Improving exclusive breastfeeding in low and middle-income countries

Olufunlayo, Tolulope; Roberts, Alero Ann ; MacArthur, Christine; Thomas, G Neil; Odeyemi, Kofoworola Abimbola ; Price, Malcolm; Jolly, Kate

DOI:
10.1111/mcn.12788

Interventions to improve breastfeeding exclusivity in low and middle-income countries: a systematic review and meta-analysis

Tolulope Florence Olufunlayo[123],Alero Ann Roberts[12], Christine MacArthur[3], Neil Thomas[3], Kofoworola Abimbola Odeyemi[12], Malcolm Price[3], Kate Jolly[3]

[1]Department of Community Health & Primary Care, College of Medicine, University of Lagos, Nigeria

[2]Department of Community Health & Primary Care, College of Medicine, University of Lagos, Nigeria

[3]Institute of Applied Health Research, University of Birmingham, Birmingham, UK

Correspondence to:

Kate Jolly, Institute of Applied Health Research, University of Birmingham, Birmingham, B15 2TT, UK. Email: c.b.jolly@bham.ac.uk

Contributors

TFO, KJ, CM and NT conceived the idea for the review. TFO developed the protocol and search strategy with input from KJ, CM and NT. TFO and AAR undertook inclusion, exclusion and data extraction with input from KJ and CM; TFO, KO and KJ did risk of bias assessment; TFO undertook the meta-analysis with support from MP and KJ. TFO drafted the paper with input from KJ and CM. All authors critically reviewed the paper.

Declaration of interests

We declare no competing interests

Acknowledgements

We acknowledge Susan Bayliss of the Institute of Applied Health Research, University of Birmingham for her help with development of the search strategy. Prof. John Ehiri of the University of Arizona Mel and Enid Zuckerman College of Public Health, and Fulbright Scholar to the College of Medicine University of Lagos, gave expert advice on data synthesis and risk of bias assessment for non-randomised studies.

Funding: Needs Assessment Intervention Fund of the University of Lagos, Lagos, Nigeria

Word count: abstract – 250; main body –4,315. References - 20; Tables & figures – 7

ABSTRACT

Exclusive breastfeeding (EBF) rates until six months in most low and middle income counties (LMICs) are well below the 90% WHO benchmark. This systematic review sought to provide evidence on effectiveness of various interventions on exclusive breastfeeding until six months in LMICs, compared with standard care. Experimental and observational studies with concurrent comparator promoting EBF, conducted in LMICs with high country rates of breastfeeding initiation, were included. Studies were identified from a systematic review and PUBMED, Cochrane and CABI databases. Study selection, data abstraction, and quality assessment were carried out independently and in duplicate. Relative risks with 95% confidence intervals were calculated for individual studies and pooled. High heterogeneity was explored through pre-specified sub-group analyses for the primary outcome (EBF until six months) by context and by intervention for the randomised controlled trials. Prediction intervals were calculated for each effect estimate. Sixty-seven studies with 79 comparisons from 30 LMICs were included. At six months, intervention group infants were more likely to be exclusively breastfed than controls (RR=2.19, 95%CI 1.73-2.77; I^2 78.4%;25 RCTs). Larger effects were obtained from interventions delivered by a combination of professional and lay persons (RR 3.90, 95%CI 1.25-12.21; I^2 46.7%), in interventions spanning antenatal and postnatal periods (RR 2.40, 95%CI 1.70-3.38; $I^2$83.6%), and when intensity was between four to eight contacts/sessions (RR 3.20, 95%CI 2.30-4.45; I^2 53.8%). Almost every intervention conducted in LMICs increased exclusive breastfeeding rates; choice of intervention should therefore be driven by feasibility of delivery in the local context to reduce infant mortality.

Keywords: Exclusive breastfeeding, breastfeeding, intervention effectiveness, developing countries, systematic review, meta-analysis.

