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<b>Title</b>	A detailed exploration of early infant milk feeding in a prospective birth cohort study in Ireland: combination feeding of breast milk and infant formula and early breast-feeding cessation
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*Title: A detailed exploration of early infant milk feeding in a prospective birth cohort study in Ireland: combination feeding of breastmilk and infant formula and early breastfeeding cessation.*

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**Abstract**

Breastfeeding initiation and continuation rates in the United Kingdom and Ireland are low relative to many European countries. As a core outcome of the prospective COMBINE birth cohort study (Cork, Ireland), we aimed to describe infant milk feeding practices in detail and examine the prevalence and impact of combination feeding of breastmilk and infant formula on breastfeeding duration. COMBINE recruited 456 nulliparous mothers (2015-2017) for maternal-infant follow-up via interview at hospital discharge (median [IQR] 3 [2, 4] days,  $n=453$ ), 1 ( $n=418$ ), 2 ( $n=392$ ), 4 ( $n=366$ ), 6 ( $n=362$ ) and 9 ( $n=345$ ) months of age. Median (IQR) maternal age was 32 (29, 34) years, 97% of mothers were of white ethnicity, 79% were Irish-born and 75% were college educated. Overall, 75% breastfed to any extent at discharge and 44% breastfed solely. At 1, 2, 4, 6 and 9 months respectively, 40%, 36%, 33%, 24% and 19% breastfed solely. Combination feeding of breastmilk and infant formula was common at discharge (31%) and 1 month (20%). Reasons for combination feeding at 1 month included perceived/actual hunger (30%), healthcare professional advice (31%) and breastfeeding difficulties (13%). Of mothers who breastfed to any extent at discharge, 45% stopped within 4 months. Mothers who combination fed were more likely to cease breastfeeding than those who breastfed solely (relative risk 2.3 by 1 month and 12.0 by 2 months). These granular data provide valuable insight to early milk feeding practices and indicate that supporting early breastfeeding without formula use may be key to the successful continuation of breastfeeding.

## Introduction

There is strong evidence to suggest that substantial health and economic benefits follow from improved nutrition in early life<sup>(1-4)</sup> and that breastfeeding is beneficial for both mother and baby<sup>(3)</sup>. Breastfeeding protects against infection and morbidity, promotes development of the infant immune system<sup>(5)</sup> and may support neurological development<sup>(6, 7)</sup>. It facilitates maternal postpartum weight normalisation<sup>(8)</sup>, with persistent benefits for maintaining a healthy body mass index<sup>(9)</sup> and reduces the risk of breast cancer<sup>(10)</sup> and endometriosis<sup>(11)</sup>. The World Health Organization (WHO) recommends exclusive breastfeeding for the first 6 months of life, with continuation alongside complementary feeding to 2 years or beyond<sup>(12, 13)</sup> and this advice is mirrored by national health organisations<sup>(3, 14-16)</sup> and expert bodies<sup>(17-19)</sup>. Because of the well-established benefits of breastfeeding to mother and baby, continuous promotion, education and assessment of infant feeding is vital, particularly in areas that traditionally have a low prevalence of breastfeeding.

Worldwide, many countries fail to meet breastfeeding recommendations and the WHO European region is reported to have the lowest rates of breastfeeding<sup>(20)</sup>. The European Perinatal Health Report 2010, with data from 19 countries, showed that while more than 95% of mothers in the Czech Republic, Switzerland, Latvia, Portugal, and Slovenia breastfed to some extent in early life, early breastfeeding rates were below 70% in Ireland, France, Scotland, Malta and Cyprus<sup>(21)</sup>. National infant feeding surveys in the United Kingdom (UK) and Scotland have reported low rates of breastfeeding in the first 6 months<sup>(22-24)</sup> and current Health Service estimates suggest that in England 46% breastfeed to any extent at 6-8 weeks<sup>(25)</sup>. In Northern Ireland 25% breastfeed at 6 weeks, 20% at 3 months and 13% at 6 months<sup>(26)</sup>. In Ireland, the latest national figures, from 2015/16, indicate that 60% of mothers breastfeed to any extent at hospital discharge, with 10% of these feeding a combination of breastmilk and infant formula<sup>(27)</sup>. Post-discharge, national data are collected at 3 months postpartum only; 42% of women are reported to breastfeed to any extent at this time<sup>(28)</sup>. Despite the continuing low prevalence of breastfeeding, secular data do suggest some improvement in breastfeeding rates in Ireland and the UK over the past decade<sup>(24, 27)</sup>, although the effect of methodological and population changes on national data challenge direct comparability across time<sup>(29)</sup>. In our previous birth cohort (participants recruited 2008-2011), we found higher breastfeeding initiation rates than nationally reported, but low levels of breastfeeding continuation<sup>(30)</sup>.

Because it has one of the lowest rates of breastfeeding initiation, as well as high rates of early breastfeeding cessation<sup>(22)</sup>, data from Ireland can provide a useful case-study to inform the design and implementation of targeted breastfeeding policies and supports. However, detailed data are lacking. This paper describes early milk feeding data collected over the first 9 months of life in a nutrition-focused, longitudinal, prospective birth cohort study, the Cork Nutrition and Development Maternal-Infant Nutrition Cohort (COMBINE). Using research midwife-administered questionnaires and in-person interviews at 6 time-points over the 9-month period, we aimed to describe infant milk feeding practices in detail and to examine the prevalence and impact of combination feeding of breastmilk and infant formula on breastfeeding duration.

