Effects of exclusive breastfeeding promotion interventions on child outcomes: a systematic review and meta-analysis

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Effects of Exclusive Breastfeeding Promotion Interventions on Child Outcomes: A Systematic Review and Meta-Analysis

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Abstract
Introduction: Interventions promoting exclusive breastfeeding (EBF) may benefit infant health outcomes, but evidence is inconsistent. The objective of this review was to assess the effect of interventions promoting EBF on health outcomes in infants and children under 7 years of age. ***Methods:*** A literature search was conducted using EMBASE, MEDLINE, CINAHL, Cochrane Central, Cochrane Database of Systematic Reviews, and WHO International Clinical Trials Registry Platform from inception to April 2022. Inclusion criteria were randomized or cluster-randomized controlled trials aiming to increase EBF that reported effects on offspring growth, morbidity, and/or mortality up to age 7 years. The primary outcome was infant/child growth. Secondary outcomes were infant morbidity and mortality and EBF rates. Data were pooled using a random-effects model. ***Results:*** Thirty-two studies (40 papers) were identified. No effect on infant/child growth was observed. EBF promotion interventions significantly improved EBF rates up to 6 months ($n = 25$; OR 3.15; 95% CI: 2.36, 4.19) and significantly reduced the odds of respiratory illness at 0–3 months by 59% ($n = 2$; OR 0.41; 95% CI: 0.20, 0.84) but not at later time-points. A borderline significant effect was observed for diarrhea ($n = 12$; OR 0.84; 95% CI: 0.70, 1.00). Effects on hospitalizations or mortality were not significant. ***Discussion/Conclusion:*** EBF promotion interventions improve EBF rates and might yield modest reductions in infant morbidity without affecting infant/child growth. Future studies should investigate the cost-effectiveness of these interventions and examine potential benefits on other health outcomes.

Introduction

Breast milk is the optimum source of nutrition for infants. Promoting and supporting breastfeeding (BF) is an important public health intervention with multiple benefits for infants and mothers, including a reduced risk of infant gastrointestinal and respiratory infections and reduced risk of breast cancer in the mother [1]. In 2001, following a systematic review on the effects on child and maternal health of exclusive breastfeeding (EBF) for 6 months versus EBF for 3 to 4 months [2], the World

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Health Organization (WHO) made a global recommendation that infants should be exclusively breastfed until 6 months of age. After 6 months, safe complementary foods are recommended with maintenance of BF up to 2 years of age or beyond. However, despite numerous initiatives over many years in different settings, globally only 44% of infants 0–6 months old are EBF [3], with particularly low rates in many Western countries.

Much of the available evidence focuses on health effects of BF rather than the impact of EBF or EBF for 6 months. Furthermore, defining causal effects of BF per se, or specific periods of EBF on health outcomes is problematic as most studies are observational, given the ethical and practical difficulties of conducting randomized trials in this field. Therefore, the optimal duration of EBF [4] and the magnitude of benefits in different settings remain uncertain. Observational studies attempt to control for possible confounding factors, but it is difficult to completely account for the complex biological, social, economic, and cultural factors that influence BF and health outcomes.

Although the process of randomizing mothers to EBF for different durations is challenging, it is possible to randomize mothers to interventions aimed at promoting a longer duration of EBF. These trials provide an opportunity to systematically synthesize evidence for health outcomes in infants and children with different EBF exposure. A systematic review and meta-analysis examining the efficacy of interventions aimed at increasing exposure to EBF found that mothers who received interventions were 2.77 times more likely to EBF up to 6 months [5]. However, this analysis did not consider the impact on infant health outcomes. To address this gap, we conducted a systematic review to evaluate the effect of interventions that aimed to increase infant exposure to EBF on their growth, morbidity and mortality up to 7 years of age in both low- and high-income settings.

Methods

Search Strategy

The full protocol is available on PROSPERO [CRD42020203796]. A systematic search of the literature was performed using medical subject headings (MeSH) and key text words pertaining to EBF interventions and infant/child mortality and health outcomes (see online supplement 1; for all online suppl. material, see https://doi.org/10.1159/000535564). The search was conducted in August 2020, and re-run on April 27, 2022. The Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trails, WHO International Clinical Trials Registry Platform (ICTRP), Cumulative Index of Nursing and Allied Health Literature, EMBASE, and MEDLINE were searched from inception. Reference lists of included articles were reviewed manually to identify additional sources. Studies were limited to those published in English and French.

Study Inclusion and Exclusion Criteria

Randomized controlled trials (RCTs) and cluster-randomized controlled trials (CRCTs) that focused on increasing infant exposure to EBF and reported at least one of the specified outcomes were included.

Population

Healthy mother-infant pairs and/or infants who were followed at any time up to age 7 years were eligible. Studies that exclusively included preterm infants or mothers living with HIV were excluded.

Intervention

Any intervention(s) aiming to increase exposure to EBF.

Control

Controls could have no intervention or receive standard care for the study setting.

Outcomes

The primary outcome was infant and child growth, including anthropometric measurements such as weight, height/length, body composition, and BMI at the latest reported time point and at 3–4 months, 6 months, and at ≥18 months, and changes in weight and length/height. Secondary outcomes were infant and child morbidity and mortality and EBF rates up to 6 months. Morbidity included prevalence or incidence of disease and/or infections at the latest available time point and at 0–3 and 4–6 months. For all outcomes, we used author definitions but this was evaluated in the quality assessment.

Setting

The review included studies from low-middle income countries (LMIC) and high-income (HIC) countries, defined according the World Bank Classification.

Selection of Studies

Two review authors independently ran the initial and updated search using Covidence (https://www.covidence.org/), scanning titles and abstracts of retrieved records; those meeting the selection criteria were assessed further through full text appraisal. Discrepancies were discussed with a third reviewer to reach consensus. Additionally, three other members of the review team checked a random sample of 10% of both included and excluded studies to ensure agreement with methodology and logic. Figure 1 shows the PRISMA [6] flowchart.

Data Extraction and Management

Data extraction was performed by two independent review authors. All data included in the meta-analysis were additionally checked by a third author. Key information was extracted using a pre-defined template on Covidence. Disagreements were resolved through discussion with the review team. For studies with incomplete data, the authors of the original study were contacted.

