerns that some young infants are being fed Toddler Milk, which cannot meet their nutritional needs.²⁸ The INC does not believe there to be robust evidence of this in Australia. However, the INC does consider that this risk highlights the nutritional differences between Infant Formula (which is a breast milk substitute) and Toddler Milk (which is specially formulated for children over 12 months).

There is no evidence that Toddler Milk marketing has reduced breastfeeding rates

Breastfeeding rates are increasing in Australia

- 45 The ACCC states in the Draft Determination that the promotion of breast milk substitutes (which the ACCC asserts includes Toddler Milk) in Australia is likely to negatively influence the rates of breastfeeding in Australia.²⁹ The INC urges the ACCC to consider the issue of whether the promotion of Toddler Milk (which, unlike Infant Formula, is not a breast milk substitute) in fact reduces breastfeeding rates in light of the available evidence.
- 46 Toddler Milk was introduced to the Australian market in the 1990s. The INC does not consider there is any evidence that the promotion of Toddler Milk has had a detrimental impact on breastfeeding rates in Australia. On the contrary, in 2012 the NHMRC reported in its Infant Feeding Guidelines that:³⁰

There have been significant increases in both the rate and duration of breastfeeding over the last few decades. Rates of breastfeeding were low in Australia in the 1960s – records from Victoria

²⁴ Under FSANZ 2.9.3-8(4) Toddler Milk labelling must include a statement describing Toddler Milk as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements, supporting the position that Toddler Milk is not a breast-milk substitute.

²⁵ NHMRC *Eat for Health - Infant Feeding Guidelines Information for Health Workers*, available at <https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers>, page 1.

²⁶ WHA, WHA69.9 Agenda item 12.1 'Ending inappropriate promotion of foods for infants and young children' (28 May 2016) available at https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf?ua=1, Resolution 1.

²⁷ WHO, 'Infant and Young Child Feeding, Factsheet' (24 August 2020) available at <https://www.who.int/news-room/factsheets/detail/infant-and-young-child-feeding>.

²⁸ Draft Determination, [4.26].

²⁹ Draft Determination, [4.17].

³⁰ NHMRC *Eat for Health - Infant Feeding Guidelines Information for Health Workers*, available at <https://www.nhmrc.gov.au/about-us/publications/infant-feeding-guidelines-information-health-workers>, page 11

show that only 50–60% of mothers were breastfeeding when discharged from hospital, with just 21% still breastfeeding after 3 months. In the early 1970s, breastfeeding rates started to rise again in Australia and comparable overseas countries, beginning in the higher socioeconomic groups. By 1983, the prevalence and duration of breastfeeding in Australia were both among the highest in the western world, with 85% of infants breastfed at discharge and 54–55% at 3 months. Breastfeeding remained around this level for the next two decades. There has been a gradual increase in initiation and duration rates in recent years.

47 Since the publication of the Infant Feeding Guidelines, a number of further studies demonstrate that the percentage of infants who are breastfed until 12 months of age has risen over the previous two decades. This is illustrated in **Table 1** below, which sets out the results of national and state-based studies on breastfeeding rates. The studies referred to in Table 1 include:

- (a) **National Health Surveys:** carried out from 1995 to present. National Health Surveys are commissioned by the Federal Government and provide an official source of independent and reliable information.
- (b) **Newby and Davies (2016):** conducted a study of 290 mothers between 18 and 40 years across Queensland during 2010-2011.³¹ A copy of this article is provided at **Annexure 1**.
- (c) **Scott et al (2019):** conducted a study of 2181 newborns and data collected at 3, 6, 12 and 24 months of age in South Australia.³² A copy of this article is provided at **Annexure 2**.
- (d) **Wen et al (2020):** conducted a study in New South Wales during 2017 and 2018 involving 1155 mothers.³³ A copy of this article is provided at **Annexure 3**.

Table 1 – Trends in breastfeeding rates in Australia over recent decades

Data source	Initiation	At 3 months	At 6 months	At 12 months
National Health Surveys (NHS)				
1995 NHS	86%	63.1%	46.6%	21.3%
2001 NHS	87.4%	64.3%	48.9%	24.8%
2004-05 NHS	87.8%	64.4%	50.4%	23.3%
2014-15 NHS	92.1%	Not reported*	59.4%	46.8%
2017-18 NHS	91.7%	Not reported*	66.8%	40.8%
Recent state-based studies				
Newby & Davies 2016 (QLD)	98%	80.7%	71%	45%
Scott et al 2019 (SA)	94.9%	66.6%	51%	32%
Wen et al 2020 (NSW)	Not reported**	Not reported**	68%	44%
<i>Average of the 3 recent state-based studies</i>	96.5%	73.7%	63%	40%

³¹ Newby, RM, & Davies, PS, 'Why do women stop breast-feeding? Results from a contemporary prospective study in a cohort of Australian women' *European Journal of Clinical Nutrition* (2016) 70, 1428–1432.

³² Scott, J, et al 'Determinants of Continued Breastfeeding at 12 and 24 Months: Results of an Australian Cohort Study' *International Journal of Environmental Research and Public Health* (2019) 16, 3980.

³³ Wen, LM, et al 'Effects of telephone and short message service support on infant feeding practices, “tummy time,” and screen time at 6 and 12 months of child age: A 3-group randomized clinical trial' *JAMA Pediatrics* (2020).

*Data is not available for these entries due to a change in methodology in the 2014-15 NHS and 2017-18 NHS which meant that results were reported at four months rather than three months.

**Data is not available for these entries because the outcome measures for this study were at six and 12 months only.

48 The National Health Survey results above in Table 1 show:

- (a) an increase in the percentage of women who initiate breastfeeding, from 86% in 1995 to 91.7% in 2017-18;
- (b) an increase in percentage of infants that are breastfed as at 6 months of age, from 46.6% in 1995 to 66.8% in 2017-18; and
- (c) an increase in percentage of infants that are breastfed as at 12 months of age, from 21.3% in 1995 to 40.8% in 2017-18.

49 Those results are broadly consistent with the average rates identified by the more recent state-based studies extracted in Table 1.

There is no evidence that Toddler Milk marketing is a cause of mothers deciding to cease breastfeeding

50 Given the high level of initiation of breastfeeding in Australia (illustrated in Table 1 above), the INC submits that the ACCC should consider the reasons why women may stop breastfeeding before their infant reaches 12 months of age. The promotion of Toddler Milk has not been identified as a reason provided by mothers as to why they decided to discontinue breastfeeding.

51 The Newby & Davies (2016) study referred to above found that the five most common reasons given by mothers for deciding to stop breastfeeding were:³⁴

- (a) mothers feeling they did not have enough milk supply;
- (b) baby was perceived to have difficulty sucking or latching on;
- (c) baby was perceived to have lost interest in breast feeding;
- (d) breast milk alone was considered to be insufficient for the baby; and
- (e) health concerns such as pain with cracked nipples or bleeding.

52 The reasons set out above accord with other Australian studies such as the Australian National Infant Feeding Survey (2010),³⁵ and research by Binns & Scott (2002).³⁶ The Breastfeeding Strategy also highlights the existence of societal and cultural barriers to breastfeeding.³⁷

The evidence cited by the ACCC does not support the proposition that Toddler Milk marketing negatively impacts breastfeeding rates

53 Given the lack of independent evidence that the promotion of Toddler Milk negatively impacts the initiation or continuation of breastfeeding in Australia, it would be ill-conceived for the ACCC to impose the Proposed Condition on the basis that the promotion of Toddler Milk undermines breastfeeding rates in Australia.

54 The studies cited in the ACCC's Draft Determination in support of the proposition that Toddler Milk marketing has a negative impact on breastfeeding are not sufficiently large or robust to support that conclusion. For example:

³⁴ Newby, RM, & Davies, PS, 'Why do women stop breast-feeding? Results from a contemporary prospective study in a cohort of Australian women' *European Journal of Clinical Nutrition* (2016) 70, 1428–1432.

³⁵ Australian Institute of Health and Welfare, *2010 Australian National Infant Feeding Survey: Indicator Results. Australian Institute of Health and Welfare: Canberra, 2011.*

³⁶ Binns, CW, & Scott, JA, 'Breastfeeding: reasons for starting, reasons for stopping and problems along the way' *Breastfeeding Review* (2002) 10, 13–19.

³⁷ COAG Health Council, 'Australian National Breastfeeding Strategy: 2019 and Beyond', p29.

- (a) The 2010 study by Berry, Jones and Iverson involved a very small sample size of 15 expectant mothers.³⁸
- (b) The 2012 study by Berry, Jones and Iverson involved a convenience sample of 439 parents or expectant parents recruited by intercept over 2 days at the 2008 Pregnancy, Babies and Children Expo in Sydney.³⁹
- 55 The limited sampling methodologies used in these studies mean that the results cannot support the conclusions reached. In relation to the 2010 study, the researchers themselves acknowledge the limitations inherent in their research results:⁴⁰
- It should be noted that the small sample sizes associated with qualitative enquiry constitute an inherent limitation to the generalisability of the findings. Therefore the results of this study should be interpreted in light of this limitation. Quantitative enquiry is required to investigate the extent of the perception that toddler milk advertising also effectively advertises infant and follow-on formula in the wider population.*
- 56 The two studies conducted by Berry et al were published in 2010 and 2012 and analysed data collected in prior periods. The data was collected well before both (i) the publication of the INC's Toddler Milk Guidance (in 2018) and the *MAIF Complaints Committee's interpretation of Clauses 5(a) & 9(b) of the MAIF Agreement relating to information on appropriate age range on infant formula labels (Staging Guidelines)* (in 2020); and (ii) consideration by the Committee and its predecessors of complaints in relation to Toddler Milks. As outlined by the Department of Health, 'significant progress has recently been made on this issue [the issue of toddler milk marketing]'.⁴¹ For this reason, the INC submits that earlier studies, particularly those with inherent methodological limitations, cannot support a conclusion that Toddler Milk marketing negatively impacts breastfeeding rates.
- 57 In addition to the two studies conducted by Berry et al, the ACCC refers to five other studies, which occurred overseas and do not account for the particular circumstances and factors in Australia.⁴² Another study referred to by the ACCC was conducted by NOP World (2005). While in an Australian context, this study concerned Infant Formula marketing generally and did not specifically address the issue of cross-promotion of Toddler Milk.

The MAIF Complaints Committee addresses the infrequent cross-promotion of infant formula through Toddler Milk marketing

The Committee addresses complaints relating to Toddler Milk marketing

- 58 The ACCC states that it is considering the Proposed Condition because of its concerns that the promotion of Toddler Milk results in the inadvertent promotion of Infant Formula.⁴³
- 59 The INC submits that advertising of Toddler Milk by signatories which results in the cross-promotion of Infant Formula is considered by the Committee to be within scope of the MAIF Agreement. Accordingly, the Committee is able to consider complaints in relation to such conduct.

³⁸ Berry, N, Jones, S & Iverson, D, 'It's all formula to me: Women's understandings of toddler milk ads', *Breastfeeding Review* (2010) 18(1).

³⁹ Berry, N, Jones, S & Iverson, D, 'Toddler milk advertising in Australia: Infant formula advertising in disguise?' *Australasian Marketing Journal*, (2012) 20(1).

⁴⁰ Berry, N, Jones, S & Iverson, D, 'It's all formula to me: Women's understandings of toddler milk ads', *Breastfeeding Review* (2010) 18(1), p28.

⁴¹ Department of Health Submission, p3.

⁴² Cattaeno et al (2014) considered infant formula in Italy, Pereira et al (2016) studied infant formula in four low and middle income countries, Harris et al (2016), Pomeranz (2018), Palafox et al (2020) considered infant formula in the US.

⁴³ Draft Determination, [4.21] to [4.28].

60 Over the past few years, the Committee and its predecessors have published numerous determinations on this issue. It has been found on a number of occasions that certain marketing practices in respect of Toddler Milk constituted a breach of the MAIF Agreement, including:

- the use of the wording 'Toddler Formula';
- any comparison made between Toddler Milk and breastmilk; and
- the use of images with infants on Toddler Milk packaging.