## Methods

### Study design

The COMBINE study, based in Cork, Ireland, is a longitudinal, prospective birth cohort study from early pregnancy to 24 months of age. Participants of the Improved Pregnancy Outcomes via Early Detection (IMPROvED) study [<http://www.clinicaltrials.gov>; trial ID: NCT01891240] formed the recruitment pool for COMBINE. IMPROvED participants were generally healthy, low risk, nulliparous women with a singleton pregnancy, who attended antenatal care at Cork University Maternity Hospital<sup>(31)</sup>. Recruitment for COMBINE commenced in late 2015 and finished in late 2017 and 903 IMPROvED participants were eligible for postnatal follow-up in COMBINE during this period. After exclusion of 12 infants who met the newborn exclusion criteria (admitted to neonatal intensive care unit for > 2 weeks or had a severe metabolic or genomic anomaly requiring ongoing specialist care in the neonatal period), 456 mother-infant pairs were recruited and participated in postnatal follow-up in COMBINE. Research midwives conducted 9 study visits with families over the first 24-months of the baby's life; the present analysis focuses on the first 9 months. Following delivery, the first follow-up visit was conducted in the maternity hospital and subsequent visits were scheduled for 1 month, 2, 4, 6 and 9 months (**Supplementary Figure 1**).

COMBINE was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects/patients were approved by the UCC Clinical Research Ethics Committee [ECM4(hh)06/01/15 and ECM3(bbb)10/04/18]. Written

informed consent was obtained from all subjects. The study is registered at <http://www.birthcohorts.net/>.

Raw data from the Cork BASELINE birth cohort study were used to investigate changes in feeding patterns over the last 8-10 years. Briefly, between 2008 and 2011, the BASELINE study recruited 2137 maternal-infant dyads, who attended antenatal care at Cork University Maternity Hospital<sup>(32)</sup>. The study design, methods and data collection were similar in BASELINE and COMBINE and in BASELINE postnatal follow-up used for this analysis was at hospital discharge, 2 months and 6 months. BASELINE was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects/patients were approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals [ECM 5 (9) 01/07/2008].

### **Data collection and preparation**

In COMBINE all feeding data were collected through interviewer-led questionnaires. At hospital discharge, simple infant feeding data were collected to ascertain the infant feeding method. At subsequent study visits, more in-depth information on feeding methods and practices were collected, with the questionnaires designed through past experience and literature review. Key questions included if the participant was breast, infant formula or combination feeding. If the participant reported breastfeeding only, data on use of infant formula top-ups since last visit were collected. Participants were asked if they had given their baby any fluids other than breastmilk or infant formula and if so, the fluid given was recorded. Consistency of data across study visits was routinely monitored. If a participant ceased breastfeeding between visits, infant age at cessation (in weeks) was recorded and participants were asked to provide their reason(s) for breastfeeding cessation in their own words. This was matched to a predefined list of common reasons for breastfeeding cessation and the match with the participant's original answer was clarified with the participant to confirm. If an answer not on the predefined list was provided, it was recorded as 'other' and an open text box used to record the specific reason for breastfeeding cessation. If a participant reported combination feeding breastmilk and infant formula a similar approach was taken to ascertain their reason(s) for doing so.

Feeding in the first 9 months of life was analysed both cross-sectionally and longitudinally. In this analysis, breastfeeding refers to breastmilk as the main milk source, although the infant may have received occasional formula top-ups and combination feeding describes

feeding both breastmilk and formula as routine. Any breastfeeding encompasses both breastfeeding (breastmilk as main milk source) and combination feeding. Infant formula feeding is defined as giving formula only, with no breastmilk. These terms allow inclusion of supplementary fluids, as well as solid foods, and do not differentiate between direct and expressed breastfeeding.

In addition, longitudinal exclusive and predominant breastfeeding as defined by the WHO<sup>(33)</sup>, are reported from birth to each visit up to 6 months. These variables were prepared to account for use of any formula (including top-ups), supplementary fluids or solid foods at a preceding time, as appropriate to each definition (see **Table 1**). The WHO exclusive and predominant breastfeeding definitions do not preclude the use of medicines, vitamins or minerals and do not differentiate between direct and expressed breastfeeding.

### Statistical analysis

Data collected during the study were stored in a bespoke, centralised, internet-deployed database (MedSciNet, Sweden), which facilitates data entry, tracking and multi-step review. Data were then exported to Excel<sup>®</sup> 2016 (Microsoft, USA) and statistical analysis was performed using IBM SPSS<sup>®</sup> version 24.0 (IBM Corp., Armonk, NY, USA) software for Windows<sup>™</sup>. Normality testing indicated that descriptive and feeding data were non-parametric and data are presented as median (interquartile range [IQR]), with categorical data presented as percentage (%). Chi-square or Fishers Exact tests were used, as appropriate, in comparisons of categorical variables between participant groups. Differences in continuous variables were assessed using the Mann-Whitney U test. Simple relative risk ratios for combination feeding and breastfeeding cessation were calculated as (Probability of breastfeeding cessation in combination feeding participants)/(Probability of breastfeeding cessation in breastfeeding solely participants)<sup>(34)</sup>. Statistical significance is defined at  $P < 0.05$ .

## Results

### Maternal and infant characteristics

Characteristics of participants of the COMBINE study ( $n = 456$ ) are presented in **Table 2**. Median (IQR) maternal age at delivery was 32 (29, 34) years. While 8% of participants were  $< 25$  years, 14% were  $> 35$  years of age. There was a high proportion of white (97%) and

Irish born (79%) mothers in the cohort. Most participants were in a stable relationship (95%), in employment (91%) and had a third level qualification (75%). Median (IQR) gestational age and birthweight were 40 (39, 41) weeks and 3.5 (3.2, 3.8) kg, respectively, and the rate of neonatal unit admittance was 15%. As shown in Supplementary Figure 1, 92% of recruited participants completed the 1-month study visit, 86% the 2-month, 80% the 4-month, 79% the 6-month and 76% completed the 9-month study visit. Mothers who left the study before the 9-month visit were less likely to be in a stable relationship (89% vs. 96%,  $P = 0.006$ ) compared with those who completed the study to 9-months, but there were no other demographic differences, including in tertiary education (64% vs. 76%,  $P = 0.17$ ) or the proportion born in Ireland (75.2% vs. 80.9%,  $P = 0.20$ ), between those who dropped-out and completed the study. The median (IQR) age of mothers who did not complete the study was 30 (25, 33) years, compared to 33 (30, 35) years in mothers who continued in the study to 9 months,  $P < 0.001$ .

