Optimal Timing of Introduction of Complementary feeding: Protocol for a systematic review and meta-analysis

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Protocol

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Abstract

Background: The complementary feeding (CF) period accompanies a critical window of vulnerability. During this time, failure to consume adequate energy, protein, vitamins and minerals is a significant concern and can lead to poor growth outcomes, increased susceptibility to infections, allergies, and diseases, and lower developmental potential. It is therefore of utmost importance to determine the most optimal time to start CF. The objective of this review is to assess the impact of early and late of introduction of CF on infant health, nutrition and developmental outcomes.

Methods: We will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We will search MEDLINE, Embase, CINAHL, CENTRAL, Web of Science, and other databases and key organizational websites using terms related to complementary feeding and infants. We will also search clinicaltrials.gov for ongoing trials. We will include experimental (randomized trials (individually or cluster) and quasi-randomized trials) and observational studies with a concurrent comparison group (cohort (prospective and retrospective), controlled before-after studies and nested case control studies). We will only include studies that enroll infants, living in low, middle- or high-income countries. Outcomes will be assessed for the following two comparisons:

1. Early introduction of CF (before 5 months of age) compared to introduction at 5 to 6.9 months of age

2. Late introduction of CF (after 7 months) compared to introduction at 5 to 6.9 months of age

All the included studies will be screened on Covidence software and analyzed on Review Manager (version 5.4.1) software.

Discussion: There are inconsistencies in the existing recommendations for the introduction of CF, as the recommended age for introducing CF ranges between four and six months of age in various international guidelines. It is imperative to evaluate of consequences of both early and late introduction of complementary foods since optimal timing of introduction may have potential beneficial short- and long-term health effects.

Systematic review registration: PROSPERO CRD42020218517

Background

Complementary feeding (CF) is the process of initiating any solid or liquid food other than breast milk or infant formula when breast milk alone does not remain sufficient to meet the nutritional requirements of infants (1, 2). According to the World Health Organization (WHO), adequate infant and young child feeding (IYCF) includes the practice of breastfeeding and the timely introduction of appropriate CF (2). The WHO/UNICEF guidelines recommends early initiation of breastfeeding within an hour of birth; exclusive breastfeeding for the first six months of life; and introduction of nutritionally-adequate and safe

complementary foods at six months of age together with continued breastfeeding up to two years of age or beyond (2, 3).

CF practices vary widely between countries. The percentage of infants introduced to CF before four months was found to be 56.7% (at 16 week) in rural Vietnam (2005) (4), 37% in North West Italy (2007/08) (5), 31.9% in the United States of America (USA) (2016-18) (6), and 30% in the United Kingdom (UK) (in birth cohort of 2010) (4, 7). In the Asia Pacific region, China initially recommended introduction of CF at 16 weeks, which has now been updated to 6 months. However, Japan still introduces CF at a child's 100th day following birth, which consists of a traditional ceremony where a child is introduced with fruit juice and soup (8). In Sri Lanka 84% of infants were introduced to CF by six months (9), 75% in the UK (10), 71% in Bangladesh (9), and 70% in Nepal (9), whereas in the USA less than 20% of infants received only infant formula, milk or breast milk by six months (10). Studies suggest range of maternal and infant related factors that are associated with early introduction of complementary food, which includes culture, maternal education, maternal age, maternal body mass index (BMI), post-natal weight gain, psychosocial factors, infant size at birth, early initiation and exclusive breastfeeding (11).

There are a few discrepancies between existing recommendations for the introduction of CF, as the American Academy of Pediatrics (AAP), the European Society for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Committee, and the European Food Safety Authority (EFSA) recommends the introduction of complementary foods between four and six months of age (3, 12). Despite the inconsistencies, none of the guidelines recommend initiating CF before four months (13–16). It is imperative to evaluate of consequences of both early and late introduction of complementary foods since optimal timing of introduction may have potential short and long term health effects (17). Early introduction of CF has been associated with increased morbidity due to gastro-intestinal diseases (such as diarrheal diseases), particularly in areas where food and water hygiene is a concern. Early and inappropriate CF is also associated with poor growth and malnourishment (14), while long term health impacts include increased risk of atopy and allergic reactions, type 1 and 2 diabetes, obesity and neuromuscular development (17–19). In contrast, late introduction of CF leads to micronutrient deficiencies including low iron and zinc levels, which affects cognitive and neurological development and may also lead to feeding difficulties (8).