The Committee addresses concerns arising from product line information

61 The ACCC states in the Draft Determination that issues of cross-promotion through product line marketing have not been found to breach the MAIF Agreement.⁴⁴

62 The INC submits that the ACCC should consider the rationale behind the Committee's findings. Relevantly, the Committee has found that:

- A complaint relating to marketing material including the progression of products was not a breach of the MAIF Agreement because the webpage and pack shot images could only be accessed after the appropriate disclaimer was accepted by the user.⁴⁵
- A complaint relating to a product range guide for healthcare professionals found in a pharmacy was not a breach of the MAIF Agreement, however, the design of the guide should be changed to appeal more to healthcare professionals rather than consumers.⁴⁶
- In relation to a number of complaints about labelling of Infant Formula in a range, the conduct was not a breach of the MAIF Agreement because the labelling provided age appropriate information and was not promotional in nature.⁴⁷

63 The above examples demonstrate that Committee carefully considers product line marketing on a case by case basis. To the extent that any product line information is in fact promotional in nature and does not include age appropriate information or suitable disclaimers the Committee will determine complaints accordingly.

64 In addition, as previously outlined by the INC in its response to the third party submissions, the Committee has published Staging Guidelines. These were finalised by the Committee and approved by the Department of Health. The Staging Guidelines seek to address concerns about the cross-promotion of infant formula through the use of staging information, ie product line marketing.

65 The Staging Guidelines indicate that, on Infant Formula labels:

- (a) manufacturers and importers must include information relating to the range of age appropriate for that infant formula product;
- (b) manufacturers and importers may include additional factual information relating to the range of age appropriate for that infant formula products;
- (c) the use of symbols and/or infographics showing all numbers and/or stages of the product range, including highlighting where the product being purchased is in the range, is not appropriate; and

⁴⁴ Draft Determination, [4.33].

⁴⁵ Annual Report of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) Complaints Committee 2019-202, p7-9.

⁴⁶ Annual Report of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) Complaints Committee 2018-2019, p8-9.

⁴⁷ Annual Report of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) Complaints Committee 2018-2019, p8-11.

- (d) the use of images and/or pack shots of other infant formula products in a brand range are not appropriate.

The transparency of the complaints process supports effective consideration of Toddler Milk issues

- 66 Importantly, as identified in the INC's application for authorisation, all complaints considered by the Committee, including those which do not result in a breach of the MAIF Agreement or which are considered out of scope of the MAIF Agreement are publicly available. They are published on both the Department of Health website and in the Annual Reports published by the Committee (also available on the Department of Health website).⁴⁸
- 67 The INC submits that the enhanced transparency of the complaints process has enabled the Committee to more effectively address concerns regarding Toddler Milk marketing. This is particularly so given the adverse publicity associated with the publication of the Committee's determinations provides an effective mechanism to regulate the conduct of signatories to the MAIF Agreement.

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⁴⁸ INC Submission, p20.

Annexure 1 - Newby, RM, & Davies, PS, 'Why do women stop breast-feeding? Results from a contemporary prospective study in a cohort of Australian women' *European Journal of Clinical Nutrition* (2016) 70, 1428–1432

ORIGINAL ARTICLE

Why do women stop breast-feeding? Results from a contemporary prospective study in a cohort of Australian women

RM Newby^{1,2} and PSW Davies¹

BACKGROUND/OBJECTIVES: Australian guidelines recommend infants be breast-fed for at least their first year of life; however, for a variety of reasons many mothers cease breast-feeding before this age. The objective of this study was to determine the reasons why women stop breast-feeding their infant completely, in relation to the age of the infant.

SUBJECTS/METHODS: Primiparous Australian women aged between 18 and 40 years underwent a self-administered questionnaire-based birth cohort study on infant-feeding attitudes, behaviours and feeding patterns. Data were extracted from the demographic questionnaire and from questionnaires administered at 2, 4, 6 and 12 months of infant age between October 2010 and September 2011.

RESULTS: Breast-feeding initiation in this cohort was 97%; however, by 52 weeks of infant age 46% of mothers had completely ceased breast-feeding. In those mothers who had ceased breast-feeding before 26 weeks the most common reason was 'I did not have enough milk'. In those mothers who had completely stopped breast-feeding between 26 and 52 weeks the most common reason reported as being very important in the decision to cease breast-feeding was 'My baby lost interest'.

CONCLUSIONS: Maternal concerns regarding breast trauma, milk supply and infant satiety were central mediators of breast-feeding duration among these Queensland women. Further research into the antecedents of sucking pathologies and reasons for nipple trauma is indicated. Health professionals can assist women to recognise cues of hunger and satiety in their infants and understand the dynamics and natural history of breast-feeding to prolong breast-feeding relationships.

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BACKGROUND

The current National Health and Medical Research Council infant-feeding guidelines in Australia recommend exclusive breast-feeding for infants up to around 6 months of age, and that breast-feeding should be continued until 12 months of age and beyond, for as long as the mother and child desire.¹ These guidelines are based upon numerous studies that have identified the protective nutritional and health benefits of breast-feeding.^{2–8}

Although the percentage of Australian mothers who initiate breast-feeding has increased during the past few decades,⁹ it is well known that guidelines regarding the duration of breast-feeding are not followed by many women, for a wide variety of reasons.¹⁰ The recent 2010 Australian National Infant Feeding Survey¹¹ reported that, although breast-feeding was initiated in 96% of women surveyed, 31% of these women had completely stopped breast-feeding by 4 months of age and that this figure rose to 40% at 6 months of age. Moreover, only 15% of mothers had exclusively breast-fed their infant to around 6 months of age, in line with National Health and Medical Research Council guidelines, and 42% were still breast-feeding between 7 and 12 months of age. Among women who had ceased breast-feeding before 6 months of age, the reason most commonly cited was that they did not have enough breast milk (56%), and that the child had lost interest (34%).¹¹

The retrospective design of many existing studies on infant feeding has been criticised by a number of authors as it may lead to misclassification of feeding practices and data that contain inaccuracies related to the nature of maternal recall of feeding behaviours (for example Donath and Amir,¹² Sloan *et al*¹³ Lin *et al*,¹⁴ Burnham *et al*¹⁵). In a review article Li and colleagues¹⁶ reported that even with a short recall period (less than 3 years) the majority of mothers could only recall the duration of breast-feeding to within a month of the actual duration, and the recall of mothers relating to timing of cessation of breast-feeding was even more inaccurate. Indeed, even the recent 2010 Australian National Infant Feeding Survey was retrospective via a single questionnaire to families with infants aged less than 24 months.¹¹ Prospective data collection in infant-feeding studies is important if data are to be considered both valid and reliable.

The development of additional measures to promote breast-feeding practices in line with evidence-based guidelines requires understanding of reasons for failure of many mothers to meet best practice. The aim of this study was to collect prospective data related to infant-feeding practice, via questionnaires, in a cohort of contemporary Australian first-time mothers to record the reasons why breast-feeding was ceased. We report here data obtained from questionnaires administered when infants were aged 4, 6 and 12 months.

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MATERIALS AND METHODS

This report presents longitudinal data from the Feeding Queensland Babies Study – a questionnaire-based prospective birth cohort study on infant-feeding attitudes and behaviours among mothers in Queensland, Australia. Recruitment was by convenience sampling at a public event for families and by word of mouth, social and traditional media. A detailed description of the Feeding Queensland Babies Study has been previously published.^{17,18} Suffice it to say here, participants were healthy primiparous women aged between 18 and 40 years and resident in Queensland who delivered healthy singleton infants between 37 and 42 weeks of gestation. For this article, participants were excluded from the analysis if they or their infant suffered from postnatal morbidity that impacted feeding. All participants were pregnant at the time of providing their consent, and were invited to complete an antenatal survey followed by a demographic survey and five further surveys during their infants' first year of life at ages 2, 4, 6, 9 and 12 months.

Measures

Questionnaires were delivered on paper or online less than 4 weeks before the target infant age for the questionnaire. Email reminders were sent to women if necessary and included a link to request a replacement survey or to the online survey. Participants were retained in the study and were sent questionnaires at every scheduled infant age timepoint regardless of whether prior surveys had been completed or returned. Each data set may therefore be used as a cross-sectional snapshot in addition to contributing to a longitudinal data series. An online demographic survey was sent to all participants through Checkbox software between November 2010 and April 2011 with questions framed to reference the time that the participant first became pregnant with the study infant, with reminders emailed to non-responders. It contained questions on maternal social, educational and economic circumstances.

Survey content

Questionnaires used for this research were minimally adapted from the Infant Feeding Practices Study II¹⁹ developed in the United States by the Food and Drug Administration in collaboration with the Centers for Disease Control and Prevention. Postnatal surveys were modular in nature, and response items offered at various timepoints included questions about the mother's birth experience and her health and diet, infant health and feeding behaviours including the use of prescribed and non-prescribed medications, sources of support and advice around breast-feeding, formula use and the introduction of non-milk foods, maternal employment and child care, infant sleep patterns and food allergies. This article reports data from the 2-, 4-, 6- and 12-month questionnaires.

At each postnatal survey mothers were asked 'Have you completely stopped breast-feeding and expressing breast milk for your baby?' and to report her infant's age in weeks at the time of breast-feeding cessation. In the first survey in which they answered in the affirmative, they were invited to respond to a set of 33 questions (3 groups of 11) with the title 'How important was each of the following reasons for your decision to stop breast-feeding your baby? (Please answer each item)' and asked to rate each reason as being 'not at all important', 'not very important', 'somewhat important' or 'very important' in their decision to cease breast-feeding. The question order was not randomised. The full set of 33 questions are shown in Table 1. Mothers were also asked 'How many weeks old was your baby when you completely stopped breast-feeding and expressing breast milk?' The demographic questionnaires contained questions on maternal social, educational and economic circumstances.

Data analysis

Respondent characteristics reported from the demographic survey were maternal age (<30 years/30+ years), socio-economic status (high/medium/low), education level (< degree/degree or higher), country of birth (Australia/other), language spoken at home (English/other), employment (employed/not employed), marital status (partnered/not partnered) and family income (\$100 000/>\$100 000 per annum). Socio-economic status was categorised at the postcode level using the Socio-economic Index for Areas, a composite measure of social advantage and disadvantage.²⁰

Summary statistics are reported as frequencies and percentages. Infant age at breast-feeding cessation was used to categorise infants into one of four groups: age less than 12 weeks; 12–25 weeks; 26–52 weeks; and

Table 1. All possible responses offered as reasons for breast-feeding cessation on a 4-point Likert scale

Set 1 Questions	
1	My baby had trouble sucking or latching on
2	My baby became sick and could not breast-feed
3	My baby began to bite
4	My baby lost interest in nursing or began to wean him or herself
5	My baby was old enough that the difference between breast milk and formula no longer mattered
6	Breast milk alone did not satisfy my baby
7	I thought that my baby was not gaining enough weight
8	I had trouble getting milk flow to start
9	I didn't have enough milk
10	My nipples were sore, cracked or bleeding
11	My breasts were overfull or engorged
Set 2	
1	My breasts were infected or abscessed
2	My breasts leaked too much
3	Breast-feeding was too painful
4	Breast-feeding was too tiring
5	I was sick or had to take medicine
6	Breast-feeding was too inconvenient
7	I did not like breast-feeding
8	I wanted to be able to leave my baby for several hours at a time
9	I wanted to go on a weight loss diet
10	I wanted to go back on my usual diet
11	I wanted to smoke again or more than I did while breast-feeding
Set 3	
1	I had too many household duties
2	I could not or did not want to express or breast-feed at work
3	Expressing milk no longer seemed worth the effort that it required
4	I was not present to feed my baby for reasons other than work
5	I wanted or needed someone else to feed my baby
6	Someone else wanted to feed the baby
7	I did not want to breast-feed in public
8	I wanted my body back to myself
9	I became pregnant or wanted to become pregnant again
10	I was not confident that I was breast-feeding correctly
11	I prefer to bottle feed because I can see how much milk my baby is drinking

Respondents were asked: How important was each of the following reasons for your decision to stop breast-feeding your baby? (Please answer each item).

greater than 52 weeks (still breast-feeding in response to the 12-month questionnaire). A one-way analysis of variance was conducted to determine whether maternal age was significantly related to age at which breast-feeding ceased.