### Infant milk feeding practices

**Figure 1** details infant milk feeding practices at 6 time-points over the first 9 months. At hospital discharge, 75% of mothers provided any breastmilk (breast or combination fed) and this decreased to 60% by 1 month. Just over half (51%) and a quarter (26%) of the cohort breastfed to any extent at 2 and 9 months, respectively.

At hospital discharge, 44% of mothers breastfed as the main milk source, which decreased to 40% by the 1-month follow-up visit and continued to decline to 24% at 6 months and 19% at 9 months. One-third (31%) combination fed both breastmilk and formula at discharge and one-fifth (20%) did so at 1 month. Combination feeding halved to 11% between 1 and 4 months and fluctuated slightly thereafter (13% and 7% at 6 and 9 months, respectively). The prevalence of infant formula feeding increased throughout the study; 25% of mothers formula fed at hospital discharge and 49% did so at the 2 month follow-up. By 9 months, 74% provided formula as the main milk source.

### Breastfeeding patterns

Women who breastfed to any extent at hospital discharge were slightly older [33 (30, 35) vs. 31 (27, 34) years,  $P < 0.001$ ] and less likely to be < 25 years old at delivery (4% vs. 18%,  $P < 0.001$ ), born in Ireland (75% vs. 91%,  $P < 0.001$ ) and of white ethnicity (95% vs. 100%,  $P = 0.016$ ) than those who never breastfed. A higher proportion had a third-level qualification



(84% vs. 49%,  $P < 0.001$ ) and were in a stable relationship (97% vs. 90%,  $P = 0.004$ ). Among breastfeeding mothers, 29% had given at least one formula top-up between hospital discharge and 1 month, and the equivalent figures were 14%, 19% and 9% in the intervals between 1-2 months, 2-4 months and 4-6 months. Most reported infrequent formula top-ups; at each time-point 45-63% had not given infant formula more than 3 times since the previous visit.

Of the three-quarters of mothers who breastfed to any extent at discharge, 20% did so for < 1 month, 25% for 1-4 months, 9% for 4-6 months, 14% for 6-9 months and 32% were still breastfeeding at 9 months. Among those who stopped breastfeeding within the 9-month study period, the median (IQR) infant age at cessation was 7 (2, 22) weeks and 26% stopped breastfeeding within the first 2 weeks. There were many reasons for breastfeeding cessation (**Supplementary Table S1**). The most common reason given was an insufficient milk supply (perceived/actual) or failure to thrive (27%); these mothers stopped breastfeeding earlier than those who gave alternative reasons for cessation of breastfeeding [6 (2, 10) vs. 11 (3, 26) weeks,  $P = 0.005$ ].

### *Exclusive and predominant breastfeeding*

Longitudinal exclusive and predominant breastfeeding practices from birth to 6 months are presented in **Figure 2**. Exclusive and predominant breastfeeding were not differentiated at hospital discharge. At discharge, 40% of participants had exclusively breastfed since birth and 22% continued to breastfeed exclusively to 1 month. Participants who exclusively breastfed to hospital discharge but not 1 month lost exclusive breastfeeding status through the use of water or other supplementary fluids (48%), at least one formula top-up (22%), initiation of combination feeding (33%) and/or cessation of breastfeeding (30%). The rate of exclusive breastfeeding to 2 months was 18%, and 15% exclusively breastfed from birth to 4 months. Whilst 38% of infants were receiving breastmilk at 6 months, only 1.9% (6 mothers) breastfed exclusively to this time-point. All participants ( $n = 42$ ) who lost exclusive breastfeeding status between 4 and 6 months initiated complementary feeding during this time, although all were still breastfeeding to some extent at 6 months. **Supplementary Table S2** details use of supplementary fluids in the cohort.

Rates of predominant breastfeeding (infant may have received water or other supplementary fluids but not infant formula) were slightly higher than exclusive breastfeeding at 1, 2 and 4 months, at 29, 21 and 18%, respectively. In those who had predominantly breastfed, water

was the most commonly given liquid, but inappropriate fluids, including herbal teas, were also used.

### Combination feeding patterns

Between 7 and 31% of participants reported feeding both breastmilk and infant formula on a daily basis during the study (Figure 1). Although the reasons for combination feeding varied over time (**Figure 3**), a concern that baby was hungry was commonly expressed (30, 43, 40 and 27% at 1, 2, 4 and 6 months, respectively). Up to 4 months, between 21 and 31% of participants reported receiving advice from a healthcare professional to combination feed. At each visit, 13-17% reported sleep-related reasons (infant sleeps better or sharing burden of night feeds) for giving infant formula as well as breastmilk. While 7% reported inclusion of family members as a reason for combination feeding at 1 month, this increased to 21% at 6 months. Other reasons for combination feeding at 1 month included low breastmilk supply/latching difficulties (13%) and maternal pain/illness (7%), as well as initiation of infant formula use in the neonatal unit with continuation on discharge (5%). At 6 months, weaning (19%) and return to work (15%) were commonly cited as other reasons for using infant formula. Embarrassment at breastfeeding in public was not commonly reported at any visit (0-5%).