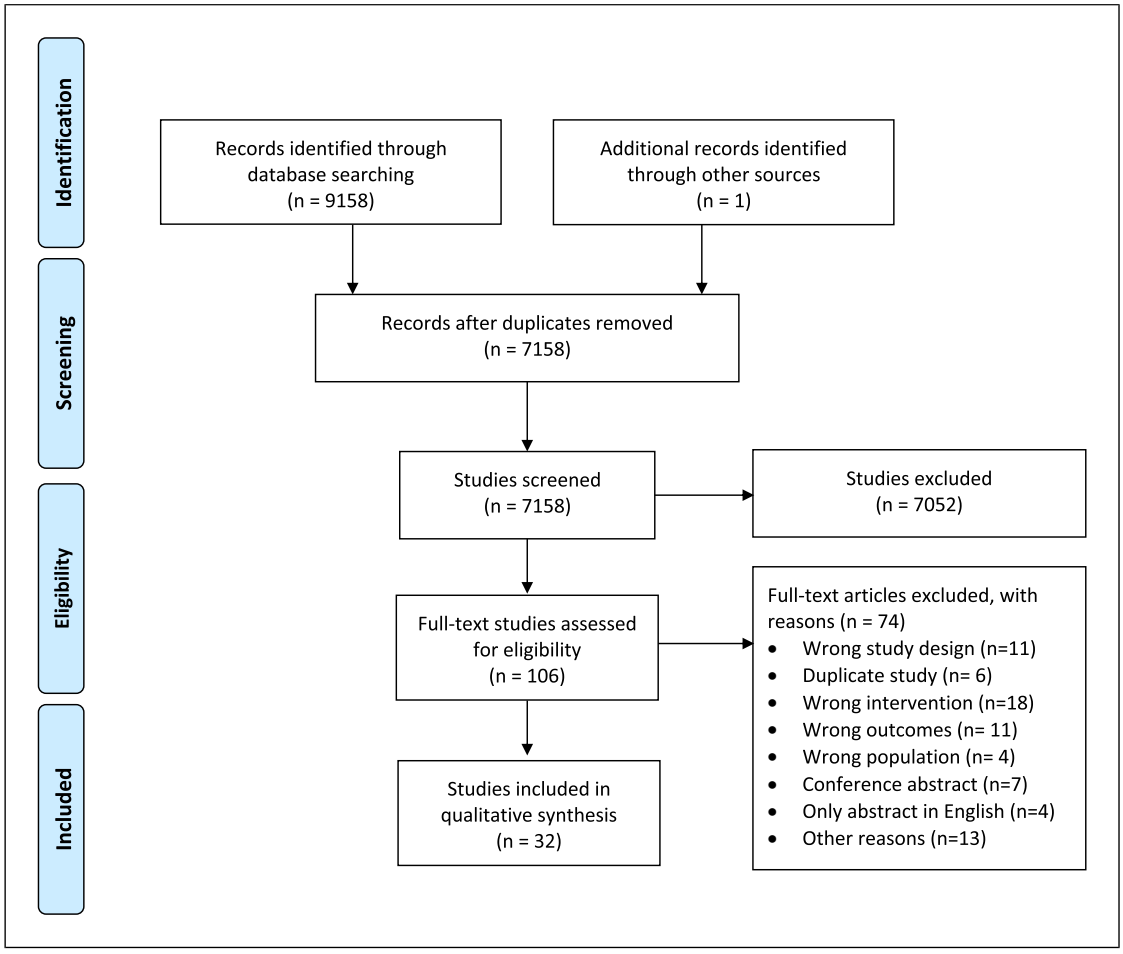

Fig. 1. PRISMA flowchart.

Assessment of Risk of Bias

Two authors independently assessed the risk of bias (ROB) for included studies using the Cochrane Handbook for Systematic Review of Interventions with disagreements resolved by discussion [7]. In addition, for CRCTs we assessed the risk of (i) recruitment bias; (ii) baseline imbalance; (iii) loss of clusters; (iv) incorrect analysis; and (v) comparability with individually randomized trials as outlined in the Cochrane Handbook for Systematic Reviews of Interventions [8]. Each ROB category was classified "high risk," "low risk," or "unclear risk." As specified in the protocol, "high quality" was defined as a trial having adequate sequence generation, allocation concealment and an attrition rate <25%.

Data Synthesis

For two or more studies reporting similar outcome measures, we undertook statistical analysis using the Review Manager software (RevMan 2014). We analyzed outcomes on an intention-to-treat basis whenever possible. Random-effects meta-analysis was used given variability in baseline characteristics, interventions, and outcome reporting [9]. Results were presented as mean treatment effect with 95% confidence intervals (CIs) using odds ratio for dichotomous data and standardized mean difference for continuous data.

For CRCTs that did not adjust for clustering in their analyses (or did not report adjusted results), we adjusted the sample sizes using the methods described in the *Cochrane Handbook* [Section 23.1] [10] using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study in a similar population. Meta-analysis using the generic inverse variance method was undertaken in RevMan using the adjusted estimates from CRCT that adequately accounted for the cluster design within the analysis, alongside an approximated effect estimate for the CRCTs that did not.

Heterogeneity was assessed through the χ^2 and I^2 statistics. An I^2 statistic of 50% or greater or χ^2 significance level $p < 0.1$ was regarded as indicating substantial heterogeneity between studies [7].

Subgroup Analysis

To identify potential sources of substantial heterogeneity, subgroup analysis according to country income classification, type of intervention, and timing of intervention was performed when at least

two studies were available in each comparator. We also planned subgroup analysis according to maternal BMI, baby-friendly initiative accreditation and family socioeconomic status but data did not allow for these analyses. Additionally, subgroup analysis for child growth, morbidity, and mortality outcomes was performed, stratified by whether the intervention resulted in a significant improvement in the odds of EBF at latest available timepoint, 6 months, 3–4 months, or 1–3 months.

Sensitivity Analysis

Sensitivity analysis was performed based on the quality of the included trials determined by ROB to identify the impact on the overall results. For cluster-randomized trials, sensitivity analysis was also used to investigate the effect of variation in the ICC and unit of randomization. We initially adjusted the sample size for unadjusted outcomes using the ICC of 0.1 [11] then undertook sensitivity analysis using varying ICC from 0.01 to 0.3 [12, 13].

Assessment of Reporting Bias

For outcomes that were reported in ≥10 trials, we investigated reporting biases by visually examining asymmetry in funnel plots. We also undertook the Egger, Smith [14] regression asymmetry test using Stats Direct software, with $p < 0.10$ taken as evidence of small study effects.

Results

Studies Selected

We initially identified 9,158 studies, of which 7,158 were screened and 106 full-text articles were reviewed (Fig. 1). A total of 32 studies (40 publications) were eligible for inclusion [11–13, 15–51].

Study Characteristics

Of the included studies (Table 1), 17 were RCTs and 15 were CRCTs, 28 were in LMIC and only 4 were in HIC, with sample size between 108 and 140,048 participants. Year of publication was 1994–2021, with 23 studies published in the last 10 years. Most interventions lasted longer than 1 month (25 interventions), four lasted 1 week to 1 month and four lasted 1 week or less (one study contained two interventions, one <1 week and one >1 month). The type of intervention varied, with most ($n = 20$) involving peer counselling and/or home visits while five studies targeted hospital/clinic practices. Three studies investigated the effects of longer versus shorter durations of EBF by randomizing infants to complementary feeding from 4 months or EBF until 6 months. Two studies provided mobile phone-based support to BF mothers. Two studies involved BF support provided by community representatives or members. One study was undertaken in three separate countries; effect size estimates were given separately for each country, so they were entered into the meta-analyses separately.