Maternal postcode was converted to Socio-economic Indexes for Areas deciles for each participant, with values from 1 to 10.²⁰ Socio-economic Indexes for Areas is an index developed by the Australian Bureau of Statistics, which ranks areas in Australia according to relative socio-economic advantage and disadvantage. As demographic data were available for only a portion of the sample of respondents, we used logistic regression to undertake sensitivity analysis of Socio-economic Indexes for Areas, and found it to be valid as a proxy measure of maternal education for those participants for whom demographic data were not available.

The study was approved by the Behavioural and Social Sciences Ethical Review Committee of The University of Queensland (#2009001237) and written or electronic informed consent was obtained from the mothers. Data analyses were performed using Microsoft Excel 14.4.7 and IBM SPSS Statistics for Windows (version 22.0; IBM Corp., Armonk, NY, USA).

RESULTS

Data were available from 290 mothers in relation to whether they were still breast-feeding, or regarding infant age when breast-feeding ceased. Breast-feeding was initiated by 98% of respondents. The number of women who had ceased breast-feeding at each time period or were still breast-feeding at 12 months' infant age is shown in Table 2, along with data relating to maternal age and maternal Socio-economic Indexes for Areas category.

Among mothers who had ceased breast-feeding before their infant had reached 52 weeks of age there was a significant positive correlation ($r=0.24$; $P < 0.01$) between maternal age in years and the length of any breast-feeding in weeks. *Post hoc* comparisons using ANOVA indicated that mean maternal age was significantly lower in the group of mothers who had ceased breast-feeding before 12 weeks than in either those who had ceased between 26 and 52 weeks and those still breast-feeding at 52 weeks.

Table 3 shows the four most common reasons reported by mothers for ceasing breast-feeding within the three groups of women who had stopped breast-feeding. The top reason cited as being very important in their decision to cease breast-feeding within the 'less than 12 weeks' and '12–26 weeks' groups was 'I did not have enough milk'; this was also the second most commonly reported reason within the '26–52 weeks' group. Measurement of actual breast milk output via test weighing or other methods was not undertaken in this cohort. The most common reason reported as being very important in the decision to cease breast-feeding between 26 and 52 weeks was 'My baby lost interest'.

Table 2. Infant age category at which mother reported that breast-feeding ceased

Infant age category at breast-feeding cessation				Maternal age (years)		SEIFA ^a category		
Age of infant (weeks)	N	%	Cumulative %	Mean	SD	1–4	5–7	8–10
<i>Stopped breast-feeding</i>								
< 12	56	19.3	19.3	27.9	5.2	20.4	33.3	46.3
12 to 26	28	9.7	29.0	29.4	5.2	7.2	46.4	46.4
26 to 52	77	22.2	55.6	30.6	4.8	15.3	22.2	62.5
<i>Still breast-feeding</i>								
> 52	129	44.5	100	30.0	3.9	17.1	33.1	49.8

^aSocio-economic Indexes for Areas, a composite measure of social advantage and disadvantage.

DISCUSSION

Decisions pertaining to infant feeding contribute to women's complex and sometimes competing goals for health and wellness for themselves and their infants.²¹ In this context, and now that breast-feeding initiation in Australia has reached near saturation at 96%¹¹ (98% in this cohort), the investigation and monitoring of women's reasons for breast-feeding cessation, which may change depending on infant age, is of particular importance. Furthermore, the distinct motivators and barriers that impact breast-feeding initiation must clearly be viewed differently from those that influence persistence through the first year of life. This distinction is important because identification of age-specific behavioural targets for infant-feeding promotion and communication are required in order to provide maximal benefit to mother and child.

Many maternal and infant factors are known to be associated with the duration of breast-feeding. Parity, birth order and infant gestational age have been controlled for by the design of this study, but the positive association between maternal age and breast-feeding duration known to exist among Australian women²² has been confirmed by our data. We have chosen not to account for biological factors such as adiposity and mode of delivery in order to focus exclusively on those reasons selected by respondents for breast-feeding cessation.

Our research findings support those of previous studies^{23–25} in that lactational difficulties including nipple pain and latch are among the primary reasons why mothers cease breast-feeding early in infancy, while concerns with milk supply are the most cited reason for the cessation of breast-feeding by 26 weeks of infant age. As such, of the six different reasons most frequently reported by this sample of women for breast-feeding cessation during the first year, the two in common across all three time periods examined are 'I did not have enough milk' and 'Breast milk alone did not satisfy my baby'.

Adequate weight gain in infants on an exclusive diet of maternal breast milk must by definition be supported by adequate maternal supply. In an attempt to explore reported maternal perceived low supply within this cohort we determined the percentage of women who reported as very important in their decision to stop breast-feeding both 'I did not have enough breast milk' and 'My infant was not gaining enough weight'. The percentage of women reporting both of these reasons was much lower than the percentage of women reporting 'I did not have enough breast milk' (shown in Table 3), being 13, 14 and 10% in the three age categories previously described. This suggests that while mothers might perceive that they are unable to produce sufficient breast milk to meet their infants' nutritional requirements, their rate of milk production is in fact likely to be adequate. The alternate possibility that weight gain may have been enhanced by infant formula supplementation in infants receiving

Table 3. Proportion of respondents selecting the listed reasons for stopping breast-feeding categorised by infant age at breast-feeding cessation

Age of infant (weeks) at cessation of breast-feeding	Reason	%
<i>Why did you stop breast-feeding your infant at that age?</i>		
< 12 (n = 56)	I did not have enough milk	53.6
	My baby had trouble sucking or latching on	48.2
	Breast milk alone did not satisfy my baby	37.5
> 12 < 26 (n = 28)	My nipples were sore, cracked or bleeding	30.4
	I did not have enough milk	50.0
	Breast milk alone did not satisfy my baby	28.6
> 26 < 52 (n = 77)	My baby had trouble sucking or latching on	14.3
	My baby lost interest	14.3
	My baby lost interest	28.6
	I did not have enough milk	27.7
	Breast milk alone did not satisfy my baby	20.8
	My baby began to bite	15.6

both breast and infant formula is a practice of concern because of the risk that supplementation poses to maternal breast milk supply secondary to insufficient infant time spent suckling.²⁶

Maternal concern with breast milk supply implies the intermediate assumption by mothers that signs such as suckling duration and frequency, and infant behaviours such as fussiness and crying, represent evidence of infant hunger due to insufficient breast milk supply. While these assumptions are known to frequently be incorrect,²⁷ even if true, breast-feeding management strategies delivered by well-trained health care providers (HCPs) may assist many women to overcome such perceived barriers to continued breast-feeding.²⁸

One of the most common reasons cited by mothers as being very important in the decision to completely stop breast-feeding, regardless of the age of the infant, was 'I did not have enough milk'. This has also been reported as a key reason for breast-feeding cessation in other studies over a number of years, as well as in several countries.^{23–25,29,30} Scott and Binns found concern about milk supply in 23% of the primiparous women in their study among women in Perth¹⁰ with a significant proportion of mothers continuing to express this concern at 6 months of infant age. This is both interesting and important as it has been reported that less than 5% of women are physiologically incapable of producing sufficient milk or are unable to achieve desirable infant growth through breast-feeding alone.^{31–33} Indeed, it has been suggested that 'I did not have enough milk' may be a socially acceptable reason for breast-feeding cessation,^{24,34} or a reflection of the negative influences of medicalisation and commercialisation on women's confidence in their ability to nourish their infants.³⁵

Both 'I did not have enough milk' and 'Breast milk alone did not satisfy my baby' have been linked to a lack of breast-feeding self-efficacy^{36,37} and associated concern over the productive, nutritive functions of breast-feeding. In contrast, two of the remaining reasons – 'My baby had trouble sucking or latching on' and 'My nipples were sore, cracked or bleeding' – are acute breast-feeding management issues most likely to occur during the early phases of lactation, which may be addressed by skilled health professional intervention at that time.^{38–40} Biting behaviour in infants was included among the four most commonly cited reasons for breast-feeding cessation only in the sample between 6 and 11 months of infant age. A recent study²⁴ provided 'perception of insufficient milk' as a response option instead of 'I did not have enough milk'. If the issue here is a perception rather than a reality, routinely educating individual mothers in this area would be extremely important and could lead to a longer breast-feeding duration in a substantial number of cases as has been shown before.^{41–43}

A recent Australian study²⁷ has clarified that, for mothers who are breast-feeding exclusively, the frequency and duration of breast-feeding sessions naturally decrease during the first 6 months of infancy, with resulting reduction in time spent at the breast. This finding suggests that, rather than being an indication of insufficient milk supply or lack of interest on the part of the infant, in successful breast-feeding there is an increase in the infant's efficiency in extracting milk over the first 6 months of life.²⁷ Knowledge of the normal course of lactation may assist HCPs to reassure mothers about normal variation in breast-feeding patterns and avoid the use of unnecessary infant formula feeding and its associated risk for premature cessation of breast-feeding.^{23,25}

Furthermore, breast-feeding cessation must be seen as an inappropriate strategy on several counts to solve problems of milk supply. Infant behaviours that engender within mothers the idea that their infant is not satisfied with breast milk are known to commonly be erroneous,²⁸ and such problems may be resolved by effective education on the supply and demand nature of breast-feeding and support in increasing milk supply – that is breast-feeding management. Breast-feeding cessation is an unnecessary response to either problem even when they were

proved to be accurate, as continued breast-feeding following the introduction of non-milk foods continues to provide benefits to both mother and infant well into the second year of life.⁴⁴ Finally, introduction of additional or alternate foods and fluids to meet the infant's perceived hunger cues will exacerbate the actual low supply, even when it was initially adequate.^{23,25}

Although many of the reasons cited by women for breast-feeding cessation may modify the breast-feeding duration, none by themselves necessarily benefit from breast-feeding cessation and may therefore be amenable to remediation by proactive and well-trained HCPs. HCPs have substantial influence on women's knowledge, attitudes and behaviours towards breast-feeding,⁴⁵ particularly during the antenatal and immediate postnatal period. This research suggests that HCPs should act early during infancy to leverage their influence proactively for prolonging breast-feeding through the first and into the second year of life. Such a strategy would require discussion of longer-term goals for breast-feeding once initial breast-feeding difficulties such as 'sore, cracked or bleeding nipples' have been resolved, and the changing nature of breast-feeding dynamics across the first postpartum year.