### *Combination feeding and breastfeeding continuation*

As shown in **Figure 4**, successful breastfeeding was associated with continuation of breastfeeding; at every visit those who breastfed were significantly more likely than those who combination fed to be giving any breastmilk at the next visit (all  $P < 0.001$ ). Eighty-six percent (86%) of mothers who were breastfeeding at hospital discharge breastfed to any extent at 1 month, compared to 68% of those who were combination feeding on discharge ( $P < 0.001$ ). This translates to a relative risk of breastfeeding cessation by 1 month of 2.3 in those combination feeding at hospital discharge, as compared to those breastfeeding solely. In terms of breastfeeding duration, in participants who ceased breastfeeding during the study, the duration of breastfeeding was halved in those who combination fed at discharge compared with those who breastfed [median (IQR); 6 (2, 19) vs. 12 (4, 26) weeks,  $P = 0.006$ ].

Substantial differences were also observed at later visits. For example, 95% of mothers who breastfed as the main milk source at 4 months breastfed to any extent at 6 months ( $P < 0.001$ )

versus 53% of those who were combination feeding. The rate of any breastfeeding at 9 months was 89% in those who breastfed at 6 months, compared to 33% in those who combination fed ( $P < 0.001$ ). The relative risk for breastfeeding cessation if combination feeding, as compared to breastfeeding solely, was 12.0 between 1 and 2 months, 14.7 between 2 and 4 months, 9.1 between 4 and 6 months and 6.3 between 6 and 9 months.

### Changes in feeding patterns over time

To investigate changes in milk feeding patterns over the last decade, differences in feeding practices between the BASELINE (recruited 2008-2011) and COMBINE (recruited 2015-2017) studies were examined. As shown in Table 2, participants in the recent COMBINE cohort were slightly older than participants in earlier BASELINE cohort [32 (29, 34) vs. 31 (28, 34) years,  $P = 0.001$ ], although there were no differences in the proportion of participants  $< 25$  or  $> 35$  years of age between the two cohorts (both  $P > 0.05$ ). A slightly higher proportion of participants in the earlier cohort were of white ethnicity (98% vs. 97%,  $P = 0.042$ ) and smoked during pregnancy (13% vs. 7%,  $P < 0.001$ ), compared to participants in the recent cohort, but other maternal demographic characteristics did not differ (all  $P > 0.05$ ). At hospital discharge, 75% of participants in the recent COMBINE cohort breastfed to any extent, compared to 69% in the earlier BASELINE cohort ( $P = 0.011$ ), and the proportion giving any breastmilk remained higher in COMBINE at 2 (51% vs. 44%,  $P = 0.009$ ) and 6 (38% vs. 23%,  $P < 0.001$ ) months. While rates of combination feeding were similar at each time point (all  $P > 0.05$ ), a higher percentage of mothers breastfed as the main milk source in the recent COMBINE cohort than the earlier BASELINE cohort at 2 (36% vs. 27%,  $P = 0.01$ ) and 6 (24% vs. 12%,  $P < 0.001$ ) months, with no significant difference at hospital discharge (44% vs. 40%,  $P = 0.25$ ) (**Figure 5**). There was a consistently lower prevalence of formula feeding in the more recent cohort than the earlier cohort; 25% vs. 31% at hospital discharge ( $P = 0.011$ ), 49% vs. 55% at 2 months ( $P = 0.009$ ) and 62% vs. 77% at 6 months ( $P < 0.001$ ).

### Discussion

We have presented a detailed description of early infant feeding practices in a large and well-characterised prospective cohort study in Ireland, which has a history of low breastfeeding rates. Through multiple closely timed follow-ups, we identified frequent changes in feeding methods over the first months of life and showed that precise breastfeeding definitions are

required to accurately capture feeding patterns. High rates of early breastfeeding cessation persist; one-quarter of women who ceased breastfeeding did so within 2 weeks. Women who fed a combination of breastmilk and infant formula were less likely to continue breastfeeding than those who fed breastmilk only. This is highly relevant given that a substantial proportion of mothers used combination feeding during the first month.

The most recent national report in Ireland suggests that 60% of mothers breastfeed to any extent at hospital discharge, with 50% breastfeeding solely<sup>(27)</sup>. There was a higher rate of any breastfeeding in this cohort (75%), but a smaller proportion were breastfeeding solely (44%). The higher rate of any breastfeeding may be reflective of study demographics, but potential differences in data collection and specification of feeding methods challenge direct comparisons. Nationally collected data are not as rigorously specified, which may account for the lower proportion of women breastfeeding solely in the cohort despite a higher rate of any breastfeeding.

Recognising that early breastfeeding cessation is a major challenge, infant feeding policies increasingly target improvements in breastfeeding duration<sup>(35-37)</sup>. Collectively, national data highlight low rates of breastfeeding continuation through the first months of life<sup>(22-26, 28)</sup>, but can be limited in the time-points examined, by the use of retrospective recall and through a lack of standardised and specific feeding definitions. Our data show that the most substantial drop in any breastfeeding occurred between discharge and 1 month, with continuing decreases thereafter. Almost half of participants who breastfed at discharge did so for less than 4 months, and given that one-quarter of those who stopped breastfeeding during the study did so within the first two weeks of birth, the problem of early cessation, despite a relatively high prevalence of breastfeeding initiation, appears to be a critical one from the point of view of breastfeeding support service provision.

Support from healthcare professionals, as well as maternal satisfaction with support, predict breastfeeding continuation<sup>(38)</sup> and a mothers own experience is the most influential factor to continuation<sup>(39)</sup>. Thus, directing resources towards early feeding support and overcoming initial difficulties, thereby increasing maternal understanding and confidence, may prove most beneficial to improving breastfeeding duration. In addition to healthcare professionals, formal and informal peer and family support can positively influence breastfeeding duration<sup>(40, 41)</sup>. Because breastfeeding intention prior to birth influences breastfeeding initiation and continuation<sup>(23)</sup>, antenatal breastfeeding support is also essential, particularly in

population groups with lower breastfeeding initiation rates, such as young, lower educated or lower socio-economic groups<sup>(22)</sup>.