The type of feeding adopted in the first years of life may also be associated with adverse outcomes later in childhood and in adulthood (20–25). The CF period accompanies a critical window of vulnerability. During this time, failure to consume adequate energy, protein, vitamins and minerals is a significant concern and can lead to poor growth outcomes, increased susceptibility to infections, allergies, and diseases, and lower developmental potential. It is therefore of utmost importance to determine the most optimal time to start CF for different populations of infants. Thus, our review aims to study the impact of early and late of introduction of CF on infant health, nutrition and developmental outcomes.

Objective

The objective of this systematic review is to evaluate the impact of timing of CF introduction on health, nutrition and developmental outcomes in healthy full-term infants. The impact will be assessed for the following two comparisons:

1. Early introduction of CF (before 5 months of age) compared to introduction from 5 to 6.9 months of age

2. Late introduction of CF (after 7 months) compared to introduction from 5 to 6.9 months of age

Methods

Criteria for considering studies for this review

Types of studies: The review is registered at PROSPERO with a registration number of CRD42020218517. We will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (26) guidelines and include experimental (randomized trials (individually or cluster) and quasi-randomized trials) and observational studies with a concurrent comparison group (cohort (prospective and retrospective), controlled before-after studies and nested case-control studies). We will exclude case reports, case series, opinions, editorials, commentaries, letters, conference abstracts, and reviews or systematic reviews.

Types of participants: We will only include studies that enroll infants, living in low-, middle- or high-income countries. We will exclude animal studies and studies enrolling only infants with an existing illness (cancer, diabetes, metabolic disorder, HIV, congenital abnormalities etc.). However, given the burden of some of these conditions in certain populations, we do anticipate that these children will be included in the overall sample.

Type of exposure/intervention: We will include studies that compare the effect of the timing of introducing CF:

1. Early introduction of CF (before 5 months of age) compared to 5 to 6.9 months of age
2. Late introduction of CF (after 7 months) compared to 5 to 6.9 months of age

We will assess the effect of early and late introduction on the health, nutrition and developmental outcomes at any time point in life, regardless of the type of milk-feeding (breastfed, formula-fed or mixed-fed) provided to the infant. We will include studies that have appropriately defined the timing and constitution of CF (i.e. foods and beverages other than human milk or infant formula including liquids, semisolids, and solid food).

Types of Outcomes

Primary Outcomes

- Anthropometric Measures (Height/length; Height/length gain; Weight/Weight gain; Head circumference; Stunting (height-for-age z-score <-2 SD); Wasting (weight-for-height z-score <-2 SD); Underweight (weight-for-age z-score <-2 SD); Overweight; Obesity; BMI; HAZ; WAZ; WHZ)
- Morbidity (including fever, upper respiratory infections, lower respiratory infections, diarrhea, malaria, other infections, atopic dermatitis etc.)
- Anemia
- Child Developmental Measures (cognitive, socio-behavioral, motor etc.)
- Food preferences
- Dietary patterns/dietary diversity
- Food allergies
- Non-Communicable Diseases (NCD) including glucose intolerance, diabetes, hypertension, cardiac, inflammatory or auto-immune diseases, cancers
- Infant and child mortality

Secondary Outcomes

- Hemoglobin level
- Micronutrient status (including serum micronutrient levels for iron, serum ferritin, transferrin receptor, vitamin A, zinc, folic acid, B12 and fatty acids)
- Waist circumference
- Skinfold thickness
- Gut health and the microbiome
- Bone mineral density/bone mineral content
- Maternal outcomes: Lactational amenorrhea, maternal birth spacing

Search methods for identification of studies

Electronic search and search strategy : Using the key terms (Annex 1), we will search MEDLINE , EMBASE, Web of Science Index Medicus, CINAHL, Lilacs, CENTRAL (Cochrane Library) and eLENA (WHO), Index Medicus for the WHO Eastern Mediterranean Region (IMEMR), Western Pacific Region Index Medicus (WPRIM), Index Medicus for South-East Asia Region (IMSEAR), and African Index Medicus. We will also search for ongoing trials from clinicaltrials.gov, and non-indexed and grey literature from Google Scholar and key organizational websites. To identify any missing papers, we will search the bibliography of all included studies and all relevant systematic reviews. We will not employ any language or date restriction.