It has been suggested that health-care professionals should be specifically skilled in supporting breast-feeding women and in particular providing families with information on markers of adequate breast milk intake, such as appropriate weight gain and frequency of wet nappies, as a strategy to monitor the adequacy of breast milk intake. Mothers should also be strongly encouraged not to make infant-feeding decisions based solely on their own but should seek help, guidance and advice from appropriate health-care professionals if they believe that they are not able to supply sufficient breast milk.²⁸

This study cannot be considered broadly representative of all first-time mothers in Australia because of the relatively high socio-economic status of its participants. The question order was not randomised in this set of 33 reasons for breast-feeding cessation. The major strength of the data presented here is that they have been collected from women within weeks of these infant-feeding transitions occurring, unlike many previous studies that have relied on the questionable accuracy of parental recall often many years afterwards.^{12,13,46}

CONCLUSIONS

Research into the antecedents of sucking pathologies and reasons for nipple trauma is indicated by this research as a propriety activity for lactational physiologists, particularly in addressing issues that impede breast-feeding during early infancy. In addressing mothers' widely held misunderstandings regarding low milk volume and adequacy of breast milk intake, health professionals can assist women to recognise cues of hunger and satiety from their infants and understand the relationship between infant demand for breast milk and maternal supply. Support for the establishment of breast-feeding goals early in infancy and communication of the social and emotional value of breast-feeding during later infancy may also contribute to longer breast-feeding duration for Australian infants.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Annexure 2 – Scott, J, et al 'Determinants of Continued Breastfeeding at 12 and 24 Months: Results of an Australian Cohort Study' *International Journal of Environmental Research and Public Health* (2019) 16, 3980



Article

Determinants of Continued Breastfeeding at 12 and 24 Months: Results of an Australian Cohort Study

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Abstract: Breastfeeding to 12 months and beyond offers considerable health benefits to both infants and mothers. Despite these recognized benefits, relatively few women in high income countries breastfeed for 12 months, and rarely breastfeed to 24 months. The aim of this study was to identify the prevalence and determinants of continued breastfeeding to 12 and 24 months amongst a cohort of Australian women participating in the Adelaide-based Study of Mothers' and Infants' Life Events affecting oral health (SMILE). Duration of breastfeeding was known for 1450 participants and was derived from feeding related data collected at birth, 3, 6, 12 and 24 months. Multivariable logistic regression analysis was used to investigate the relationship between explanatory variables and continued breastfeeding to 12 and 24 months. In total, 31.8% of women breastfed to 12 months and 7.5% to 24 months. Women who were multiparous, university educated, had not returned to work by 12 months and whose partners preferred breastfeeding over bottle feeding were more likely to be breastfeeding at 12 months. While women who had introduced complementary foods before 17 weeks and formula at any age were less likely to be breastfeeding at 12 months. Mothers who were born in Asian countries other than India and China, had not returned to work by 12 months and had not introduced formula were more likely to be breastfeeding at 24 months. The majority of the determinants of continued breastfeeding are either modifiable or could be used to identify women who would benefit from additional breastfeeding support and encouragement.

Keywords: continued breastfeeding; determinants; formula; sociodemographic

1. Introduction

The World Health Organization recommends that infants be exclusively breastfed for the first six months of life, after which time nutritionally adequate complementary foods should be introduced and breastfeeding continued to at least 2 years of age [1]. The importance of breastfeeding for the growth and health of infants in the first year of life is well-established and there is convincing evidence that breastfeeding beyond 12 months has a positive influence on a child's health and development [2,3]. In addition to being a source of nutrients, breast milk includes a host of bioactive components that guide the development of an infant's immune system [4]. Research has shown that these immunological factors are maintained to two years [5] and protection against mortality and morbidity from infectious diseases extends well into the second year of life [3]. Women who breastfeed for 12 months and beyond have been found to be more in tune with their infant's satiety and hunger cues, enabling the establishment of better eating patterns and likely reducing the risk of obesity [6,7]. A clear inverse dose response relationship between breastfeeding duration and risk of obesity has been established [8] and in a recent study, an Australian cohort of children breastfed for 52 weeks had half the risk of being

overweight or obese at 24–36 months compared with those never breastfed or breastfed for less than 17 weeks [9].

Research has shown that breastfeeding can also benefit the mother by reducing the risk of breast cancer [10], ovarian cancer [11], type 2 diabetes mellitus [12], hypertension [13], metabolic syndrome [14], cardiovascular disease [15,16] and possibly osteoporosis [17]. In all of these studies, an inverse association between each outcome was seen with longer duration per child and/or cumulative (lifetime) duration of breastfeeding.

While the World Health Organization (WHO) recommends that women breastfeed their infants to 2 years and beyond [1], and despite the recognized benefits for infants and mothers, few Australian women contemplate breastfeeding to this age [18]. For this reason, breastfeeding recommendations issued by relevant authorities in Australia [19] and other high income countries such as the USA [20] have modified the WHO guidelines and recommend a culturally more attainable goal that women breastfeed to 12 months and beyond. Even so, relatively few women in most high income countries achieve this recommendation, where on average the prevalence is lower than 20% [3]. In Australia, the most recent data on breastfeeding practices come from the 2014–15 National Health Survey which reported that 27.5% of children aged 13–24 months were breastfed at 12 months [21].

Several terms have been used to describe breastfeeding beyond the first year of life including ‘continued’ [3], ‘sustained’ [2], ‘extended’, ‘long-term’ and ‘prolonged’ [22]. On their own, these terms are culturally subjective unless anchored with an age. Furthermore, several of these terms, the latter two in particular, may have negative connotations in high income countries, where disapproving attitudes increase, and support for breastfeeding decreases, as the age of the child increases [22–24]. Care therefore, needs to be taken in the use of terminology when encouraging women to continue to breastfeed beyond 12 months. For the purposes of this paper we have chosen the term ‘continued breastfeeding’ as used by Victora et al. [3] in the recent Lancet Breastfeeding Series. The aim of this study was to identify the prevalence and determinants of continued breastfeeding to 12 and 24 months amongst a cohort of Australian women.

2. Materials and Methods

The study is a secondary analysis of infant feeding data collected as part of the Study of Mothers’ and Infants’ Life Events Affecting Oral Health (SMILE), a population-based longitudinal birth cohort study [25]. SMILE was originally funded to recruit and follow a cohort of socioeconomically-diverse South Australian newborns from birth into their third year of life, and additional funding has been secured to follow the SMILE cohort until 7 years of age. The primary health outcomes of SMILE are two related conditions: early childhood dental caries and obesity/overweight.

2.1. Setting and Recruitment

Between July 2013 until August 2014 a total of 2147 women and 2181 newborns, including 34 pairs of twins, were recruited from three major maternity hospitals in Adelaide, Australia. All new mothers with sufficient competency in English to understand the description and instructions of the study were invited to participate. While there were no specific exclusions related to gestational age and birthweight, mothers with infants in the NICU were not invited to participate. Those women who indicated their intention to move out of the greater Adelaide area within a year were excluded. Efforts were made to over-recruit from those hospitals which service the more socially disadvantaged communities in Adelaide to account for an anticipated higher attrition rate.

Women were recruited, from the postnatal wards of the participating hospitals, usually within 48 h of giving birth. Those agreeing to participate in the study were invited to complete a baseline questionnaire and follow-up questionnaires at 3, 6, 12 and 24 months. Further details of the study protocol have been reported elsewhere [25].

2.2. Statistical Analysis

Of the 2147 women recruited, 2112 (98.3%) completed a baseline questionnaire. The analysis population consists of the 1450 women for whom breastfeeding duration was known, that is they were known to have stopped breastfeeding prior to, or to still be breastfeeding at, 24 months. The primary outcome variables in this analysis are continued breastfeeding at 12 and 24 months postpartum. These variables were derived from questions on infant feeding practices—including current feeding method, age of cessation of breastfeeding and age of introduction of formula, complementary foods and other beverages—collected from follow-up questionnaires (either postal or online), self-completed by women at baseline and when their child was 3, 6, 12 and 24 months of age. With regards to breastfeeding practices, no distinction was made between whether a mother was directly breastfeeding from the breast or feeding an infant expressed breast milk via a bottle. The age at which these feeding events occurred were reported in weeks and/or months. Ages reported in weeks were divided by 4.33 and rounded to calculate age in months, with 26, 52 and 104 weeks representing 6, 12 and 24 months respectively.

Explanatory variables known or suspected to be associated with maintenance of breastfeeding to 12 months or more [26] were derived from the baseline questionnaire and included: mother's age in years (<25, 25–34 or ≥35 years); education (high school/vocational or some/completed university); country of birth (Australia/New Zealand, UK, India, China, Asia-other or Other); age of child when mother returned to work (before 12 months or not by 12 months); parity (primiparous or multiparous); pre-pregnancy body mass index (BMI) (<25, ≥25 kg/m²) based on self-reported weight and height; partner's feeding preference (prefers breastfeeding or prefers formula /ambivalent) as perceived by the mother. The Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) was generated using household postcode and used as a measure of socioeconomic position (SEP)[27]. The IRSAD was categorized from deciles into 5 groups from most to least disadvantaged. Infant related explanatory variables included infant sex; birth weight (<2500, 2500–3999 or 4000 g); age of introduction of solids (<17, 17–25 or ≥26 weeks) and age when formula was introduced (<4 weeks, 4–7 weeks, 8–15 weeks, 16–25 weeks, ≥26 weeks or never received formula).

Simple binary logistic regression was used to investigate the relationship between explanatory variables and continued breastfeeding to 12 and 24 months (results not shown). To reduce the risk of residual confounding those variables in the simple analysis with a *p*-value < 0.20 were entered into a multivariable model [28]. Results are reported as adjusted odds ratios (AOR) with 95% confidence intervals (CI).

There were minimal missing data for sociodemographic variables. No attempt was made to impute missing data for these variables on the basis that a previous sensitivity analysis for other dietary outcomes investigated in this cohort, in which missing data for sociodemographic explanatory variables were imputed under the assumption that data were missing at random, revealed that distributions of variables in the imputed data sets were consistent with the complete case data [29]. However, data on age at which the mother returned to work were missing for a substantial number of cases (19.2%), and a sensitivity analysis was conducted with the multivariable analyses being repeated without this variable to determine if its exclusion changed the findings of this study.

The study was approved by the Southern Adelaide Clinical Human Research Ethics Committee (HREC/50.13, approval date: 28 Feb 2013) and the South Australian Women and Children Health Network (HREC/13/WCHN/69, approval date: 7 Aug 2013). Signed informed consent was obtained from women who were advised that their participation was voluntary and that they could withdraw at any time without prejudice.

3. Results

3.1. Subject Characteristics

The majority of women in this analysis (*n* = 1431) were aged 25 to 34 years (66.1%), had commenced or completed university (50.8%) and were born in Australia (71.4%) (Table 1). Mothers who provided

baseline data but without data on breastfeeding status at 24 months were younger, less educated, more socially disadvantaged and more likely to have been born outside of Australia. The population was similar to the profile reported by the Pregnancy Outcome Unit for South Australia for births in 2013 with regards to country of birth, but our sample consisted of slightly fewer younger (<25 years) mothers [30] (Table S1).

Table 1. Characteristics of SMILE participant mothers and children with known breastfeeding duration up to 24 months.

Characteristic	Total (n = 1450)		BF at 12 Months (n = 461)		BF at 24 Months (n = 108)	
	n	%	n	%	n	%
<i>Maternal Characteristics</i>						
Age (years)						
<25	190	13.1	28	6.1	9	8.3
25–34	958	66.1	315	68.3	61	56.5
≥35	298	20.6	118	25.6	38	35.2
Missing	4	0.3				
Highest level of education						
High school/vocational	707	48.8	141	30.6	38	35.2
Some ^a university or graduate	737	50.8	317	68.8	69	63.9
Missing	6	0.4	3	0.7	1	0.9
IRSAD ^b deciles						
IRSAD deciles 1–2	277	19.1	64	13.9	15	13.9
IRSAD deciles 3–4	301	20.8	82	17.8	21	19.4
IRSAD deciles 5–6	285	19.7	96	20.8	22	20.4
IRSAD deciles 7–8	269	18.7	84	18.2	27	25.0
IRSAD deciles 9–10	307	21.3	132	28.6	22	20.4
Missing	11	0.8	3	0.7	1	0.9
Country of birth						
Australian & New Zealand	1035	71.4	306	66.4	61	56.5
UK/Ireland	52	3.6	15	3.3	5	4.6
China	110	7.6	36	7.8	10	9.3
India	50	3.4	24	5.2	4	3.7
Asia-other	104	7.2	39	8.5	16	14.8
Other	89	6.1	38	8.2	11	10.2
Missing	10	0.7	3	0.7	1	0.9
Age of infant when returned to work						
≤12 months	659	45.4	210	45.6	34	31.5
Not by 12 months	512	35.3	205	44.5	65	60.2
Missing	279	19.2	46	10.0	9	8.3
Pre-pregnancy BMI (kg/m ²)						
<25	762	52.6	301	29.5	68	63.0
≥25	586	40.4	136	14.3	29	26.9
Missing	102	7.0	24	5.2	11	10.2
Parity						
Primiparous	666	45.9	198	43.0	47	43.5
Multiparous	715	49.3	250	54.2	60	55.6
Missing	69	4.8	13	2.8	1	0.9
Partner's feeding preference						
Prefers breastfeeding	934	64.4	364	76.8	82	75.9
Prefers bottle feeding or ambivalent	495	34.1	99	21.5	22	20.4
Missing	21	1.4	8	1.7	4	3.7
<i>Child characteristics</i>						
Sex						
Male	765	52.8	247	53.6	56	51.9
Female	685	47.2	214	46.4	52	48.1
Birth weight (g)						
<2500	94	6.5	23	5.4	6	5.6
2500–3999	1189	82.0	385	83.5	88	81.5
≥4000	155	10.7	47	10.2	13	12.0
Missing	12	0.8	4	0.9	1	0.9

Table 1. *Cont.*

Characteristic	Total (n = 1450)		BF at 12 Months (n = 461)		BF at 24 Months (n = 108)	
	n	%	n	%	n	%
Age received complementary foods						
<17 weeks	368	25.4	66	14.3	16	14.8
17–25 weeks	876	60.4	319	69.2	70	64.8
≥26 weeks	117	8.1	61	13.2	17	15.7
Missing	89	6.1	15	3.3	5	4.6
Age received formula						
<4 weeks	643	44.3	113	24.5	33	30.6
4–7 weeks	138	9.5	18	3.9	4	3.7
8–15 weeks	157	10.8	33	7.2	5	4.6
16–25 weeks	115	7.9	32	6.9	12	11.1
≥26 weeks	124	8.6	60	13.0	5	4.6
Never received formula	192	13.2	164	35.6	40	37.0
Missing	81	5.6	41	8.9	9	8.3

^a Commenced but did not complete University. ^b IRSAD: Index of Relative Socio-Economic Advantage and Disadvantage with decile 1 = most disadvantaged and 10 = most advantaged BF = breastfeeding; BMI = Body Mass Index.