The practice of combination feeding breastmilk and infant formula was common, particularly in the postpartum period, and at every study visit women who combination fed were more likely to cease breastfeeding. Given this, the reasons provided for combination feeding are of interest. Data on the reasons for combination feeding in hospital were not available, but other studies have reported reduced breastfeeding duration and increased likelihood of cessation, irrespective of the reason for in-hospital infant formula use<sup>(42, 43)</sup>.

From one month on, concern that baby was hungry, indicating an insufficient milk supply, was commonly cited as a reason for combination feeding. Studies suggest that perceived milk insufficiency can relate to factors such as breastfeeding self-efficacy, confidence, support and knowledge<sup>(44, 45)</sup>, rather than actual milk insufficiency. Although common infant behaviours, crying, fretfulness, discontentment and unsettledness, as well as changes in feeding pattern, frequency or duration may be interpreted as hunger signals and thus perceived as indicators of milk insufficiency<sup>(46-48)</sup>. While not precisely known, the prevalence of biological milk insufficiency, where enough milk cannot be produced to satiate the infant, is thought to be low<sup>(44)</sup>. However, quantifying actual milk production, through measurement of breastmilk transfer, is challenging and not routinely practiced in clinical settings<sup>(49)</sup>. Infant growth can be tracked as a proxy indicator of milk sufficiency and will identify cases of growth faltering, where combination feeding may be medically indicated. In this regard, exploration of the relationship between maternal reported milk insufficiency and infant growth is of interest. Where there is no evidence of growth faltering and breastfeeding continuation is deemed appropriate, adequate resourcing and support systems should facilitate mothers to continue breastfeeding without the use of infant formula, should they choose to do so.

In Scotland, a 10-11% increase in any breastfeeding at 4 and 6 months between 2010 and 2017 has been reported, with no change in initiation rate<sup>(24)</sup>. National data in Ireland suggests an increase in the proportion who breastfed to some extent at discharge between 2010 and 2016 (54% to 60%)<sup>(27)</sup>, and although only collected for the first time in 2015, an increase in any breastfeeding at 3 months between 2015 and 2019 (34% to 42%)<sup>(28, 50)</sup>. However, caution may be warranted due to the well-established and potentially substantial effects of changing demographics<sup>(29)</sup>. Conducted in the same maternity hospital, using similar methods, the COMBINE (recruited 2015-2017) and BASELINE (recruited 2008-2011) birth cohorts

provide a useful backdrop from which to examine trends in feeding over an 8-10 year period. The proportion who breastfed solely in COMBINE was 1.3-fold higher at 2 months and 2-fold higher at 6 months, indicating an increase in breastfeeding duration over this time-frame, with little change in initiation. Participants in COMBINE had additional study visits at 1 and 4 months and, although strictly an observational cohort, were afforded the opportunity to discuss any queries they had with research staff at each visit, which could have influenced breastfeeding rates at subsequent visits. However, the magnitude of the increases are not likely attributable to the two additional study visits, nor the 1-year increase in median maternal age and 1% increase in non-white ethnicity.

Participant demographics, including the high proportion of white mothers, are largely reflective of the Irish population and that of many European countries, but this cohort was not designed to be nationally representative. All participants were nulliparous, increasing uniformity but potentially limiting generalisability. Nulliparous women may experience breastfeeding differently to multiparous women, being more likely to experience early difficulties and report cessation due to latching problems and milk insufficiency<sup>(51)</sup>. Successfully breastfeeding a first child may potentiate breastfeeding of subsequent children<sup>(52, 53)</sup>. In the UK and Ireland, where there is a high incidence of early cessation, particularly due to reported breastfeeding difficulties, this may discourage mothers from breastfeeding in subsequent pregnancies, leading to a negative effect of multiparity<sup>(22, 23)</sup>. Enabling successful breastfeeding experiences in nulliparous women may therefore prove most effective in increasing breastfeeding rates.

A common challenge of longitudinal cohort research is participant retention, particularly with frequent study visits<sup>(54)</sup>. Although COMBINE had a relatively high retention rate, mothers who left the study early were younger and less likely to be in a stable relationship than those who completed the study, which may limit generalisability of results to young or single mothers. Given the potential for bias if selective attrition of younger, lower socio-economic or minority groups occurs<sup>(55)</sup> and possible socio-demographic differences in infant feeding patterns, future studies could implement tailored retention strategies toward particular groups. In interpretation of results, the possibility of an ecological fallacy should be considered; aggregate data at the cohort level may not apply at the individual level<sup>(56)</sup>.

This work is strengthened by description of infant feeding practices according to a number of precise definitions. Although the WHO indicators for exclusive and predominant

breastfeeding are often based on 24- or 48- hour recalls, we have reported them on a continuum since birth, as in the 2010 UK Infant Feeding Survey<sup>(23)</sup>, because use of infant formula top-ups and other fluids, which is common in the current context, will introduce bias and may substantially overestimate the true rate of exclusive/predominant breastfeeding. Reported breastfeeding rates can depend greatly on the definition used. For example, the rate of any breastfeeding, an aggregate of feeding patterns, was 7-31% higher than that of breastfeeding solely at each visit. At 6 months, the rate of any breastfeeding was 14-fold higher than WHO-defined exclusive breastfeeding from birth. Although often reported, the rate of any breastfeeding can be misleading, depending on the context of the feeding practices, and because of a decreased likelihood of breastfeeding continuation and potential dose-response effects of breastfeeding<sup>(3, 5)</sup>, distinguishing those who feed both breastmilk and infant formula is pertinent. Clear, specific and standardised definitions of feeding patterns are essential for future population and epidemiological studies to ensure accuracy in collected statistics, comparability and usability of data and we echo calls for the development of robust and consistent definitions of infant feeding to provide a core indicator set for use at local, national and international level<sup>(57)</sup>.