Searching other sources: We will search the reference list of all the included studies and relevant systematic reviews to look for studies missed during the electronic search. We will also put the title of included studies on google web and search the first 50 hits to identify any missing papers. We will also contact authors in case of missing/unpublished data.

Data collection and analysis

Selection of Studies: Within Covidence (online web-based systematic review tool), two review authors will independently screen for potential inclusion of all titles and abstracts identified as a result of the search (27). Following title and abstract screening, full texts will be independently screened for inclusion. Any disagreements will be resolved through discussion or by consulting a third review author, if required. Reasons of exclusion will be recorded for all the studies excluded at the stage of full text screening.

Data Extraction and Management: Data extraction for study characteristics and outcome data will be done in a data collection form. Two review authors will independently extract data and discrepancies will be resolved through discussion until consensus has been achieved or by consulting a third reviewer, if required. Attempts will be made to contact authors of included studies to obtain clarifications or additional data. We will extract data on the following study characteristics:

- *Study Methods*: journal, publication year, study design, total duration of study, study location, study setting, and withdrawals
- *Participants:* number, mean age, age range, gender, inclusion criteria, exclusion criteria infant feeding prior to and after introduction of CF, birth weight, gestational age, potential key confounders (for e.g. education, socioeconomic status, sex of caregiver, maternal/paternal age, race and/or ethnicity, milk feeding practices (breast milk, infant formula, or both))
- *Interventions/exposures*: intervention/exposure description, duration of intervention/exposure and comparison group description
- *Outcomes*: primary and secondary outcomes specified and collected, time points reported, and extraction methods used.
- *Additional information*: trial funding sources, study limitations and notable conflicts of interest of trial authors.

After data extraction, one review author will transfer data into Review Manager (RevMan) 5.4 software (28). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author will spot check study characteristics for accuracy against the study reports.

Quality Assessment of Included Studies: Quality assessment will be done by using Cochrane risks of bias tool (29) for trials and risk of bias in non-randomized studies of intervention (ROBBINS-I) (30) for observational studies. Two independent authors will assess quality of all eligible studies and disagreements will be resolved by consensus or contacting a third author.

For trials, we will assess risk of bias according to the following domains:

- Random sequence generation
- Allocation concealment

- Blinding of participants and personnel
- Blinding of outcome assessment
- Incomplete outcome data
- Selective outcome reporting
- Other bias

We will judge each potential source of bias as high, low, or unclear and provide a quote from the study report together with a justification for our judgement.

For observational studies, the risk of bias will be judged based on confounding factors, selection of participants into the study, classification of interventions, deviations from intended intervention, missing data, measurement of outcomes, and selection of the reported results (30).

Measures of Treatment Effect: We will enter outcome data on RevMan software 5.4. Data from intervention and observational studies will be analyzed separately. Data will also be analyzed separately for the following two comparisons:

1. Early introduction of CF (before 5 months of age) compared to 5 to 6.9 months of age
2. Late introduction of CF (after 7 months) compared to 5 to 6.9 months of age

For dichotomous outcomes, we will use risk ratio (RR) while for the continuous outcomes, we will use mean difference (MD) or standardized mean difference (SMD) along with 95% confidence interval (CI). Data reported as a medians and interquartile ranges will be converted to means and standard deviations using standard formulas. We will undertake meta-analyses only where it is meaningful, i.e., if the exposures, participants, and the underlying clinical question are sufficiently similar for pooling.

Data Synthesis: Where data is available from two or more studies for a particular outcome, we will perform meta-analysis by pooling data on RevMan software. We will perform a random effects analysis for all comparisons, using inverse variance and Mantel-Haenszel methods to calculate the weights for continuous and categorical outcomes. This is a more conservative approach, as we expect the data to be heterogeneous.

Unit of Analysis Issues: We will conduct a meta-analysis separately for different study designs and for outcome subcategories. We will also analyze data of observational studies separately. For experimental studies, we will include both individually randomized trials and cluster-randomized in the analyses. For cluster-RCTs that have not been adequately adjusted for clustering, we will use the reported intra-cluster correlation coefficient (ICC) from trials' original data sets along with the mean cluster size (M) to calculate the design effect. We will then use the methods set out in the Cochrane Handbook for Systematic Reviews of Interventions to calculate the adjusted sample sizes using the design effect (31). We will use an estimate of the ICC derived from the study (if possible), or from a similar study and study population if this is not possible. If we identify both cluster-RCTs and individually randomized trials that

are similar in exposure and outcome assessment, then we will consider it reasonable to combine the results from both in one meta-analysis. We will meta-analyze effect sizes and standard errors using the generic inverse-variance method using RevMan software.