Quality Assessment

The quality of included studies based on pre-defined criteria was poor, with 24/32 studies of low or uncertain quality and only eight of high quality (online suppl. 2). Eighty-seven percent (14/16) of CRCTs had high risk of recruitment bias where individuals were recruited after randomization of clusters. All studies had low ROB when considering imbalance between randomized groups. Two studies had high ROB for not undertaking adjustment for clustering and two had potentially high ROB due to loss of clusters.

Meta-Analysis Results for Infant/Child Growth

EBF promotion interventions did not have an overall effect on infant weight (Fig. 2; SMD = −0.01 [95% CI: −0.11, 0.09], 11 studies, 11,556 participants, I^2 67%), infant length/height (Fig. 2; SMD = 0.01 [95% CI: −0.03, 0.05], 12 studies, 28,817 participants, I^2 21%) nor BMI/weight-for-length (Fig. 2; SMD = −0.04 [95% CI: −0.10, 0.03], 11 studies, 27,702 participants, I^2 54%) at the latest time-point reported. There were also no effects at 3–4 months, 6 months nor at ≥18 months (online suppl. 3). Similarly, there were no effects on gain in length or weight (online suppl. 3).

Meta-Analysis Results for Infant/Child Morbidity and Mortality

There was a trend toward reduced odds of infant diarrhea with EBF promotion interventions at the latest available time-point (Fig. 3; OR = 0.84 [95% CI: 0.70, 1.00], 12 studies, 24,060 participants, I^2 42%), but not at 0–3 months and 4–6 months (online suppl. 3). There was no effect of EBF promotion interventions on respiratory illness at the latest time-point (Fig. 3; OR = 0.80 [95% CI: 0.60, 1.06], 5 studies, 19,718 participants, I^2 44%) nor at 4–6 months; however, there was a significant reduction in the odds of respiratory illness at 0–3 months (online suppl. 3; OR = 0.41 [95% CI: 0.20, 0.84], 2 studies, I^2 0%). No differences were found in infant hospitalization (Fig. 3; OR = 0.56 [95% CI: 0.31, 1.02], 5 studies, 3,162 participants, I^2 53%) nor infant mortality (Fig. 3; OR = 0.98 [95% CI: 0.75, 1.28], 5 studies, 60,918 participants, I^2 52%).

Meta-Analysis Results for EBF

The interventions were successful at improving the odds of EBF (pooled odds ratio 3.15 [95% CI: 2.36, 4.19, 25 studies, 202,644 participants, I^2 85%]) at any time point from 0 to 6 months (Fig. 4). Similar effects were observed at 6 months, 3–4 months, and 1–3 months separately (online suppl. 3). Across all settings, the median EBF rate at 3–4 months was 66.7% (IQR 25.4; 10.4–83.1) and 34.6% (IQR 26.7; 6.2–80.1) in the intervention and control groups

Table 1. Overview of included studies

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Abdulahi [11] (2021)	Ethiopia (LMIC)	CRCT	Pregnant women (2nd/3rd trimester)	468	BF education and support intervention delivered by peer-supporters	7 months starting at the 8th month of pregnancy	↑ EBF at 6 months; ↑ EBI	↔ WAZ, LAZ, underweight, stunting, wasting at 6 months; ↓ acute respiratory illness at 6 months
Agudelo [15] (2021)	Colombia (LMIC)	RCT	Mothers of healthy FT infants	297	Immediate skin-to-skin contact (in the first minute after birth)	60 minutes starting post-delivery	↔ EBF at 3 and 6 months	↔ %weight change between birth and the first week of life
Ara [12] (2019)	Bangladesh (LMIC)	CRCT	Married pregnant women with <4 living children	350	IYCF counselling and psychosocial stimulation education provided by peer counsellors involving the mothers and key family members	Before delivery until infant was 11 months old (~11–19 months)	↑ EBF at 1, 3, and 5 months	↑ Change in length over 12 months
Bashour [16] (2008)	Syria (LMIC)	RCT	Mothers of healthy FT infants	876	Home visits conducted by midwives (group A: 4 HV on days 1, 3, 7, and 30 post-delivery; group B: 1 HV on day 3)	Varies but a maximum of 30 days in group A	↑ EBF at 4 months in groups A and B; ↔ BF	↔ Diarrhea, jaundice, fever, cold, cough, or infection at 4 months
Bhandari [17] (2003)	India (LMIC)	CRCT	Mother-infant pairs	1,115	Health and nutrition workers were trained to counsel mothers for EBF and to deliver messages promoting EBF to community representatives	24 months starting at birth	↑ EBF at 3, 4, 5, and 6 months	↔ Mean weight, length, WAZ <2, LAZ <2 at 3 and 6 months; ↓ Diarrhea (in previous 7 days) at 3 and 6 months
Birungi [18] (2015)	Uganda (LMIC)	CRCT	Pregnant women intending to BF	765	EBF peer-counselling during pregnancy and postpartum	~29 weeks starting in the third trimester	↔ BF duration at 5 years	↔ Dental caries at 5 years
Chapman [19] (2013)	USA (HIC)	RCT	Participants considering BF and had a pre-pregnancy BMI >27 and income <185% of the federal poverty level	154	Routine care plus prenatal, hospital and postpartum visits from a specialized BF peer counsellor	Varies but at least 10 weeks starting prenatally	↔ EBF and BF at 2 weeks, 1 month, 3 months, and 6 months	↔ Otitis media and emergency department visits at 3 and 6 months; ↓ hospitalization at 3 and 6 months; ↑ diarrhea at 6 months
Cohen [20] (1994)	Honduras (LMIC)	RCT	First-time healthy low-income mothers of FT infants weighing at least 2 kg willing to EBF for 26 weeks	141	SF: Introduction of CF at 4 months with ad libitum nursing from 4–6 months; SF-M: introduction of CF at 4 months with maintenance of baseline nursing frequency from 4 to 6 months	2 months starting at 4 months	↓ Breast milk intake at 5 and 6 months in SF and SF + M groups	↔ Weight gain from 16-26 weeks; ↔ diarrhea at 26 weeks; ↑ coughs (and respiratory illness p=0.05)
Cui and Wang [21] (2021)	China (LMIC)	RCT	Mothers of healthy FT infants who were between 25–35 years	200	Routine care plus postpartum family visits. Mothers were also given a diet plan and encouraged to eat more protein.	Does not specify	↑ EBF at 1, 2, and 3 months.	↔ Length and weight at 3 months; ↓ Incidence of adverse events (red buttocks, eczema, jaundice, umbilical infection) at 3 months

Table 1 (continued)