Through a well-characterised, prospective birth cohort, with frequent, closely timed follow-up visits and precisely specified breastfeeding definitions, we have provided an analysis of current early infant milk feeding practices in Ireland. The rate of early breastfeeding cessation, particularly in the first weeks post-partum, remains very high and we identified that mothers who combination fed breastmilk and infant formula were more likely to subsequently cease breastfeeding than mothers breastfeeding solely. Given this, and an increased breastfeeding duration in the past 8-10 years in mothers who do successfully establish breastfeeding, the first weeks may be a critical window of opportunity for breastfeeding support services. The acknowledged importance of breastfeeding and its myriad benefits mean this should be prioritised as a public health intervention.

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## **Authorship**

MEK designed the COMBINE cohort study and is Principal Investigator, AH and MEK formulated the research questions, DF conducted COMBINE study visits, ED and DMM provided clinical advice and governance, AH and TB conducted quality control and constructed the database, AH analysed the data, prepared and drafted the manuscript. All authors read and approved the final manuscript.

## **Conflict of interest**

None



## Tables and figures

Table 1. Exclusive and predominant breastfeeding definitions according to the World Health Organization<sup>(33)</sup>

<b>Feeding practice</b>	<b>Requires that the infant receives</b>	<b>Allows the infant to receive</b>	<b>Does not allow the infant to receive</b>
<i>Exclusive breastfeeding</i>	Breast milk	Vitamins, minerals and medicines	Anything else
<i>Predominant breastfeeding</i>	Breast milk	Certain liquids (water and water-based drinks, fruit juice), vitamins, minerals and medicines	Anything else <sup>1</sup>

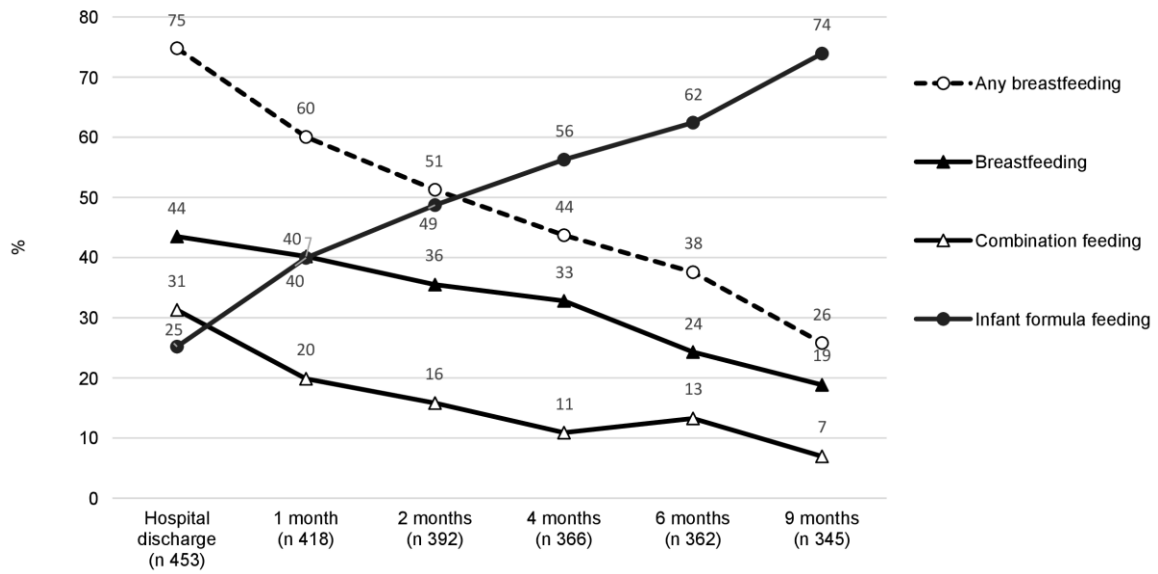
<sup>1</sup>In particular infant formula

Table 2. Demographic characteristics of participants in the COMBINE ( $n = 456$ , recruited 2015-2017) and BASLINE ( $n = 2137$ , recruited 2008-2011) birth cohort studies