Assessment of Heterogeneity: Statistical heterogeneity will be assessed using τ2, I2, and significance of the χ2 test; we will also assess heterogeneity by visually inspecting forest plots. Based on prior clinical knowledge, we expect clinical and methodological heterogeneity in included studies and therefore, we will attempt to explain any observed statistical heterogeneity using subgroup analysis.

Assessment of Reporting Biases: For outcomes including more than 10 studies, we will create and examine a funnel plot to explore possible small-study and publication biases.

GRADE and Summary of Finding Tables

We will construct Summary of Finding (SoF) tables for primary outcomes for both the comparisons summarizing the quality of evidence according to the outcomes as per the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) criteria (32). It covers consideration of within-study risk of bias, directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias. We will rate the certainty of evidence for each key outcome as “high”, “moderate”, “low”, or “very low”. For non-randomized studies, the evidence quality will be upgraded based on large magnitude of effect, dose-response relationship, and effect of all plausible confounding factors in reducing the effect (where an effect is observed) or suggesting a spurious effect (when no effect is observed).

Sub-group Analysis

We will perform sub-group analysis for the following groups:

- By type of feeding before introduction of CF - exclusively breastfed, exclusively formula-fed, mixed breast and formula fed
- By timing of introduction of CF
- For the first comparison: <4 months, 4-5 months
- For the second comparison: 7-8 months, > 8months
- By age at outcome assessment – (till 23 months of age, 24-59 months, 5-10 years)
- By income regions - Low- and middle-income countries, high-income countries
- By birthweight - Normal birthweight, low birthweight, very low birthweight
- BY gestation at delivery – term, preterm
- By gestation – normal, small-for-gestational-age

Sensitivity Analysis

We will also perform a sensitivity analysis to examine only studies which had controlled for potential confounders. If numbers permit, sensitivity analyses will be performed on the primary outcomes to

consider the impact of high risk of bias relating to sequence generation and/or allocation concealment.

Discussion

Appropriate and timely transition to CF is of unparalleled significance for the growth and development of an infant. Existing infant and young child feeding recommendations by the WHO suggest exclusive breastfeeding in the first six months of life and continued till 2 years, while complementary foods are to be introduced at 6 months following birth. CF is defined as a transitioning process starting from the time when breastmilk alone is unable to fulfil the nutritional demand of infants so therefore infants are provided with liquid and semi-solid food along with breastmilk. Optimal time of introduction of CF outweighs all the potential risk of early or late introduction of complementary food. Existing evidence suggests variations in the timings of introduction of CF along with inconsistencies across studies in various contextual factors including feeding practices, type of CF, and timings of the health outcome assessment (8, 33-36). Studies have shown that the timing of introduction of CF was affected by maternal age (33), difference in socio-economic status (33), maternal education (33-35), frequent antenatal care visits (33), duration of breastfeeding (8), birth order (33) and cultural characteristics (33). There is a need to synthesize evidence addressing the relationship between timing of CF introduction and health and nutritional status of infants. Findings from this review will assist a better understanding of the relationship between CF introduction and risk of nutrition and developmental disorders in infants and in their later life.

We anticipate a few limitations for our systematic review based on previously published data (36). These limitations include: lack of evidence; methodological limitations associated with the observational studies; variation in included study designs and outcome definitions. We have planned our review and analysis catering to these limitations. Firstly, we plan to perform separate analyses for the experimental and observational studies. Moreover, we also plan to assess the risk of bias separately for experimental studies (using Cochrane risk of bias tool) and observational studies (using ROBBINS-I criteria). Secondly, we aim to extract data on the potential confounding variables especially from the observational studies including education, socioeconomic status, sex of child and caregiver, maternal age, race and/or ethnicity, milk feeding practices (breast milk, infant formula, or both). This will help contextualize the evidence synthesis from the observational studies. Thirdly, we plan to conduct various sub-group analysis based on type of feeding before introduction of CF; timing of introduction of CF (within the two major comparisons); age at outcome assessment; country; and birthweight. These subgroup analyses will help address the heterogeneity in the existing evidence and generate context-specific conclusions. And finally, we aim to summarize the evidence according to the GRADE criteria.