Almost all women (94.9%) had initiated breastfeeding and 31.8% had breastfed to 12 months and 7.5% to 24 months (Table 2 and Figure S1).

Table 2. Prevalence of breastfeeding up to 24 months (n = 1450).

Months	%	95% CI
Birth	94.9	93.8–96.0
1	82.2	80.2–84.2
3	66.6	64.2–69.0
6	51.2	48.6–53.8
12	31.8	29.4–34.2
18	12.1	10.4–13.8
24	7.5	6.1–8.9

The overall median duration of breastfeeding was 28.7 weeks and, with the exception of women born in the United Kingdom (UK) and Ireland, the median duration for women born in Australia (26.5 weeks) was significantly lower ($p < 0.001$) than for women born in other countries (Table 3).

Table 3. Median duration of breastfeeding by mother's country of birth.

Country	Median Duration (weeks)
Total	28.7
Australia/ New Zealand	26.5 ^{a,b,c,d}
UK/Ireland	24.3
India	34.3 ^a
China	34.8 ^b
Asia-Other	34.8 ^c
Other	42.5 ^d

Kruskal-Wallis $H = 26.441$, $df = 5$, $p < 0.001$. Median duration was significantly different ($p < 0.001$) for Australian born mothers and groups with similar superscript letters e.g., ^a indicates that Australia was significantly different to India. ^b indicates that Australia was significantly different to China. ^c indicates that Australia was significantly different to Asia-Other country. ^d indicates that Australia was significantly different to Other country.

3.2. Determinants of Breastfeeding to 12 Months

Women who were multiparous (AOR 1.52, 95%CI 1.08–2.15), had commenced or completed a university degree (AOR 2.28, 95%CI 1.57–3.31) and had not returned to work within 12 months of

the birth of their child (AOR 1.45, 95% CI 1.04–2.02) were significantly more likely to breastfeed to 12 months and beyond compared with primiparous women, those with a high school or vocational level education and those who had returned to work, respectively (Table 4). Women whose partners preferred breastfeeding were 76% more likely to breastfeed to 12 months than those who reported that their partner preferred formula feeding, or was ambivalent about how they fed their child (AOR 1.76, 95%CI 1.22–2.56). Finally breastfeeding at 12 months was independently negatively associated with the use of formula and the very early introduction of complementary foods. Women who introduced complementary foods before 17 weeks were less likely to be breastfeeding at 12 months (AOR 0.43, 95%CI 0.23–0.80) compared women who introduced complementary foods at or after 26 weeks. The introduction of formula at any age before 12 months was strongly negatively associated with breastfeeding at 12 months. There was no independent association with maternal age or country of birth.

Table 4. Factors independently associated with breastfeeding at 12 months and 24 months postpartum.

Characteristics	BF at 12 Months		BF at 24 Months	
	AOR	95%CI	AOR	95%CI
<i>Maternal characteristics</i>				
Age (years)				
<25	0.56	0.27–1.18	0.55	0.17–1.82
25–34	0.86	0.58–1.30	0.66	0.37–1.18
≥35	1.00		1.00	
Highest level of education				
High school/vocational	1.00		1.00	
Some ^a university or graduate	2.28	1.57–3.31	1.34	0.74–2.43
Country of birth				
Australian & New Zealand	1.00		1.00	
UK/Ireland	0.65	0.25–1.70	1.93	0.64–5.85
India	0.83	0.46–1.50	1.83	0.80–4.15
China	1.59	0.74–3.40	1.48	0.40–5.50
Other Asia	0.94	0.51–1.73	2.88	1.35–6.11
Other	1.55	0.78–3.07	1.91	0.81–4.51
Age of infant when returned to work				
By 12 months	1.00		1.00	
Not by 12 months	1.45	1.04–2.02	2.58	1.56–4.31
Pre-pregnancy BMI (kg/m ²)				
<25	1.00		1.00	
≥25	0.56	0.40–0.80	0.66	0.37–1.16
Parity				
Primiparous	1.00		1.00	
Multiparous	1.52	1.08–2.15	1.01	0.60–1.70
Partner's feeding preference				
Prefers breastfeeding	1.76	1.22–2.56	1.56	0.84–2.87
Prefers bottle-feeding or ambivalent	1.00		1.00	
<i>Child characteristics</i>				
Age received complementary foods				
Before 17 weeks	0.43	0.23–0.80	0.73	0.29–1.82
Between 17 and 25 weeks	0.68	0.40–1.15	0.91	0.44–1.79
At 26 weeks or later	1.00		1.00	

Table 4. Cont.

Characteristics	BF at 12 Months		BF at 24 Months	
	AOR	95%CI	AOR	95%CI
Age received formula				
Before 4 weeks	0.05	0.03–0.09	0.28	0.15–0.52
Between 4 and 7 weeks	0.03	0.02–0.07	0.10	0.02–0.44
Between 8 and 15 weeks	0.05	0.03–0.10	0.17	0.06–0.51
Between 16 and 25 weeks	0.05	0.03–0.11	0.47	0.21–1.07
At 26 weeks or later	0.15	0.08–0.28	0.21	0.08–0.58
Never received formula	1.00		1.00	

^a Commenced but did not complete University. AOR Adjusted Odds ratio, BF = breastfeeding, BMI = Body Mass Index

3.3. Determinants of Breastfeeding to 24 Months

Again the use of formula at any age up to 12 months was strongly negatively associated with the odds of breastfeeding to 24 months, and women who had not returned to work by 12 months were significantly more likely to breastfeed to 24 months than those who had returned to work (AOR 2.58, 95%CI 1.56–4.31). While mother's country of birth was not independently associated with breastfeeding to 12 months, women born in Asian countries other than India and China (AOR 2.88, 95%CI 1.35–6.11) had significantly greater odds of breastfeeding to 24 months compared with Australian women.

3.4. Sensitivity Analysis

The exclusion of the explanatory variable 'age of infant when mother returned to work' from the breastfeeding at 12 months model resulted in maternal age being a significant independent predictor of breastfeeding, with younger mothers (<25 years) being less likely to breastfeed to 12 months compared to older mothers (≥35 years); all other variables remained significant (Supplementary Table S2). However, the exclusion of this variable from the breastfeeding at 24 months model had no effect on the results with age of introduction of formula and maternal country of birth remaining as significant predictors of breastfeeding to 24 months.

4. Discussion

This research provides insight into the prevalence of continued breastfeeding to 12 and 24 months amongst a contemporary cohort of South Australian mothers. In this study, just under one third of women continued breastfeeding to 12 months or beyond which is similar to that reported for the USA (30.7%) [31] and Norway (36%) [32]. When compared to earlier Australian studies, including a secondary analysis of the 2010 Australian National Infant Feeding Survey (31.2%) [33], the 2014–15 National Health Survey (27.5%) [21] and the 2004 national Longitudinal Study of Australian Children (LSAC) (30%) [34], the proportion of infants breastfed to 12 months has remained relatively unchanged over the last decade or so. Hence, the majority of Australian infants and their mothers are continuing to be deprived of the considerable benefits of continued breastfeeding.

Compared to low income countries where more than 60% of children are breastfed for 20 to 23 months [3], breastfeeding to 2 years is rare in Australia and other high income countries. In this study, only 7.5% of mothers were still breastfeeding at 2 years which was similar to the 5.6% of women reported to breastfeed beyond 24 months in a large Canadian study [35]. Data from the 2011 UK Diet and Nutrition Survey of Infants and Young Children suggests that the prevalence would be even lower in the UK as only 8% of children aged 12 to 18 months were still being breastfed [36]. Slightly higher prevalence rates have been reported for a study of women in northern Italy (12%) [37] and a study of WIC participants in California (11%) [38].

This study identified a significant association between continued breastfeeding and a number of sociodemographic factors, although not all factors were associated with continued breastfeeding

to both 12 and 24 months. Consistent with other studies of women from high income countries [26], level of maternal education was strongly associated with continued breastfeeding and compared to women with a high school or vocational education, those with at least some university education were more than twice as likely to breastfeed to 12 months. Secondary analysis of the 2010 NIFS data found also that university educated women were more likely to breastfeed to 12 months than less educated women [33], and this association between continued breastfeeding to 12 months and higher level of education has been reported in the Australian Longitudinal Study on Women's Health (ALSWH) [39] as well as US [40] and Italian [37] studies.

Parity was independently associated with continued breastfeeding, with the odds of breastfeeding to 12 months being 52% higher for multiparous women compared to first time mothers. Parity has not been consistently associated with continued breastfeeding [26] however, in Australia where at least nine out of every 10 women initiate breastfeeding [41], multiparity may serve as a proxy measure of prior breastfeeding experience which has been associated with continued breastfeeding [26]. For example, a longitudinal analysis of the ALSWH revealed that Australian women were much more likely to breastfeed their second child for 6 months or more if they had breastfed their first child for at least 6 months [39]. This finding is important as it highlights the importance of helping first time mothers to successfully establish breastfeeding and achieve their intended duration goals so that subsequent infants can benefit from this experience. It also highlights the importance of identifying multiparous women who have had an unsuccessful breastfeeding experience with their first infant and providing them with additional support to increase the duration of breastfeeding for the latest and subsequent children [39].

While foreign born mothers have been shown to be more likely to breastfeed to 12 months than US-born mothers [38] and Swedish-born mothers [42], the association between country of birth and continued breastfeeding has been rarely investigated in Australian studies. The median duration of breastfeeding in this study was significantly lower amongst Australian and UK-born women than women born in India, China and other Asian countries. While maternal country of birth was not associated with continued breastfeeding to 12 months, women born in Asian countries other than India and China were more likely to breastfeed to 24 months than Australian women. Women in this latter group were predominantly from South East Asian countries such as the Philippines, Thailand, and Vietnam which are known for their high rates of continued breastfeeding [3]. There is evidence that migrant mothers become acculturated and adopt the breastfeeding practices of their host country [43,44] and therefore, women from countries with a tradition of continued breastfeeding should be encouraged and supported to maintain their cultural practices in Australia.