INTRODUCTION

Infant nutrition plays a major role in child health and impacts significantly on survival. In low and middle income countries (LMICs) infants not breastfed are six to ten times more likely to die in the early months than those breastfed (World Health Organization, 2009). The World Health Organisation (WHO) and UNICEF recommend that infants should be exclusively breastfed (EBF) until six months of age, with breastfeeding continuing to be an important part of nutrition until at least two years (WHO, 2001; World Health Organization, 2009).The benefits of EBF until six months are well documented, improving growth, health and survival (Rollins et al., 2016; Sankar et al., 2015; Victora et al., 2016). A Lancet review of systematic reviews to describe breastfeeding rates internationally and benefits of breastfeeding concluded that protection, promotion and support of breastfeeding is crucial to achieving several Sustainable Development Goals (Victora et al., 2016). If EBF rates were to attain near universal coverage 13.8% of all child deaths below two years in LMICs, corresponding to over 800,000 child deaths annually, could be averted (Victora et al., 2016).

Despite this, EBF rates are far below optimal; 37% of infants under six months in LMICs were exclusively breastfed in recent country surveys (Victora et al., 2016), well below the WHO 90% benchmark (UNICEF, 2013). Despite evidence that early initiation of breastfeeding significantly reduces neonatal mortality, even in countries with high initiation rates there is often a delay in initiating breastfeeding, with less than half (42%) of newborns globally breastfed within one hour (UNICEF, 2013).

Breastfeeding patterns differ markedly between LMICs and high income countries (HICs). Late breastfeeding initiation and low EBF rates characterize the patterns in most LMICs; in HICs there is the added problem of short duration of any breastfeeding (McFadden et al., 2017; Victora et al., 2016). Previous systematic reviews of breastfeeding interventions have

included HICs and LMICs studies combined (Haroon, Das, Salam, Imdad, & Bhutta, 2013; Jolly et al., 2012; McFadden et al., 2017; Renfrew, McCormick, Wade, Quinn, & Dowswell, 2012; Sinha et al., 2015); however, since culture, maternal education, maternity services, and feeding patterns, differ considerably between HICs and LMICs, and much more than between LMICs, it is important that systematic reviews focused solely on LMICs are conducted to provide adequate evidence of what works there. A recent review by Sinha et al investigated effectiveness of types of interventions in LMICs for EBF aged 1-5 months combined (Sinha et al., 2017),but did not ascertain interventions that would be effective in improving EBF up until the recommended six months of age for all. A review to determine which interventions work most effectively to improve EBF until six months is therefore critical to provide robust evidence for scaling-up breastfeeding intervention programmes in LMICs, thereby reducing mortality and accelerating progress towards the Sustainable Development Goals (SDGs) by 2030 (UNICEF and WHO, 2015).The main aim of this study therefore was to determine the effect of various interventions on breastfeeding exclusivity until 6 months in LMICs with high breastfeeding initiation rates.

METHODS

Protocol and registration

The protocol for this systematic review is registered in PROSPERO International prospective register of systematic reviews, University of York: CRD42016037029.

Eligibility criteria

This review included experimental and observational studies with concurrent comparator promoting EBF, conducted in LMICs (defined by World Bank's classification of countries by income (Fantom, 2016) at the time of primary study) with high country breastfeeding

initiation rates (≥80% initiation)(McFadden et al., 2017); almost all LMICs have high initiation rates. The interventions were delivered to mothers in the antenatal and/or postnatal period, in one or more contexts identified in previous conceptual frameworks as follows: health systems and services, home and family, community, workplace/employment, and policy environment (Rollins et al., 2016; Sinha et al., 2015). The comparator group comprised usual care.

Exclusion criteria:

Studies with interventions targeted primarily at sick mothers or babies, or with special/medical needs, such as prematurity, low birth weight or tuberculosis, were excluded.