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Davies-Adetugbo [22] (1997)	Nigeria (LMIC)	RCT	Mothers who took their infants (<=3 months of age) to a primary care facility for uncomplicated acute diarrhea	161	3 sessions of BF counselling and lactation management at days 0, 2, and 7 to solve BF issues faced and to promote EBF	7 days, starting at day infants were presented to the primary care facility (mean age: control mean=55.6 (22.0); intervention mean= 52.9 (21.4) days).	↑ EBF at days 7 and 21	↔ Recurrence of diarrhea by day 21
Dewey [23] (1999)	Honduras (LMIC)	RCT	Mothers of FT infants weighing 1.5–2.5 kg at birth, who were willing to EBF for 6 mo	119	Mothers were advised to initiate complementary feeding at 4 months while maintaining baseline (at 4 months) BF frequency.	2 months starting at 4 months of age	↓ Breast milk intake at 6 months	↔ Weight, length, head circumference change from 16 to 26 weeks, WAZ and LAZ in first 12 months; ↔ % days with fever or respiratory illness from 16 to 26 weeks; ↑ %days with diarrhea from 16 to 26 weeks
Fadnes [24] (2016)	Uganda (LMIC)	CRCT	Pregnant women intending to BF	765	EBF peer-counselling during pregnancy and postpartum	~29 weeks starting in the third trimester		↑ Stunting at 2 years and underweight at 5 years
Fang [25] (2021)	China (LMIC)	RCT	Mothers of singleton FT infants, who have inverted nipples and successfully breastfed at the hospital.	114	Multi-dimensional postpartum visits involving online support, continuing health education in the community, and home visits	Does not specify	↑ EBF at 1, 3, and 6 months	↓Incidence of infant hospitalization at 6 months
Gabida [26] (2015)	Zimbabwe (LMIC)	CRCT	Mothers in antenatal care register who delivered within the selected clusters	357	Routine care plus cIYCF training for village health workers in two groups and provision of a BF newsletter in two groups. The newsletter contained nonfinancial incentives to encourage mothers to EBF until at least 14 weeks.	One time newsletter at delivery	↑ EBF at 14 weeks in the newsletter group; ↔ EBF at 20 weeks and in cIYCF group	↓Recurrent episodes of diarrhea at 20 weeks in newsletter groups; ↓ pneumonia in newsletter groups and cIYCF groups at 20 weeks; ↔ morbidity at 14 weeks
Hanson [27] (2015)	Tanzania (LMIC)	CRCT	All pregnant women in intervention wards (groups of 3-4 villages)	140,048	Home-based counselling intervention on issues including hygiene, EBF, and care for LBW babies	From as soon as pregnancy identified until early postpartum.	↑ EBF for the first 3 days; ↑ EBI	↔ All-cause neonatal mortality rate in the first 28 d of life
Hmone [28] (2017)	Myanmar (LMIC)	RCT	Women from 28 to 34 weeks gestation who could access a networked mobile phone and had an uncomplicated singleton pregnancy	353	BF promotional text messages were sent 3 times per week in the evening	Over 9 months: from the time of recruitment until 6 months postdelivery.	↑ EBF over 6 months; ↑ BF over 6 months; ↔ EBI	↓ALRI at 3 and 5 months and over 6 months; ↓ diarrhea at 3 months and over 6 months; ↔ ALRI at 1 month, diarrhea at 1 and 5 months, fever or cold at 1, 3, and 5 months or over 6 months

Table 1 (continued)

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Jakobsen [29] (2008)	Guinea-Bissau (LMIC)	RCT	Mothers living in the area during pregnancy and present when visited by the field assistant	1,721	Home visits involving education focused on encouraging mothers to postpone introduction of water and weaning food until the age of 4–6 months	Varies but from birth to 6 months of age unless the infant was reported to have started both water and weaning food.	Weaning food was significantly delayed	↓Weight at 4-6 months; ↔ weight at 7–12 days; ↔ diarrhea or hospitalizations in first 6 months; ↔ mortality in first 6 months
Khan [30] (2013)	Bangladesh (LMIC)	RCT	Pregnant women (30 weeks) who were previously participating in the MINIMat trial	2,845	EBF counselling provided by trained counsellors on a one-to-one basis (but could also include key family members) at home over 8 visits (2- last trimester, 1-within 7 days of delivery, 5- monthly intervals up to 6 months)	8 months starting at 8th month of pregnancy	↑ EBF at 4 and 6 months	↔ Child growth from birth to 54 months of age (WHZ, HAZ, and WAZ)
Kramer [31, 48, 49] (2001)	Belarus (LMIC)	CRCT	Healthy mothers who intended to BF and their healthy, FT singleton infants	17,046	The experimental intervention was modelled on the BFHI and included intervention polyclinics to provide postnatal support	Does not specify	↑ EBF at 3 and 6 months; ↑ BF at 3, 6,9, and 12 months	↔ Height, BMI, waist, and hip circumferences, triceps, and subscapular skinfold thickness at 6.5 years; ↓GI infections and atopic eczema in first 12 months; ↔ respiratory tract infections in first 12 months, systolic and diastolic blood pressure at 6.5 years, infant allergy and asthma at 6.5 years; ↔ infant mortality
Le Roux [32, 50] (2013)	South Africa (LMIC)	CRCT	Pregnant women	1,238	PIP: standard care plus home visits by community healthcare workers where messages were provided on good maternal nutrition and preparing for BF; regular antenatal clinic attendance; HIV testing and prevention, stopping alcohol, BF and growth monitoring; medical adherence (immunizations, prevention for HIV-exposed children); infant bonding; and securing the child grant.	Started antenatally and up to 12 months post-birth	↑ EBF at 6 months	↑ HAZ > -2 at 6 months and WAZ > -2 at 18 months; ↔ WAZ <–2, WHZ <–2 at 6 months

Table 1 (continued)

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Lewycka [33] (2013)	Malawi (LMIC)	CRCT	All women aged 10–49 living in the study area who consented to participate	26,262	Women's group intervention where women's groups were established supported by a cluster facilitator who was trained to discuss and help with maternal and child health problems. Volunteer peer counselling intervention delivered by trained counsellors who made five home visits during and after pregnancy (third trimester, within 1st week after birth, 1 month, 3 months, and 5 months) Combination of WGI and VPC	Does not specify	↑ EBF at 6 months	↔ IMR
Morandi [34] (2019)	Italy (HIC)	CRCT	Primary pediatricians of healthy FT infants	569	Pediatricians were trained to provide parents with information about BF, feeding on demand, responsive feeding, timely CF, and other obesity prevention behaviors at all routine visits scheduled at 1, 3, 6, 12, and 24 months	23 months starting at 1 month	↔ EBF at 3 months; ↔ BF at 3 and 6 months	↑ Length at 3 months; ↔weight, W/L or BMI at 3, 6, 12, and 24 months or length at 6, 12, or 24 months; ↔ overweight/obesity at 24 months
Morrow [35] (1999)	Mexico (LMIC)	CRCT	All pregnant women identified by a semiannual door-to-door census.	130	In the 3-visit group, peer-counsellors visited in late pregnancy and in the first and second weeks postpartum. In the six-visit group, peer-counsellors also visited in mid-pregnancy and at weeks 4 and 8 postpartum. These visits encouraged and helped with BF and EBF, and included key family members.	~21- 35 weeks for the 6 visit group starting at mid-pregnancy and ~14 weeks for the 3 visit group starting at late-pregnancy	↑ EBF at 3 months in 3-visit and 6-visit groups; ↑ EBF duration in 3-visit and 6-visit groups	↓Diarrhea in the first 3 months (cumulative incidence)
Nair [36] (2017)	India (LMIC)	CRCT	Pregnant women identified in rural districts in eastern India	5,781	Community-based workers conducted a single home visit to each pregnant woman in the third trimester of pregnancy for counselling on maternal nutrition followed by monthly home visits with counselling for growth promotion and IYCF. They also facilitated 2-3 participatory meetings with local women's groups per month to address underlying causes of undernutrition including birth spacing, nutrition in pregnancy, water, sanitation, and women's agency.	Nearly 2 years starting at last trimester of pregnancy until 2 years of age	↔ EBF at 6 months	↓ Underweight; ↔ LAZ, WAZ, MUAC, stunting, wasting at 18 months; ↔ diarrhea, cough or fever at 6 months; ↓ infant mortality