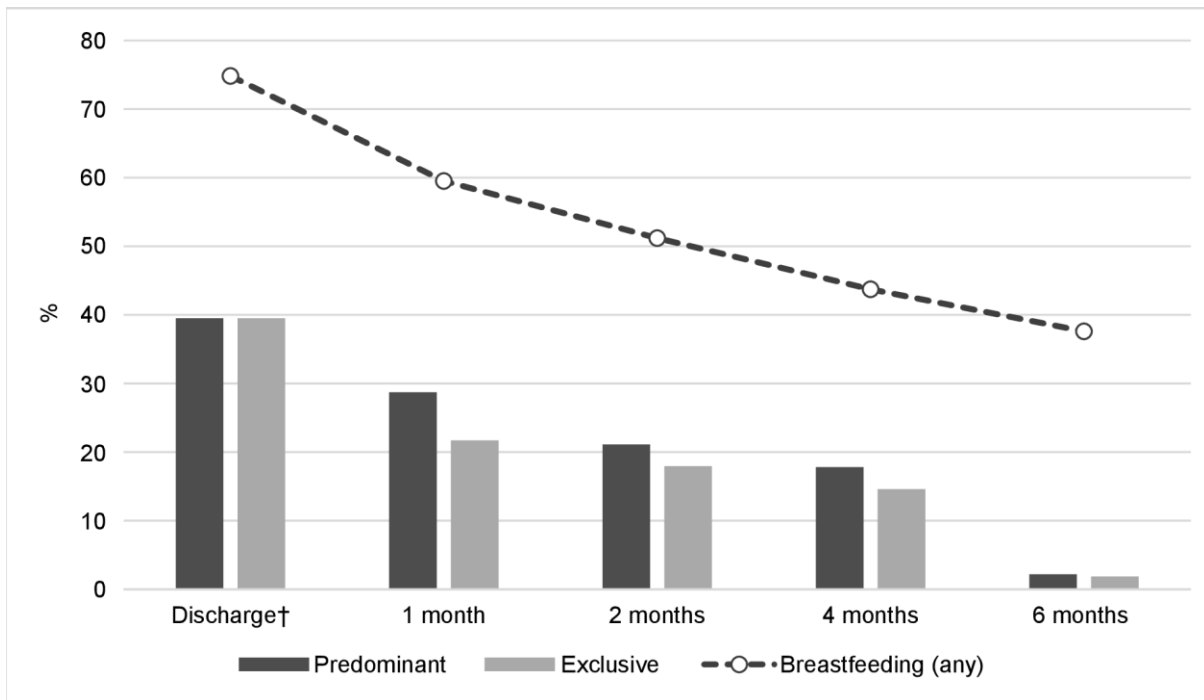
Characteristic	COMBINE		BASELINE		<i>P</i> -value
	Median or %	IQR	Median or %	IQR	
<b>Maternal</b>					
Age at delivery (years)	32.0	(29.0, 34.0)	31.0	(28.0, 34.0)	0.001
< 25		7.5		9.6	0.159
> 35		13.9		14.7	0.633
White ethnicity	96.5		98.2		0.022
Born in Ireland	79.2		82.8		0.069
Partner (married/defacto relationship)	94.7		94.0		0.523
Education ( $\geq 13$ years primary and secondary education)	89.3		87.6		0.338
In employment during pregnancy	90.8		87.8		0.073
Smoked during pregnancy	7.2		13.2		< 0.001
BMI at 15 weeks' gestation ( $\text{kg}/\text{m}^2$ )	25.1	(22.9, 27.9)	24.0 <sup>1</sup>	(22.0, 26.9)	< 0.001
<b>Infant</b>					
Sex – female	42.8		49.7		0.007
Gestational age (weeks)	40.3	(39.3, 41.0)	40.1	(39.1, 41.0)	0.149
Birthweight (kg)	3.5	(3.2, 3.8)	3.5	(3.2, 3.8)	0.493