Compared to women who entered pregnancy with a healthy BMI, those with a high pre-pregnancy BMI were roughly half as likely to continue breastfeeding to 12 months. Excess body weight has been consistently associated with a lower odds of initiating breastfeeding and a shorter duration of exclusive and any breastfeeding [45,46]. Women with obesity are more likely to deliver by caesarean section [47] and therefore are more likely to miss out on the opportunity to practice early skin-to-skin feeding [48], which in turn has been shown to be more closely associated with exclusive breastfeeding among mothers with obesity than other mothers [48]. Physical barriers such as larger breasts, bigger areolas and additional body tissue can make positioning and attachment difficult [49], while having overweight and obesity have been associated with delayed onset of lactation [46]. Embarrassment and discomfort with breastfeeding is heightened in women with overweight and obesity, even in the hospital setting where women may be in a shared room or open ward with a constant stream of familiar and unfamiliar visitors [49]. Women with overweight and obesity require additional support and guidance in hospital to overcome the physical barriers associated with larger breasts, and strategies and support from partners and family members to tackle the perceived stigma associated with obesity and breastfeeding in public [49].

The importance of partner support for breastfeeding was demonstrated in this study, with women whose partners preferred breastfeeding being 76% more likely to breastfeed to 12 months than those

whose partners either preferred formula feeding or were ambivalent about the feeding method. Partner approval and support of breastfeeding has been consistently shown to be a key determinant of breastfeeding success including the decision to breastfeed and to continue breastfeeding [50,51]. Partner support is likely to be even more important in the case of continued breastfeeding to 12 months and beyond, as societal acceptance, particularly amongst men, of continued breastfeeding and breastfeeding in public decreases as the age of the breastfed child increases [23,24].

Continued breastfeeding was negatively associated with maternal employment, with those who had not returned to work by the time their child was 12 months old being significantly more likely to be breastfeeding at 12 and 24 months. Maternal employment has not consistently been associated with continued breastfeeding to 12 months, with a recent review reporting that most studies that assessed maternal work failed to find an association [26]. However, a study of WIC participants in California reported that women who returned to work within 3 months of delivery were significantly less likely to breastfeed to either 12 or 24 months postpartum compared to women who returned to work after their infant was 7 months or older [38]. Similarly, participation in childcare, which can be taken as a proxy indicator of maternal employment, has been shown to be associated with a reduced likelihood of continued breastfeeding to 12 months in a US [40] and Norwegian [52] study.

Even when available, not all women will be eligible for maternity leave, or for financial reasons able to take maternity leave. Therefore the level and type of support provided within their place of employment on return to work may influence their decision to breastfeed and duration of breastfeeding [53,54]. Employers should be encouraged, or even required, to offer supportive work arrangements to enable a woman to continue breastfeeding after she returns to work. This includes at the very least flexible scheduling and sufficient time to express milk and a designated lactation space other than a bathroom (toilet). Interestingly, a US study revealed that women working within the service and production/transportation industries—those who for financial reasons are most likely to return to work when their child is only months old—received a lower level of workplace support than women within the professional/ management industry [53].

In-hospital formula supplementation has been consistently shown to reduce the likelihood of a woman being able to attain exclusive breastfeeding by hospital discharge [55] and to have a detrimental effect on overall-duration of breastfeeding [56–58]. This study demonstrates however that the detrimental effect of formula is not just contained to the in-hospital use of formula but that the introduction of formula at any age has a negative effect on overall duration. Even the introduction of formula after the age of 6 months, by which time breastfeeding has been successfully established, was independently negatively associated with continued breastfeeding to 12 and 24 months. The reasons for giving formula will vary according to the age of the child, with perceived insufficient milk supply and poor latch being reasons for in-hospital use of formula [57], whereas mothers who first give formula after 6 months may do so for employment-related reasons or the perception that their infant was hungry [59]. Whatever the reason, women should be supported to overcome problems and circumstances which result in the introduction of formula in order to extend the duration of breastfeeding.

A limitation of this secondary analysis is that the primary purpose of the SMILE study was not to investigate continued breastfeeding practices. Therefore, we were unable to investigate important determinants such as a mother's breastfeeding intentions and attitudes towards continued breastfeeding, her knowledge of recommendations related to breastfeeding duration and events which may have impacted on her ability to continue to breastfeed to 12 months and beyond. Exploration of these factors is warranted in future studies specifically designed to investigate continued breastfeeding practices amongst Australian women. A further limitation is that breastfeeding practices were self-reported and may therefore have been susceptible to social desirability bias and misreporting, although as the primary focus of this study was oral health this bias may not be as much of an issue compared to a study which focused on infant feeding practices. The findings with regards to country of birth may not be generalizable as recruitment was limited to those women who were

sufficiently competent in English to complete the surveys, although the ethnic profile of the analysis population was similar to that of women who gave birth in South Australia in 2013 [30]. According to the most recent population census data for 2016, 36% of Australian women aged 20–40 years have completed a university degree [60], indicating that the study population was more highly educated than the general population. However, the census data does not account for women in this age group who may be currently studying at a university or who had dropped out of university. Despite the sociodemographic difference between participants and non-participants, a strength of the study was the intentional oversampling of participants from socially disadvantaged areas [25] which resulted in a socio-economically diverse analysis population which was relatively representative of the population from which it was drawn [30].

5. Conclusions

This study found that just under one-third of Australian women breastfed to 12 months as recommended in the Australian Infant Feeding Guidelines and fewer than 1 in 10 breastfed to 24 months as recommended by the World Health Organization. While there are benefits to be gained from breastfeeding of any duration, the majority of Australian infants and their mothers are missing out on the additional benefits of continued breastfeeding. The majority of factors associated with the practice of continued breastfeeding are potentially modifiable and could be used to identify those women who might benefit from additional breastfeeding support from health professionals in the hospital, their family and partners at home, and from employers in the workplace.

Supplementary Materials: The following are available online at <http://www.mdpi.com/1660-4601/16/20/3980/s1>, Figure S1: Proportion of children breastfed to each month of age, Table S1: Comparison of characteristics of participants and non-participants and South Australian (SA) pregnancy outcome data for 2013, Table S2: Sensitivity analysis: Factors independently associated with breastfeeding at 12 months and 24 months postpartum with age of return to work removed.

Author Contributions: Conceptualization of the SMILE cohort study, L.D., J.S. and D.H.; methodology, J.S.; formal analysis, E.A., J.S.; data curation, G.D., D.H.; writing—original draft preparation, J.S., E.A.; writing—review and editing, L.D., D.H., G.D.; funding acquisition, L.D., J.S., D.H.

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Abbreviations

The following abbreviations are used in this manuscript

AOR	Adjusted odds ratio
BF	Breastfeeding
BMI	Body mass index
CI	Confidence interval
IRSAD	Index of Relative Socio-Economic Advantage and Disadvantage
SA	South Australia
SEP	Socio-economic position
SMILE	Study of Mothers' and Infants' Life Events affecting oral health
UK	United Kingdom
US	United States
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

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Annexure 3 - Wen, LM, et al 'Effects of telephone and short message service support on infant feeding practices, “tummy time,” and screen time at 6 and 12 months of child age: A 3-group randomized clinical trial' *JAMA Pediatrics* (2020)

Effects of Telephone and Short Message Service Support on Infant Feeding Practices, "Tummy Time," and Screen Time at 6 and 12 Months of Child Age

A 3-Group Randomized Clinical Trial

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 Supplemental content

IMPORTANCE There is limited information as to whether telephone or short message service (SMS) support is effective in improving infant feeding practices and tummy time and reducing screen time.

OBJECTIVE To determine the effectiveness of either nurse-led telephone or SMS support in improving infant feeding practices and tummy time and reducing screen time.

DESIGN, SETTING, AND PARTICIPANTS This study was part of a 2-year, 3-group parallel, randomized clinical trial conducted from February 23, 2017, to November 30, 2018, among 1155 women in the third trimester of pregnancy in New South Wales, Australia. It reports the main outcomes at 6 and 12 months of child age. All analyses were conducted on an intention-to-treat principle.

INTERVENTIONS The intervention consisted of staged information booklets mailed to the intervention groups, each followed by either a nurse-led telephone support session or SMS intervention, antenatally and at 1, 3, 5, 7, and 10 months after birth.

MAIN OUTCOMES AND MEASURES The primary outcomes were infant feeding practices at both 6 and 12 months and tummy time at 6 months. The secondary outcome was screen time at 12 months.

RESULTS Of 1155 mothers, 947 (82%; mean [SD] age, 32.5 [5.0] years) completed follow-up surveys at 6 months; 920 mothers (80%) completed follow-up surveys at 12 months. Compared with the control group, telephone support led to higher odds of appropriate timing of introducing solid foods (adjusted odds ratio [AOR], 1.68 [95% CI, 1.22-2.32]), cup use (AOR, 1.54 [95% CI, 1.12-2.13]), and early-start tummy time (AOR, 1.63 [95% CI, 1.18-2.25]) at 6 months and higher odds of having no screen time (AOR, 1.80 [95% CI, 1.28-2.53]) and no bottle at bedtime (AOR, 1.73 [95% CI, 1.23-2.42]) at 12 months. Use of SMS also led to higher odds than the control group of having no screen time (AOR, 1.28 [95% CI, 1.08-1.52]) and having no bottle at bedtime (AOR, 1.29 [95% CI, 1.10-1.51]) at 12 months. No significant differences were found in breastfeeding rates between the telephone support, SMS support, and control groups.

CONCLUSIONS AND RELEVANCE Both the nurse-led telephone support and SMS interventions were effective in reducing screen time and bottle use at bedtime. Telephone support was also effective in promoting the appropriate timing of the introduction of solid foods, early-start tummy time, and cup use.

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Promoting healthy infant feeding practices, such as breastfeeding, timing of introduction of solid foods, and cup use, has been recommended as an important strategy to prevent obesity in the early years.^{1,2} The World Health Organization's Commission report on Ending Childhood Obesity highlights that the first years of life are critical in establishing good nutrition, physical activity, and reduced screen time behaviors that reduce the risk of developing obesity.³ "Tummy time," or time awake in the prone position, is a form of early movement or physical activity recommended for infants younger than 6 months.⁴ Recent research has linked tummy time to early infant motor movement and weight status.⁵

Research evidence from randomized clinical trials (RCTs) suggests that interventions communicating health information to mothers in the first years of their child's life improves infant feeding practices and tummy time. For example, the Healthy Beginnings Trial (HBT) delivered through staged home visits by community nurses led to longer duration of breastfeeding, appropriate timing of introduction of solid foods, and earlier daily practice of tummy time.⁶ Other early intervention trials implementing education sessions for groups of mothers also resulted in improved feeding practices.⁷⁻⁹ More important, the HBT also shows that improved infant feeding practices reduced the mean body mass index of children at 2 years of age.¹⁰ The commonality among these RCTs is the use of face-to-face educational sessions with mothers either at home or in group sessions, which potentially limits the reach of the intervention.

There is emerging evidence that telephone-based counseling interventions and short message service (SMS)-delivered interventions may promote a change in behavior and improve behaviors relevant to obesity prevention and weight management based on a number of meta-analyses and systematic reviews.¹¹⁻¹³ However, to our knowledge, few RCTs have tested the efficacy of using telephone or SMS support for the purpose of promoting healthy infant feeding practices to reduce the early onset of childhood obesity. To our knowledge, no research trial has reported using telephone or SMS support to prevent infant screen time exposure. Findings from a handful of RCTs that used telephone support¹⁴⁻¹⁷ and SMS support¹⁸⁻²⁰ were promising but inconclusive. The lengths of intervention in these studies (predominantly focused on breastfeeding) were relatively short, ranging from 2 weeks to 6 months after birth. To our knowledge, the literature on telephone or SMS support for the appropriate timing of the introduction of solid foods and cup use is scarce.

Thus, a 3-group RCT²¹ was conducted to determine the effectiveness of nurse-led telephone or SMS support in communicating Healthy Beginnings advice^{6,10} to mothers for the promotion of healthy infant feeding practices and for the prevention of early-onset childhood obesity. The aim of this particular study was to report on the findings from the trial at 6 and 12 months of child age.

Methods

Study Design

This study was part of a 2-year, 3-group, parallel RCT conducted from February 23, 2017, to November 30, 2018. The trial

Key Points

Question Is either nurse-led telephone or short message service support effective in improving infant feeding practices and tummy time and reducing screen time?

Findings This randomized clinical trial found that telephone support increased rates of appropriate timing of introducing solid foods, early-start tummy time, and cup use, while telephone and short message service support increased rates of having no screen time and having no bottle at bedtime.