Table 1 (continued)

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Nikiema [37] (2017)	Burkina Faso (LMIC)	CRCT	Pregnant women in the catchment areas of the 12 selected health centers	2,253	Nutrition counselling intervention that was implemented within the usual care environment, where the provider's training was focused on pregnant women's diet, BF, and CF	>18 months starting during pregnancy	↑ EBF at 6 months; ↔ EBI	↔ Wasting and stunting; ↔ incidence of diarrhea, fever or ARI; ↑ mean incidence of child illness
Ogaji [38] (2020)	Nigeria (LMIC)	RCT	Mothers of healthy infants who initiated BF after delivery in baby-friendly hospital	150	Mobile phone-based support plus usual care, where the women received monthly advisory support service from the same pediatrician. An average of 8 phone calls was made during which the mothers were reminded of the benefits of EBF and questions related to BF and the wellbeing of the mother and baby were answered.	6 months starting at 1 week post-delivery	↔ EBF at 6 months	↑ Weight, length, WAZ at 6 months and weight gain over 6 months
Schwartz [40] (2015)	Brazil (LMIC)	RCT	Adolescent mothers (<20 years) who live in the same household as their own mothers recruited from a baby-friendly hospital	323	Sessions at the maternity ward and at the participants' homes at 7, 15, 30, 60, and 120 days post-delivery during which advice on EBF, infant feeding challenges, and complementary feeding and supporting material were given	120 days starting at birth	↑ EBF duration; ↔ BF durations	↔ BMI for age, HAZ, overweight (%), obesity (%), and stunting (%) at 4-7 years.
Sehhatie [41] (2019)	Iran (LMIC)	RCT	Pregnant women (third trimester) who visited the health-care centers and had an unsuccessful previous BF experience and a singleton pregnancy	108	BF counselling sessions in groups of 5–7, four counselling sessions were held with a one-week interval during the third trimester. Phone or if necessary in-person counselling was offered to mothers on day 15, 2 months, and the end of the month 4 postpartum.	Varies, around 1–5 months	↑ EBF at 15 days, 2 months, and 4 months	↑Weight at 15 days; ↔ weight at 2 months and 4 months
Tylleskar [39, 44, 51] (2011- a)	Burkina Faso (LMIC)	CRCT	Pregnant women intending to BF	794	EBF peer-counselling during pregnancy and postpartum	~29 weeks starting in the third trimester	↑ EBF at 3 and 6 months; ↔ EBI	↓ WLZ at 12 and 24 weeks; ↑ wasting at 12 weeks; ↔ diarrhea prevalence at 12 and 24 weeks
Tylleskar [39, 44, 51] (2011-b)	Uganda (LMIC)	CRCT	Pregnant women intending to BF	765	EBF peer-counselling during pregnancy and postpartum	~29 weeks starting in the third trimester	↑ EBF at 3 and 6 months; ↑ EBI	↓ WLZ at 24 weeks; ↓ WAZ at 12 and 24 weeks; ↑ wasting at 12 and 24 weeks; ↔ diarrhea prevalence at 12 and 24 weeks

Table 1 (continued)

Author name and date	Country	Study design	Population	Sample size	Intervention description	Duration of intervention	BF outcomes	Infant/child outcomes
Tylleskar [39, 44, 51] (2011- c)	South Africa (LMIC)	CRCT	Pregnant women intending to BF	1,020	EBF peer-counselling during pregnancy and postpartum	~29 weeks starting in the third trimester	↑ EBF at 3 and 6 months; ↔ EBI	↑ WLZ at 24 weeks; ↔ diarrhea prevalence at 12 and 24 weeks
Wells [42, 45] (2012)	Iceland (HIC)	RCT	Mothers of healthy, FT, EBF infants at well-baby clinics	119	Mothers were asked to continue EBF until 6 months of age	2 months starting at 4 months of infant's age	↑Breast milk intake	↔Lean mass, fat mass, WAZ, LAZ, HAZ, or BMI-for-age at various time points from 6–38 months
Wen [43, 46] (2011)	Australia (HIC)	RCT	Pregnant women (24-34 gestation) attending antenatal clinics	667	The trained community nurse visited families 8 times at home, once at 30–36 weeks gestation and seven times after the birth (at 1, 3, 5, 9, 12, 18, and 24 months) where she taught the mother specific skills and knowledge in relation to healthy infant feeding practices and active play.	At least 28 months starting 30–36 weeks of pregnancy	↔ EBF at 6 months; ↑ BF at 6 and 12 months	↓BMI at 24 months
Yotebieng [13, 47] (2015)	DR Congo (LMIC)	CRCT	Women who had a healthy singleton birth in the randomized health facilities and who intended to attend well-baby clinic visits	975 [13] 931 [47]	BFHI steps 1–9 were implemented at the selected facilities or BFHI steps 1–10 where steps 1–9 were implemented at the facilities, support was provided in well-child clinics and flyers were distributed to address the main BF barriers.	Hospital stay for those at steps 1–9 and 24 weeks for those at steps 1–10.	↑ EBF at 1, 6, and 14 weeks in steps 1–9 and steps 1–10 groups; ↑ EBF at 24 weeks in Steps 1–9 group; ↔ EBF at 24 weeks in steps 1–10 group; ↔ EBI	↓ Diarrhea prevalence at 24 weeks in steps 1-9 group; ↑ diarrhea prevalence at 14 and 24 weeks in steps 1–10 group; ↔ respiratory infection prevalence at 14 and 24 weeks in both groups

BF, breastfeeding; BFHI, baby-friendly health initiative; CF, complementary feeding; cIYCF, community infant and young child feeding; CRCT, cluster-randomized controlled trial; EBF, exclusive breastfeeding; FT, full-term; HAZ, height-for-age Z-score; HIC, high-income country; HV, home visit; LAZ, length-for-age Z-score; LMIC, low- and middle-income country; RCT, randomized controlled trial; WAZ, weight-for-age Z-score; WLZ, weight-for-length Z-score.