IQR, interquartile range; BMI, body mass index

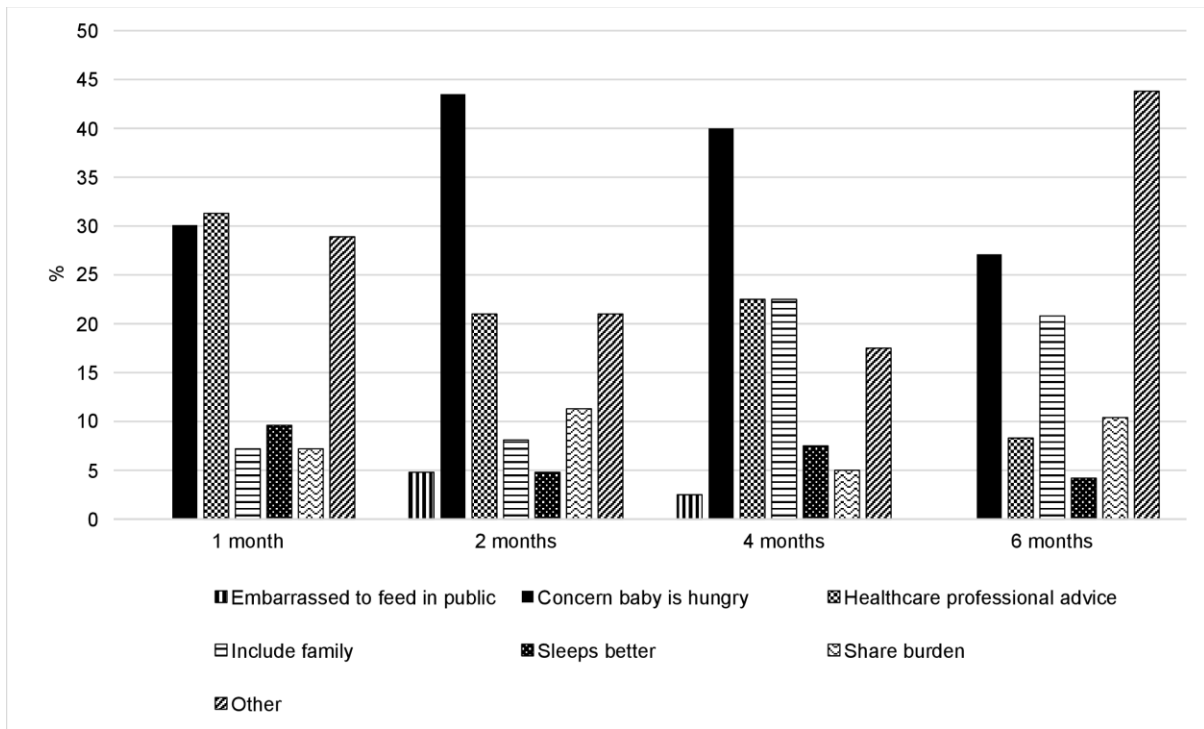
<sup>1</sup> $n = 1436$



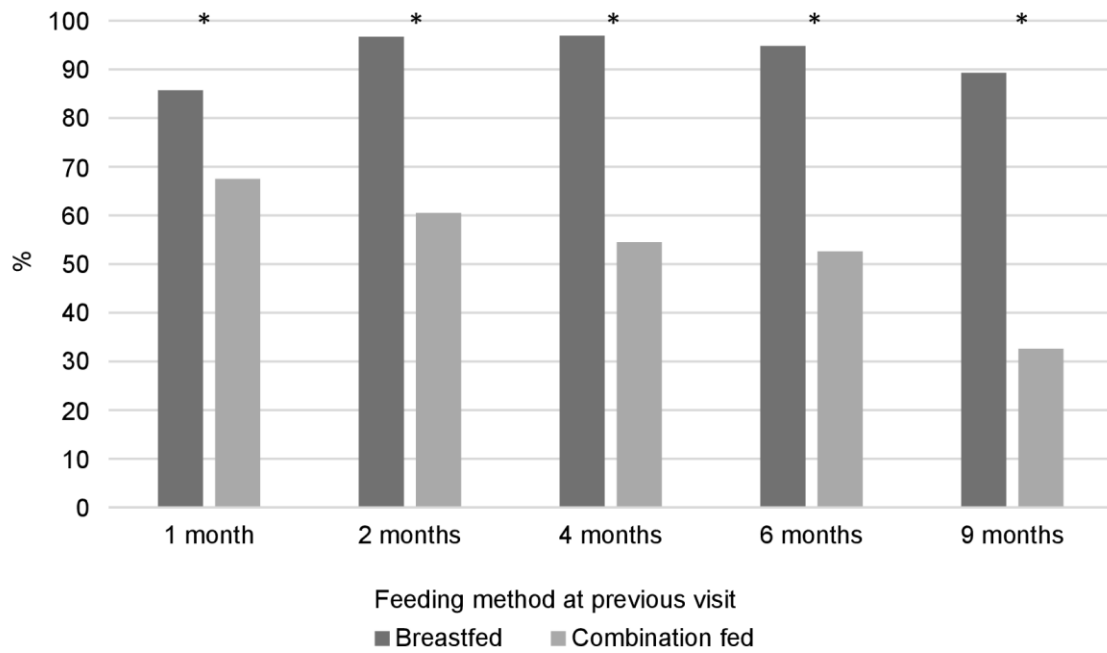
**Figure 1.** Infant milk feeding patterns in the first 9 months of life in the COMBINE birth cohort study. Any breastfeeding: breastfeeding and combination feeding. Breastfeeding: breastmilk as the main milk source. Combination feeding: both breastmilk and infant formula on a daily basis. Infant formula feeding: formula only (no breastmilk).



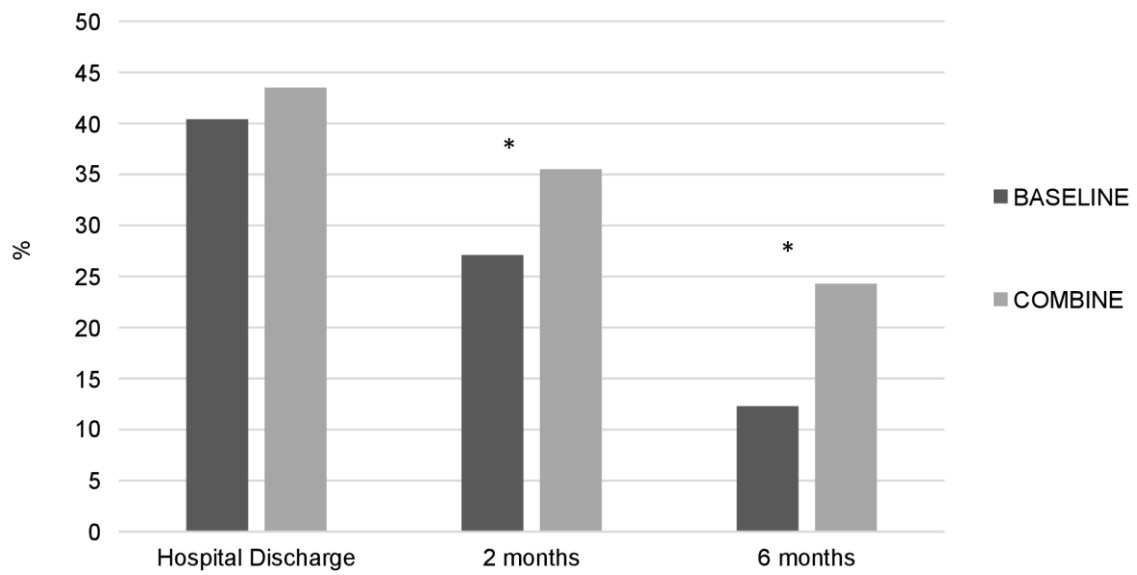
**Figure 2.** Longitudinal breastfeeding practices in the COMBINE birth cohort study showing the percentage (%) of participants predominantly and exclusively breastfeeding according to WHO definitions<sup>(33)</sup> from birth to 6 months. Predominant breastfeeding: the infant may have received water or other liquids but no infant formula or solid foods. Exclusive breastfeeding: breastmilk only, with no formula, other liquids or solid foods. Any breastfeeding: breast and combination feeding. †Exclusive and predominant breastfeeding were not differentiated at hospital discharge.



**Figure 3.** Reasons for combination feeding in the COMBINE birth cohort study. Participants may have provided more than one reason for combination feeding breastmilk and infant formula.



**Figure 4.** Percentage (%) of participants in the COMBINE birth cohort study receiving any breastmilk at each follow-up visit according to whether they were breastfed or combination fed at the previous visit. For example, 86% of infants who were breastfed at discharge received breastmilk at 1 month and 68% of infants who were combination fed at discharge received breastmilk at 1 month. Differences were assessed using Pearson chi-square,  $*P < 0.001$ .



**Figure 5.** Percentage (%) of participants in the COMBINE (recruited 2015-2017) and BASELINE (recruited 2008-2011) studies who were breastfeeding (breastmilk as main milk source) at hospital discharge, 2 months and 6 months. Differences were assessed using Pearson chi-square, \* $P < 0.05$

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