Meaning Both telephone and short message service interventions can be effective in reducing screen time, preventing a bottle at bedtime, and improving some infant feeding practices and tummy time.

was approved by the Sydney Local Health District Ethics Review Committee. Participating mothers provided written consent. A detailed description of the methods was published prior to the commencement of the study.²¹ The trial protocol was implemented without changes (Supplement 1). This study follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Setting

The study was conducted in metropolitan Sydney, New South Wales, Australia. The recruitment of study participants took place at the antenatal clinics in 7 hospitals of 4 local health districts.

Participants and Recruitment

Pregnant women were approached for their eligibility by 4 research assistants at the clinics with a letter of invitation and information about the study. Women were eligible to participate if they were aged 16 years or older, between weeks 24 and 34 of pregnancy, able to communicate in English, had a mobile telephone, and lived in the recruitment areas. Once written consent was obtained, women were required to fill in a registration form with their contact information to allow the research assistant to make further arrangements for baseline data collection and study group randomization. The full recruitment process has been reported elsewhere.²²

Randomization

A web-based randomization plan was generated using randomly permuted blocks ($n = 6$) (<http://www.randomization.com/>). The randomization was stratified by local health districts. The study participants were randomly assigned to 1 of 3 groups (ie, telephone support, SMS support, or control group) after they completed a baseline survey.

Intervention

The process of developing the intervention was informed by the Health Belief Model.²³ The 6 staged interventions from the third trimester to 12 months of the child's age were developed based on the HBT,^{6,10,21} which corresponded to key stages of child feeding and movement, including 1 intervention at the third trimester and 5 interventions postnatally at 1, 3, 5, 7, and

10 months of age. The staged intervention booklets were developed and mailed to the intervention groups matching the delivery timing of the telephone support and SMS support.

Intervention Group 1 (Telephone Support)

One week after the mailing of the intervention booklet, a child and family health nurse called the participants to provide support. Each call was approximately 30 to 60 minutes long, and the nurse and mother talked about the intervention information provided in the booklets and discussed issues raised by the mother. Guided by the HBT checklists,⁶ 6 telephone support scripts were developed to assist the nurses providing telephone support (eAppendix 1 in [Supplement 2](#)).

Intervention Group 2 (SMS Support)

One week after the mailing of the intervention booklet, a set of SMS messages were sent to the participant twice a week for 4 weeks via a 2-way automated SMS system at a predetermined time (10 AM to 1 PM). A full list of SMS messages can be found in eAppendix 2 in [Supplement 2](#). These messages were used to reinforce the intervention information and key messages in the booklets.

Control Group

Mothers in the control group received usual care from child and family health nurses in the local health districts. Home safety promotion materials and a newsletter on "Kids' Safety" were sent to the control group at the third trimester and at 3, 6, and 9 months of child age as one of the retention strategies.

Main Measures and Outcomes

As stated in the published study protocol,²¹ at 6 months of age the main outcomes included infant feeding practices (ie, breastfeeding status, timing of introduction of solid foods, and cup feeding) and tummy time (ie, time of initiating tummy time and frequency of tummy time). At 12 months of age, the main outcomes included breastfeeding status, having family meals together, the use of food as a reward, having a bottle at bedtime, and cup use, as well as play time and screen time. The questionnaires used for the outcome assessment were the same as those in the previous HBT^{6,24-26} and can be found in eAppendix 3 in [Supplement 2](#). Sociodemographic data were also collected using standard New South Wales Health Survey questions²⁷ ([Table 1](#)). Data on the reach of the intervention, including the numbers of participants who received telephone support sessions or SMS messages, were monitored and recorded.

Sample Size

Because this study was part of a 2-year, 3-group RCT, the sample size was based only on the outcome at 24 months of child age (ie, body mass index z score). In the published study protocol,²¹ a sample size of 1056 was required at baseline. This size was based on detecting a difference in the mean body mass index z score of 0.29 units between each intervention group and the control group at 2 years of age with 80% power and a 5% level of significance, allowing for a 25% loss to follow-up.

Blinding

Outcome data at 6 and 12 months were collected by a market survey company using a computer-assisted telephone interview. The interviewers were unaware of the research hypotheses and were blinded to treatment allocation. In addition, participating mothers were blinded to the specific details of the research hypotheses and were asked not to disclose treatment allocation during the assessment interviews.

Statistical Analysis

Data were analyzed using Stata, version 13 (StataCorp LLC). The intention-to-treat principle was applied for all data analyses (ie, we compared the outcomes based on participants' initial group allocations at baseline regardless of whether they received the interventions [telephone or SMS support] or not).

To address potential bias due to missing data and loss to follow-up, 3 steps were taken in comparing the outcomes. First, in complete-case analysis, we conducted comparisons of the outcomes between 1 of the intervention groups and the control group (ie, telephone support vs control and SMS support vs control) using Pearson χ^2 tests. Second, we used multiple logistic regression models to adjust for recruitment sites to determine the intervention effects. Third, multiple logistic regression models with multiple imputation were used to confirm the intervention effects. The adjusted odds ratio (AOR) was calculated with the 95% CI and *P* value. All *P* values were 2 sided, significance was set at *P* < .05, and the *P* values were further adjusted using Bonferroni correction to account for multiple testing.

Multiple imputation was conducted using chained equations to impute missing values. We imputed all missing outcome values at 6 and 12 months of child age for a full intention-to-treat analysis of all 1155 participants. The imputation model predicting missing outcome values was based on all plausible observed values of outcomes and covariates at baseline and the 6-month and 12-month follow-up periods. We used 20 imputations that have a relative efficiency of more than 99% and a power falloff of less than 1%.²⁸ We then calculated the proportions for binary outcomes using Stata's "mi estimate" command and AORs of each of the binary outcomes for those in the telephone support and SMS support groups compared with the control group after adjustments for recruitment sites, as we did for the complete-case analysis models.

Results

Baseline Characteristics and Follow-up

Of the 4429 pregnant women initially approached to participate, 3217 were eligible, and 1498 consented to participate in the study. Of those who gave consent, 1155 (77%) were randomized after completion of the baseline survey, and 343 (23%) were excluded owing to noncompletion of the baseline survey. As shown in the [Figure](#), 1155 women were randomized into either the telephone support group (*n* = 386), SMS support group (*n* = 384), or control group (*n* = 385). Of 1155 mothers, 947 (82%) completed telephone surveys at 6 months (mean [SD] age, 32.5 [5.0] years), and 920 (80%) completed tele-

Table 1. Mothers' Characteristics at Baseline by Group Allocation

Variable	Mothers, No. (%)			
	Total (N = 1155)	Telephone support (n = 386)	SMS support (n = 384)	Control (n = 385)
Mother's age, y				
16-24	97 (8)	33 (9)	33 (9)	31 (8)
25-29	272 (24)	92 (24)	81 (21)	99 (26)
30-34	442 (38)	135 (35)	162 (42)	145 (38)
35-39	270 (23)	102 (26)	87 (23)	81 (21)
40-49	74 (7)	24 (6)	21 (5)	29 (8)
Country of birth				
Australia	425 (37)	143 (37)	145 (38)	137 (36)
Other	730 (63)	243 (63)	239 (62)	248 (64)
Language spoken at home				
English	622 (54)	207 (54)	204 (53)	211 (55)
Other	533 (46)	179 (46)	180 (47)	174 (45)
Annual household income, A\$ ^a				
<40 000	136 (12)	47 (12)	44 (12)	45 (12)
40 000-79 999	252 (22)	82 (21)	80 (21)	90 (23)
≥80 000	639 (55)	213 (55)	224 (58)	202 (53)
Did not know or refused to answer	128 (11)	44 (12)	36 (9)	48 (12)
Employment status				
Employed (employed or paid or unpaid maternity leave)	711 (62)	244 (63)	247 (64)	220 (57)
Other	443 (38)	142 (37)	137 (36)	164 (43)
Unknown	1 (0.1)	0	0	1 (0.3)
Marital status				
Married or de facto partner	1075 (93)	353 (91)	360 (94)	362 (94)
Other	79 (6.9)	32 (8)	24 (6)	23 (6)
Unknown	1 (0.1)	1 (0.3)	0	0
Educational level				
Up to HSC to TAFE or diploma	392 (34)	126 (33)	125 (33)	141 (37)
University	761 (66)	260 (67)	258 (67)	243 (63)
Unknown	2 (0.2)	0	1 (0.3)	1 (0.3)
Father's employment status				
Employed	1028 (89)	336 (87)	346 (90)	346 (90)
Other	100 (9)	36 (9)	31 (8)	33 (8)
Unknown	27 (2)	14 (4)	7 (2)	6 (2)
Father's educational level				
Up to HSC to TAFE or diploma	451 (39)	150 (39)	144 (37)	157 (41)
University	653 (57)	211 (55)	229 (60)	213 (55)
Unknown	51 (4)	25 (6)	11 (3)	15 (4)
First-time mother				
No	531 (46)	177 (46)	170 (44)	184 (48)
Yes	624 (54)	209 (54)	214 (56)	201 (52)

Abbreviations: HSC, higher school certificate (year 12); SMS, short message service; TAFE, technical and further education.

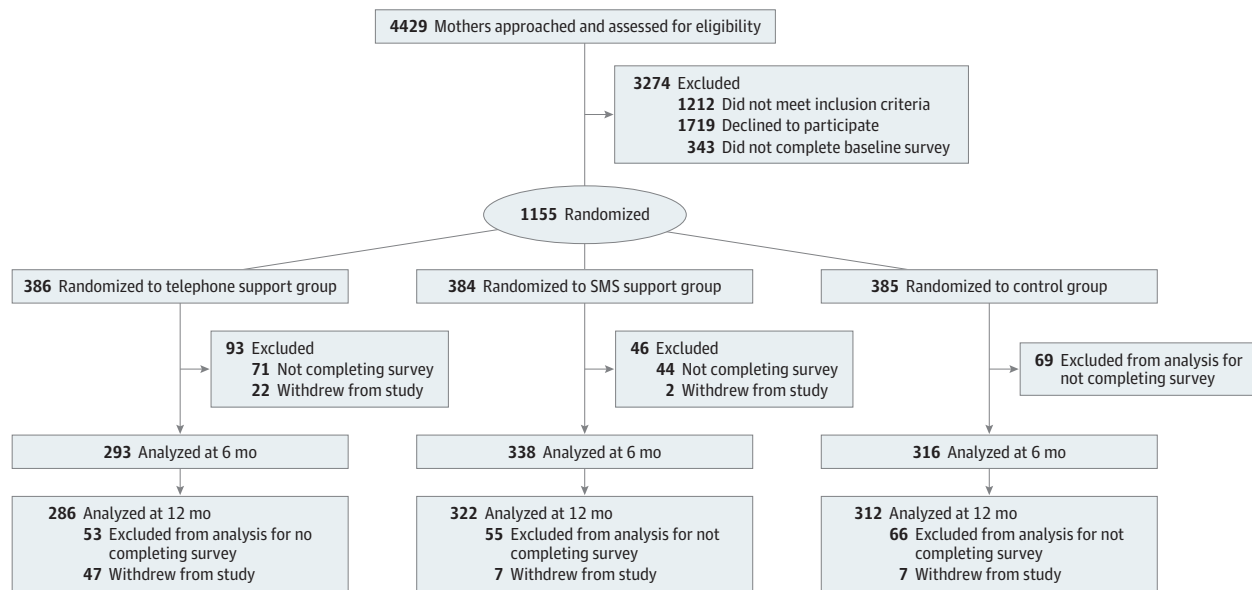
^a To convert Australian dollars to US dollars, multiply by 0.61826.

phone surveys at 12 months, with 864 (75%) completing both surveys. At 6 months, there were 293 mothers (76%) in the telephone support group, 338 mothers (88%) in the SMS support group, and 316 (82%) mothers in the control group. At 12 months, there were 286 mothers (74%) in the telephone support group, 322 mothers (84%) in the SMS support group, and 312 mothers (81%) in the control group. At 6 months, 208 mothers either did not complete the telephone survey or withdrew from the study; at 12 months, 235 mothers either did not complete the telephone survey or withdrew from the

study. More mothers from the telephone support group (n = 47) withdrew from the study than the mothers from either the SMS support group (n = 7) or the control group (n = 7) (Figure).