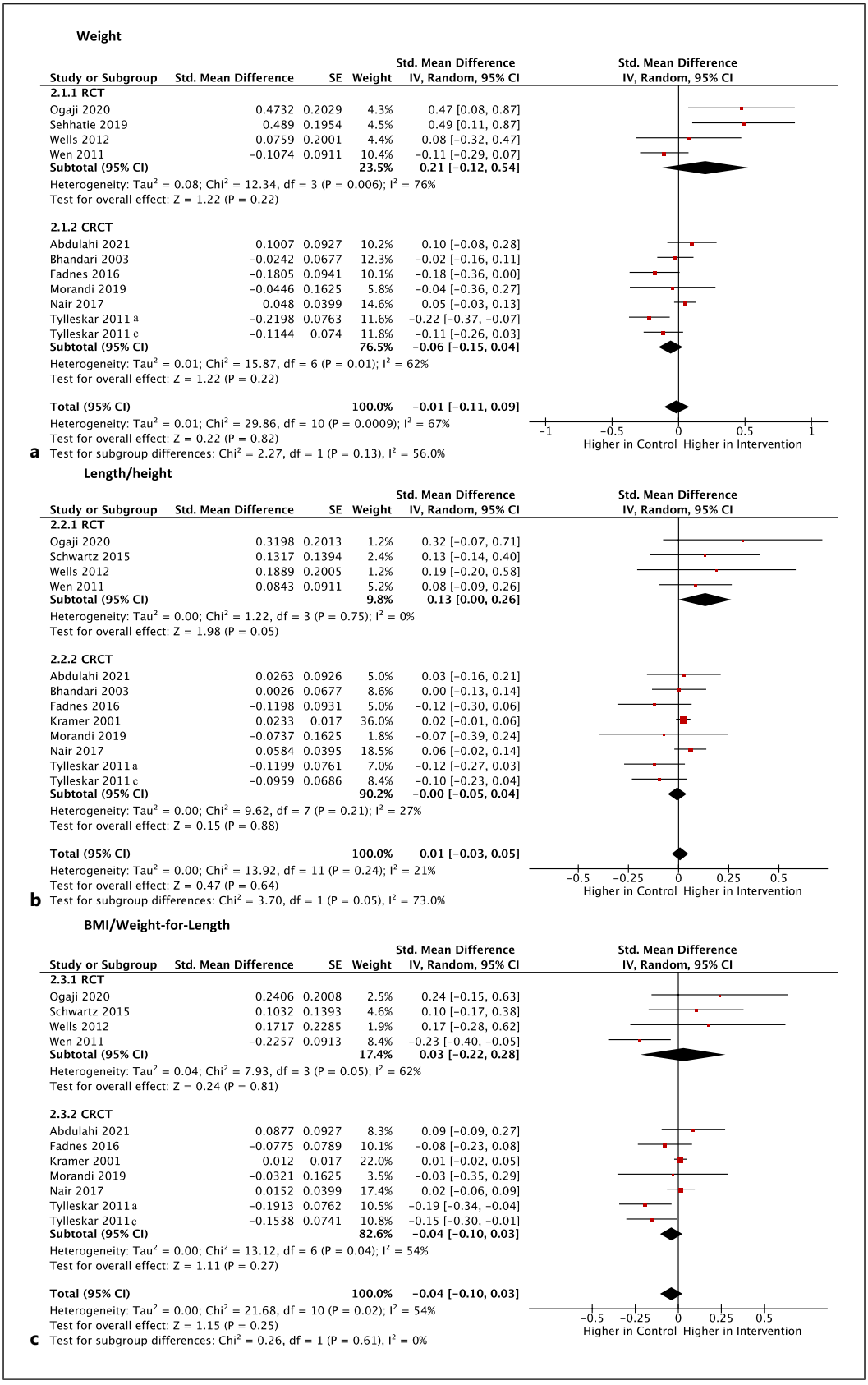

Fig. 2. Forest plot of intervention versus control comparison for outcomes: (**a**) infant weight, (**b**) infant length/height, and (**c**) infant BMI/weight-for-length at 3–>18 months. Contributing studies are sorted in chronological order. Square data markers represent effect size estimates (SMD), with size of the markers corresponding to 95% CIs and diamond data markers representing the overall effect size based on included studies.