Abbreviations

AAP	American Academy of Pediatrics
BMI	Body Mass Index
CF	Complementary Feeding
CI	Confidence Interval
EFSA	European Food Safety Authority
ESPGHAN	European Society for Pediatric Gastroenterology, Hepatology and Nutrition
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
ICC	Intra-Cluster Correlation Coefficient
IMEMR	Index Medicus for the WHO Eastern Mediterranean Region
IMSEAR	Index Medicus for South-East Asia Region
IYCF	Infant and Young Child Feeding
LMIC	Low- and Middle- Income Countries
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
MD	Mean Difference
NCDs	Non-Communicable Diseases
RevMan	Review Manager
ROBBINS-I	Risk of Bias in Non-Randomized Studies of Intervention
RR	Risk Ratio
SMD	Standardized Mean Difference
SoF	Summary of Finding
UK	United Kingdom
USA	United Stated of America
WHO	World Health Organization
WPRIM	Western Pacific Region Index Medicus

Declarations

Ethics approval

Ethics approval was obtained from the Ethics Review Committee of The Aga Khan University, Karachi and the National Bioethics Committee, Pakistan

Consent for Publication

Not Applicable.

Availability of data and materials

The data which will be used for the analysis in this study will be available from the corresponding author on a reasonable request.

Competing interests

All the authors declare no conflict of interest.

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Authors' contributions

All authors contributed in the protocol write-up.

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Annexure

Annex 1: Potential search strategy

Complementary feeding	Introduction/ provision	Children up to 10 years	Filters
compl*mentary[tw] OR supplementary[tw] OR wea*[tw] OR food*[tw] OR feed*[tw] OR nutrition*[tw] OR diet*[tw] OR solid*[tw] OR semi-solid*[tw] OR “semi solid” [tw] OR weaning[MeSH] OR infant nutritional physiological phenomena[MeSH] OR Complementary feeding[MeSH] OR complementary feedings[MeSH] OR supplementary feeding[MeSH] OR supplementary feedings[MeSH] OR OR food OR beverage*[tiab] OR beverages[mh] OR eating OR diet[tiab] OR diet[mh] OR meal*[tiab] OR meals[mh] OR "Food and Beverages"[Mesh] OR diets[tiab] OR cereal*[tiab] OR "Edible Grain"[Mesh] OR bread*[tiab] OR whole grain* OR juice*[tiab] OR milk[tiab] OR "Milk"[Mesh] OR dairy[tiab] OR "Dairy Products"[Mesh] OR meat[tiab] OR cheese[tiab] OR yogurt[tiab] OR yoghurt*[tiab] OR fruit*[tiab] OR "Fruit"[Mesh] OR vegetable*[tiab] OR "Vegetables"[Mesh] OR egg*[tiab] OR "Eggs"[Mesh] OR nut[tiab] OR nuts[tiab] OR peas[tiab] OR beans[tiab] OR legume*[tiab] OR snack*[tiab] OR bread[mh] OR honey[mh] OR vegetable*[tiab] OR "Vegetables"[Mesh] OR egg*[tiab] OR "Eggs"[Mesh:noexp] OR “egg white”[mh] OR “egg yolk”[mh] OR snack*[tiab] OR candy[mh] OR "Fast Foods"[Mesh] OR meat[mh] OR molasses[mh] OR nuts[mh] OR "Raw Foods"[Mesh] OR seeds[mh])	provi*[tw] OR train*[tw] OR introduc*[tw] OR counselling[tw] OR counselling[tw] OR instruct* OR teach*[tw] OR demonstrat*[tw] OR programme*[tw] OR program*[tw] OR interven*[tw] OR (Timing or time or introduc* or provi* or earl* or late*).tw. Education[MeSH] OR counselling[MeSH] OR teaching[MeSH]	Infant[tw] OR baby[tw] OR babies[tw] OR toddler*[tw] OR newborn[tw] OR neonat*[tw] OR child[tw] OR preschool[tw] OR nursery[tw] OR kid[tw] OR p*ediatri* OR Infant, newborn [MeSH] OR child[MeSH] OR infant[MeSH]	No language restriction No date restriction