Table 1 shows that there were no significant differences in maternal characteristics between any of the 3 groups at baseline. eTable 1 in Supplement 2 also shows comparisons of the characteristics between the mothers who did and the mothers who did not complete the follow-up surveys at 6 and 12 months of child age.

Figure. CONSORT Diagram



SMS indicates short message service.

Main Outcomes Using Multiple Imputation With Adjustments

Table 2 shows the comparisons of main outcomes between the telephone support, SMS support, and control groups at 6 and 12 months.²⁹ At 6 months, compared with the control group, the telephone support group had greater odds of appropriate timing (ie, 6 months) of introducing solid foods (AOR, 1.68 [95% CI, 1.22-2.32]), practicing tummy time within 4 weeks after birth (AOR, 1.63 [95% CI, 1.18-2.25]), and drinking from a cup (AOR, 1.54 [95% CI, 1.12-2.13]). These findings were confirmed by multiple logistic regression models. The SMS group had a higher rate of appropriate timing of introducing solid foods than the control group, but it was no longer statistically significant after Bonferroni correction.

At 12 months, compared with the control group, the telephone support group had greater odds of children having no bottle at bedtime (AOR, 1.73 [95% CI, 1.23-2.42]), having a family meal (AOR, 1.71 [95% CI, 1.23-2.39]), and having no screen time (AOR, 1.80 [95% CI, 1.28-2.53]) (Table 2).²⁹ These findings were still statistically significant after multiple logistic regression models with AORs greater than 1 and $P < .05$ after Bonferroni correction. The telephone support group showed higher rates of children drinking from a cup and having active time for more than 2 hours per day, but these rates were not statistically significant after Bonferroni correction. The SMS support group also had greater odds of children having no bottle at bedtime (AOR, 1.29 [95% CI, 1.10-1.51]) and having no screen time (AOR, 1.28 [95% CI, 1.08-1.52]). Rates of breastfeeding at 12 months were higher in the telephone support group (190 of 386 [49%]) and the SMS support group (188 of 384 [49%]) than in the control group (169 of 385 [44%]), but these differences were not statistically significant.

Main Outcomes in Complete-Case Analysis With Adjustments

eTable 2 in Supplement 2 shows comparisons of main outcomes between the telephone support, SMS support, and control groups using complete-case analysis. The results were very similar to those in Table 2 based on multiple imputation.²⁹

Process Indicators

Table 3 shows the numbers and percentages of participating mothers who received telephone support sessions or SMS messages. Not all mothers were able to participate in the telephone support sessions. Only 234 mothers (61%) received the first telephone session, only 337 mothers (87%) received the second telephone session, only 283 mothers (73%) received the third telephone session, only 245 mothers (63%) received the fourth telephone session, only 270 mothers (70%) received the fifth telephone session, and only 264 mothers (68%) received the sixth telephone session. A total of 15 participants opted out from SMS intervention by the end of 12 months. The scheduling SMS system does not allow us to identify at what time point the participants decided to opt out. Overall, the SMS intervention reached 369 participants (96%) in the SMS group.

Discussion

Principal Findings of the Study

This 3-group RCT found that telephone support may increase desired health behaviors (such as introducing solid foods at the recommended age, cup use, and practicing tummy time at an earlier age) and may also increase rates of having no bottle at bedtime and no screen time, as well as having a family meal

Table 2. Comparisons of Main Outcomes Between Each of the Intervention Groups and Control Group at 6 and 12 Months of Age^a

Outcome ^b	Participants, No. (%)			aOR (95% CI)	
	Telephone support (n = 386)	Control (n = 385)	SMS support (n = 384)	Telephone support vs control	SMS support vs control
At 6 mo					
Breastfeeding					
Exclusive	26 (7)	15 (4)	23 (6)	1.80 (0.83-1.13)	1.27 (0.88-1.82)
Current	271 (70)	260 (68)	271 (71)	1.14 (0.80-1.64)	1.08 (0.91-1.27)
Introduction of solid foods at 6 mo	184 (48)	135 (35)	165 (43)	1.68 (1.22-2.32) ^c	1.19 (1.01-1.39)
Age of starting tummy time, <4 wk	229 (59)	182 (47)	176 (46)	1.63 (1.18-2.25) ^c	0.97 (0.83-1.13)
Tummy time frequency, every day	348 (90)	343 (89)	350 (91)	1.11 (0.64-1.93)	1.13 (0.87-1.47)
Drinking from cup	167 (43)	127 (33)	154 (40)	1.54 (1.12-2.13) ^c	1.15 (0.98-1.35)
At 12 mo					
Current breastfeeding	190 (49)	169 (44)	188 (49)	1.25 (0.91-1.72)	1.11 (0.95-1.30)
Drinking from cup	321 (83)	294 (76)	311 (81)	1.53 (1.02-2.29)	1.13 (0.92-1.39)
No bottle at bedtime	229 (59)	177 (46)	226 (59)	1.73 (1.23-2.42) ^c	1.29 (1.10-1.51) ^c
Having a meal together ^d	283 (73)	302 (78)	277 (72)	0.75 (0.50-1.13)	0.84 (0.70-1.01)
Having a family meal ^d	239 (62)	187 (49)	211 (55)	1.71 (1.23-2.39) ^c	1.13 (0.97-1.32)
No use of food for reward	291 (75)	266 (69)	276 (72)	1.37 (0.96-1.97)	1.08 (0.90-1.28)
Child active time, >2 h/d	346 (90)	322 (84)	330 (86)	1.68 (1.07-2.66)	1.09 (0.88-1.35)
Never having screen time	143 (37)	95 (25)	134 (35)	1.80 (1.28-2.53) ^c	1.28 (1.08-1.52) ^c

Abbreviations: aOR, adjusted odds ratio (adjusted for recruitment sites); SMS, short message service.

^a Intention-to-treat analysis with multiple imputations.

^b Based on the Australian National Health and Medical Research Council *Infant Feeding Guidelines*.²⁹

^c $P < .05$ with Bonferroni correction.

^d "Having a meal together" refers to the parents and child sitting and eating a meal together. "Having a family meal" refers to a child eating the same meal as their parents.

at 12 months. The study also found that SMS support may lead to increased rates of having no bottle at bedtime and no screen time. However, neither intervention showed an effect on breastfeeding rate. Furthermore, the findings suggest that telephone support might be more effective than SMS support in promoting other healthy feeding practices, such as cup use and appropriate timing of introducing solid foods.

Meaning of the Study

Consistent with previous empirical evidence,¹⁴⁻¹⁷ this study suggests that the nurse-led telephone support interventions may improve some healthy infant feeding practices, particularly the appropriate timing of introducing solid foods and cup use. The results also demonstrate that both telephone and SMS interventions can reduce early exposure to screen time. With current recommendations detailing that children younger than 2 years of age should not be exposed to screen time,³⁰ this research presents potential intervention approaches for targeting these guidelines. The study's findings are particularly important in informing the development of future telephone or SMS support programs for mothers as part of an early obesity prevention strategy.

Unlike the previous HBT,⁶ which found significant improvement in breastfeeding through home visits, neither the telephone nor SMS support significantly increased breastfeeding rates. Several trials that have used telephone support to en-

hance breastfeeding outcomes have found only short-term (<6 months) effects of the intervention. For instance, a lactation counseling intervention delivered by telephone was effective in increasing breastfeeding rates at 1 month after birth but not at 4 and 6 months.¹⁷ Similarly, another telephone intervention led by a lactation consultant found no significant effect on breastfeeding duration at 3 months after birth despite a significant effect at 1 month.³¹ Another 2 telephone interventions found no significant differences in breastfeeding outcomes between the intervention and control groups, even in the short term.^{14,15}

However, our study observed that mothers in both intervention groups could be more likely to breastfeed at 12 months than mothers in the control group, although the difference was not statistically significant. This lack of significance could be owing to the sample size that was not powered to detect smaller differences. One-year postpartum breastfeeding is an important milestone because every additional breastfeeding week is associated with less illness among infants.³²

What the Study Adds

The study findings support those of the previous HBT using a home visiting model that showed that a nurse-led staged intervention improved infant feeding practices and tummy time.⁶ The unique features of these studies provide timely, needed health information for mothers according to child development stages of feeding and movement. Our findings support

Table 3. Process Indicators of Telephone and SMS Support

Support session	Participants, No./total No. (%)
Telephone support	
1	234/386 (61)
2	337/386 (87)
3	283/386 (73)
4	245/386 (63)
5	270/386 (70)
6	264/386 (68)
SMS support ^a	370/384 (96)

Abbreviation: SMS, short message service.

^a Data show only overall number of participants who remained in SMS support group by end of intervention because the time point when participants decided to opt out could not be determined by the scheduling SMS system.

that it is feasible and effective to improve infant feeding practices and tummy time using telephone support.

In this study, telephone support seemed more effective, but it might be less sustainable as more mothers in this group withdrew from the study compared with the SMS support group and the control group. The higher withdrawal rate could reflect mothers' lack of availability to participate in the telephone support sessions, which would require 30 to 60 minutes of their time. In addition, approximately 88% of the population in Australia in 2017 owned a smartphone,³³ and it can be anticipated that the number of current cell phone users would be higher. Thus, there is potential for the use of SMS to deliver health intervention messages.

Unanswered Questions and Future Research

This study detected a potential effect of the telephone or SMS support on breastfeeding outcomes at 12 months. Another RCT found that mothers who received more telephone support were more likely to breastfeed than women who received less telephone support, although no significant difference was found in the overall breastfeeding rate between the intervention and control groups.¹⁴ The effect of a greater frequency of telephone calls or SMS messages as a method of support for infant feeding outcomes is worth investigating.

Our findings suggest that telephone support might be more effective than SMS messages in improving infants' feeding practice and tummy time. This finding may be attributed to the interactive component of the telephone support. One RCT showed that an SMS intervention was effective in improving breastfeeding duration using automated 2-way SMS messaging.¹⁹ Some studies suggest that a multifaceted intervention may intensify outcomes.^{16,18} An intervention that com-

bines telephone support and SMS support, which could be universally delivered and remains cost-effective, has the potential to produce greater effects. This potential, however, warrants further investigation.³⁴ In addition, with the limited studies available on the relative costs of different types of interventions in this area, it is important for future research to examine the costs and cost-effectiveness of various intervention approaches (eg, face-to-face vs telephone or SMS support).

Strengths and Limitations

This study has some strengths. To our knowledge, this is the first large-scale RCT that examines the effects of either telephone or SMS support on a range of infants' health behaviors. Our intervention commenced in the antenatal period; early contact allowed us the opportunity to discuss and improve mothers' feeding knowledge and intention and to address their concerns in a timely manner. Our nurse-led intervention also shows potential for making a difference in healthy infant feeding practices and tummy time. Child and family health nurses delivered telephone support sessions. In addition to their base professional training, they were trained in motivational interviewing and how to address additional psychosocial issues associated to infants' health and behavioral issues. The research protocol was published prior to study commencement. The participation rate was high, with a mean of 81% at follow-up periods.

However, this study also has several limitations. First, we were not able to fully address the many social, cultural, economic, and environmental factors that are likely to be associated with infant feeding practices. Second, the design of the telephone intervention required 6 contacts between the nurses and the participants; however, approximately 30% of participants did not receive all of the telephone support sessions, which may have reduced the effect of the telephone support. Third, the sample size estimate was not based on the main outcomes assessed, nor was it powered enough for comparing effects between the interventions. Fourth, this study was also limited by the use of self-reported outcome measures.

Conclusions

Both the telephone and SMS interventions were effective in reducing screen time and bottle use at bedtime, with telephone support offering greater effects on improving some infant feeding practices and tummy time. A combination of both delivery modes may intensify the health outcomes. There is a need for future research to explore this potential.

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