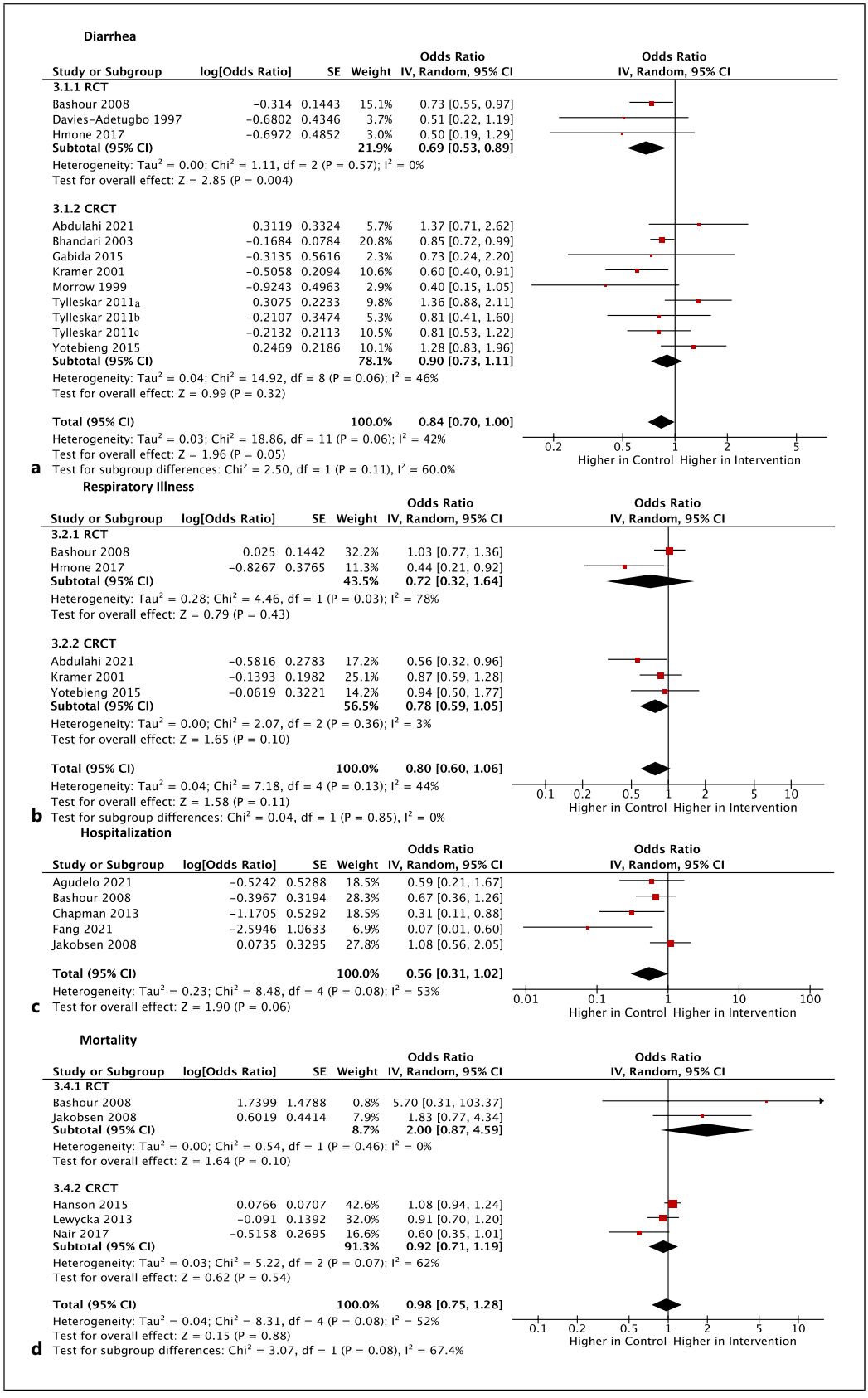

Fig. 3. Forest plot of intervention versus control comparison for outcomes: (**a**) infant diarrhea, (**b**) respiratory illness, (**c**) hospitalization, and (**d**) mortality. Contributing studies are sorted in chronological order. Square data markers represent effect size estimates (OR), with size of the markers corresponding to 95% CIs and diamond data markers representing the overall effect size based on included studies.

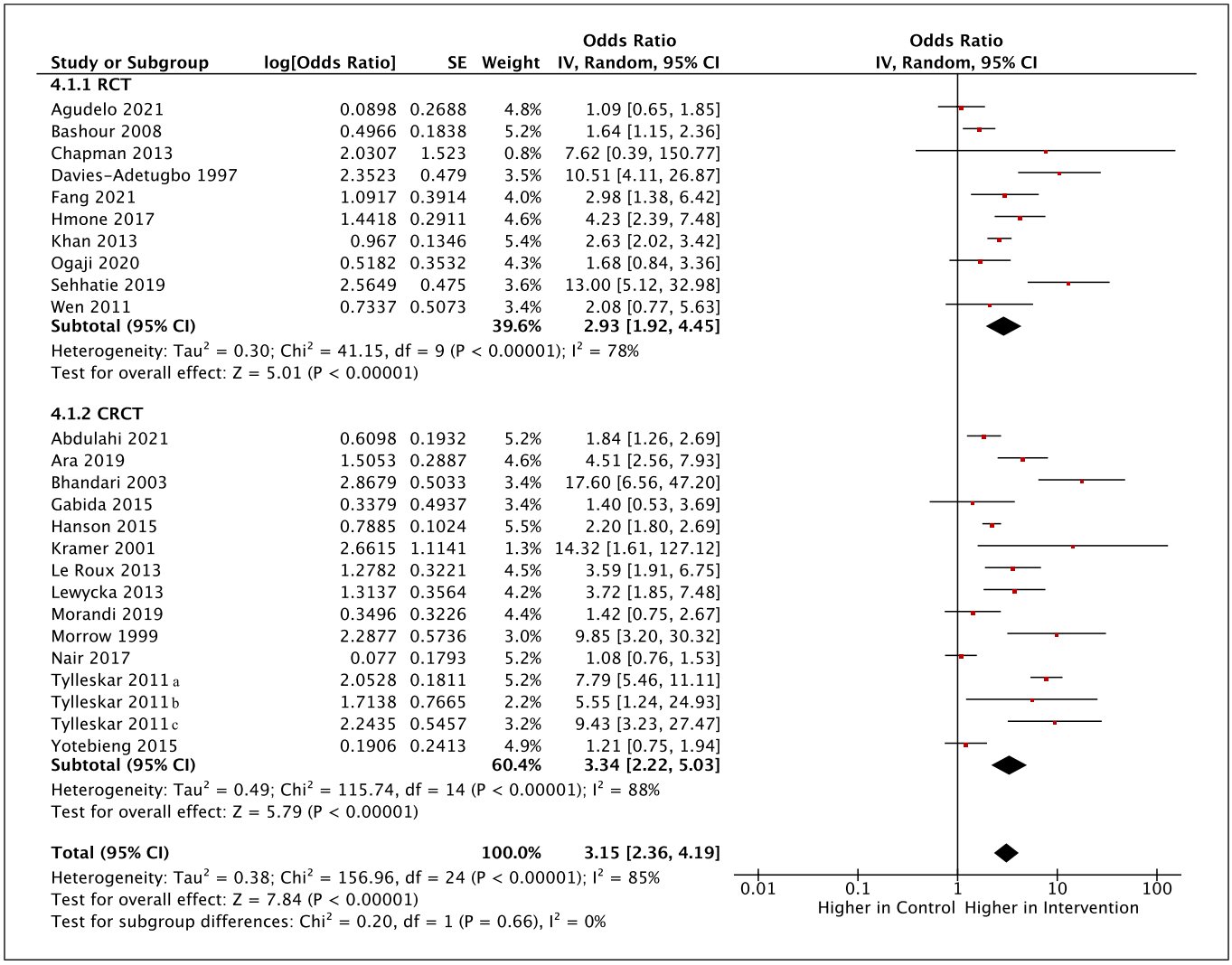

Fig. 4. Forest plot of intervention versus control comparison for EBF Contributing studies are sorted in chronological order. Square data markers represent effect size estimates (OR), with size of the markers corresponding to 95% CIs and diamond data markers representing the overall effect size based on included studies.

(17 studies), respectively. This rate was lower at 6 months (34.5% [IQR 45; 2.0–73.0] vs. 13.7% [IQR 27.6; 0.0–54.8]), respectively (18 studies).

Subgroup Analyses

Studies conducted in LMIC yielded a significantly higher OR of EBF in the intervention group compared to those in HIC (3.31 [2.44, 4.49] vs. 1.66 [0.98, 2.81]; $p = 0.02$) with 80% of the heterogeneity in EBF explained by income classification (online suppl. 4). There were significant subgroup differences in the OR of respiratory illness between interventions that started prenatally (0.51 [95% CI: 0.33, 0.79]) versus postnatally (0.97 [95% CI: 0.78, 1.20]) with 85% of heterogeneity explained by timing of the intervention. There were no significant differences in growth outcomes between subgroups stratified by whether the intervention resulted in an improvement in EBF (at latest available time point, 6 months, 3–4 months, or 1–3 months). There were insufficient studies to test these subgroup differences for respiratory illness and mortality outcomes.

Sensitivity Analysis

Confining analyses to RCTs resulted in significantly lower pooled odds of diarrhea (OR = 0.69 [95% CI: 0.53, 0.89]) and a trend toward higher length/height (SMD = 0.13 [95% CI: 0.00, 0.26]) with interventions. Conversely,

limiting inclusion to high-quality studies did not notably affect the magnitude or direction of the intervention effect and CIs. Using an ICC of 0.01 resulted in significantly lower pooled odds of diarrhea (OR = 0.83 [95% CI: 0.70, 0.99]). However, overall there was minimal impact on the magnitude of the intervention effect and CIs, and no change in the direction of effect for analyses using different ICC.

Publication Bias

There was no evidence for publication bias for weight, length/height, BMI/weight-for-length, or diarrhea (online suppl. 5). There was evidence of publication bias (Egger bias = 1.81; 95% CI: −0.09, 3.71; $p = 0.06 < 0.1$) for EBF when using data for the latest available time point within each study, but this was not evident when including data at different timepoints (6 months, 3–4 months, or 1–3 months).

Discussion

This review examined the effects of exposure to more versus less breast milk as a result of EBF promotion interventions. The interventions significantly improved EBF rates at various time-points, however, EBF rates at 6 months were low overall. Promotion of EBF reduced the odds of respiratory illness at 0–3 months. There was also a trend toward a reduction in the overall odds of diarrhea which was significant in the sensitivity analysis. No significant differences were found in infant/child growth, even when results were stratified by whether the intervention improved EBF. There were also no significant differences in hospitalizations or mortality.

Our results for infant/child growth are consistent with a previous systematic review and meta-analysis published in 2012 that concluded that EBF for a longer duration was not associated with growth deficits [4] and add to the body of evidence that promotion of EBF does not give rise to growth concerns. Interestingly, our analyses confined to RCTs also suggested better linear growth in infants whose mothers received an EBF promotion intervention.

Overall, there was a significant reduction in the odds of respiratory illness at 0–3 months following EBF interventions but not at 4–6 months or at the latest available time point. The inconsistent effects of EBF interventions on respiratory infection in different studies [11, 13, 16, 28, 31] are similar to those reported by Kramer and Kakuma [4] and contrast with previous studies that consistently show strong protective effects of BF per se against respiratory infection [52]. This might suggest that promotion of BF rather than focusing specifically on EBF could yield larger benefits in reducing respiratory infection, although this was not addressed in our meta-analysis.

There was a trend toward lower odds of diarrhea with EBF promotion interventions. Contrary to what might be expected due to clustering "herd effects," the effect on diarrhea was significant when considering only RCTs (and excluding CRCTs) and also when adjusting for clustering using a smaller ICC. Nevertheless, with the exception of three CRCTs (from Ethiopia [11], DR Congo [13], and South Africa [39, 44]) which showed higher prevalence/incidence of diarrhea in the intervention group, all other studies favored the intervention group. It is biologically plausible that promotion of EBF would protect against gastrointestinal infections as it avoids contamination from unsafe preparation of breast milk substitutes or other foods, and breast milk in general provides several antimicrobial and anti-inflammatory compounds. We were not able to explore this further as data on the infant feeding practices of participants who were not EBF was not consistently reported.

Previous BF meta-analyses of mostly observational studies such as Victora et al. [1] found that BF offers strong protection against infections and hospitalizations due to infections. They also found that BF was associated with some reductions in overweight/obesity. Direct comparisons between these findings and ours are difficult as our focus was the promotion of EBF whereas Victora et al. [1] compared groups with BF defined in several ways (for example, any BF vs. none, predominant vs. partial, EBF vs. partial/predominant). We also only included interventional studies and excluded observational studies. Furthermore, most studies included in our meta-analysis reviewed the effects of exclusive EBF promotion interventions rather than the effects of EBF; only three trials directly randomized mothers to EBF for specific durations. Therefore, the magnitude of effects on infant and child outcomes might be underestimated by non-compliance with the interventions and depends on the success of the interventions in promoting EBF. It is also possible that had we been able to subdivide the control groups according to BF intensity (predominant, vs. partial vs. not BF) or according to definition of not EBF (introduction of solids, liquids, and/or infant formula), we may have seen larger effect sizes.

Strengths of our review are the inclusion of studies from all settings and a range of health outcomes assessed up to 7 years of age, allowing a comprehensive review of the effects of EBF promotion. However, there are several limitations. We examined the effects of exposure to more versus less breast milk as a result of EBF promotion interventions and did not directly address whether EBF for 6 months has greater benefits than EBF for 4 months;

indeed, we noted that EBF rates at 6 months were low even in the intervention groups with a median of only 34.5% for studies that reported this outcome. As expected, included studies were heterogenous and country income classification, type of intervention and timing of the intervention were significant sources of heterogeneity for some outcomes. We were also unable to conduct planned subgroup analysis by maternal BMI, Baby-Friendly Initiative accreditation status, or family socioeconomic status. There were insufficient studies investigating other potential benefits of EBF promotion such as reduced risk of noncommunicable diseases or allergy/asthma. Additionally, as for all meta-analyses, decisions must be made about which data to include, for example when multiple interventions are used or the same outcome is assessed in different ways and this can potentially influence findings. We used a systematic approach and discussed these decisions to avoid introducing bias.

In conclusion, EBF promotion interventions were successful at improving EBF. There were modest reductions in respiratory infection and diarrhea with no effects on infant and child growth or mortality. However, even modest decreases in infections, which are associated with significant morbidity and mortality especially in low-income settings, could translate to significant public health benefits and reduced healthcare expenses. Future studies investigating the effects of longer versus shorter EBF durations on other outcomes, and including cost-effectiveness analysis of EBF versus BF promotion could provide further insight into this issue.

Statement of Ethics

An ethics statement is not applicable because this study is based exclusively on published literature.

Conflict of Interest Statement

S.D., F.J.F., L.J.M., A.N., A.Z.K., and H.S. have no conflicts of interest to declare. M.F. has received an unrestricted donation for research on infant nutrition from Philips (not related to the current manuscript); she is Assistant Officer for Nutrition at the Royal College of Paediatrics and Child Health UK, a member of the Infant Nutrition working group at the European Food Safety Authority (EFSA) and General Secretary of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).

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Author Contributions

Dr. Sarah Dib ran the final study search, assessed articles for inclusion, undertook quality appraisal, extraction of data, and data analysis, drafted the initial manuscript, and critically reviewed and revised the manuscript. Ms. Frankie Joy Fair developed and reviewed the study protocol, checked a random sample of included and excluded studies, cross-checked all extracted data within the analyses and assisted with the data analysis, and critically reviewed and revised the manuscript. Dr. Lucy Jane McCann assessed articles for inclusion, cross-checked all extracted data, and critically reviewed and revised the manuscript. Ms Antonia Nicholls conceptualized the study, developed the study protocol, ran the initial search, assessed articles for inclusion in the initial search, and critically reviewed and revised the manuscript. Prof Anastasia Kalea developed the study protocol and critically reviewed and revised the manuscript. Prof Hora Soltani developed and reviewed the study protocol, checked a random sample of included and excluded studies, cross checked, and critically reviewed and revised the manuscript. Prof. Mary Fewtrell conceptualized the study, developed the study protocol, undertook quality appraisal of included studies, discussed discrepancies in study inclusion, checked a random sample of included and excluded studies, and critically reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

Data Availability Statement

All data generated or analyzed during this study are included in this article and its online supplementary material files. Further inquiries can be directed to the corresponding author.

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