Outcomes

The primary outcome was the rate of exclusive breastfeeding (EBF) up until six months as defined by study authors. Secondary outcomes were EBF feeding rates at zero to one, two to three, and four to five months of age; EBF rates of infants 0-5 months; early initiation of breastfeeding (proportion of infants put to breast within one hour of birth), and continued breastfeeding at one year (World Health Organization, 2008). EBF rates were measured using 24-hour, seven day, previous month or since-birth recall; in some studies, assessment mode was not specified. The outcome measuring EBF of infants 0-5 months was derived from WHO Core Indicators for assessing infant and young child feeding practices (World Health Organization, 2008) and included any study which assessed EBF among a group of infants between 0-5 months of age; however, two estimates which measured EBF among infants 0-6 months were also included because they measured a cross-section of children in the specified age range. Studies that reported EBF at several time points contributed data to each relevant meta-analysis.

Information sources

Studies were identified from an earlier systematic review of breastfeeding interventions by Sinha et al. (Sinha et al., 2015). A systematic literature search was then carried out in PUBMED, Cochrane and CABI databases for January 2014 – November 2016, to identify studies published after the Sinha 2015 review was conducted. We searched references of included studies, and contacted authors to obtain additional published and unpublished articles, and if full text, translations and/or additional data were needed. Grey literature was sought from Conference Proceedings Citation Index (CPCI) and Science Citation Index. No language restrictions were applied to the updated searches.

Search strategy

The search was conducted using index terms and text words in various combinations relating to interventions to improve breastfeeding exclusivity in LMICs (electronic search strategy details in Appendix I). The search did not include individual LMIC country names as countries move between income groups and we categorised the country according to its status when the study was undertaken.

Study selection

Each paper from the Sinha review was screened for country; those in LMICs went on to full text review. After removal of duplicates, titles and abstracts identified from database searches were screened for eligibility; full texts of potentially eligible articles were then assessed for inclusion. Eligibility and inclusion were undertaken independently by two review authors (TFO, AAR), with a third reviewer resolving any disagreements (KJ or CM).

Data extraction

Data extraction was conducted using a proforma modified from Cochrane data abstraction form, and entered into a database. Extracted information included study details, population characteristics, context, setting, methods, and results. Details of interventions are presented in relation to their context, setting and nature, duration and intensity, and timing in relation to the birth.

Risk of Bias in individual studies

Two authors independently assessed risk of bias using Cochrane tools for randomized controlled trials (RCTs), and non-randomized studies of interventions (ACROBAT-NRSI) (Higgins, Altman,& Sterne.,2011). Studies were judged as having a high risk of bias among RCTs if one or more domains were of high risk.

Summary measures

Risk ratios for EBF with 95% confidence intervals were used as summary measures; in studies which did not report relative risk, it was calculated from raw data where available. We explored clinical heterogeneity (by qualitatively comparing characteristics among included studies) and statistical heterogeneity (using $\chi 2$ tests and I^2 statistic). We combined results from included studies for each outcome to give an overall estimate of treatment effect using random effects models throughout, on the assumption that included studies covered a range of populations, interventions, and contexts (Riley, Higgins, & Deeks, 2011).Where two or more interventions from the same study contributed to the same meta-analysis, the sample size in the control group was divided by the number of comparisons it contributed to within the meta-analysis. For meta-analyses containing ten or more studies, potential publication bias was investigated by examining asymmetry on a funnel plot.

For cluster trials we computed the design effect from data presented in the reports (intra-class correlation coefficients [ICC] and cluster adjusted estimates) and adapted the standard errors of the relative risk to make appropriate allowance for clustering (Higgins&Deeks, 2011).Authors of some cluster trials were contacted to request to obtain their ICC; an average ICC (of included cluster trials that provided the ICC in their article) was computed and used for those cluster trials for which the adjusted relative risk or ICCs were not available (Higgins&Deeks, 2011).

Prediction intervals (PIs) were calculated for effect estimates where there were at least three studies, to describe the range in which 95% of the distribution of the effects lie. These predict how the effectiveness of the intervention could vary from the average in different circumstances; for example, different contexts and populations (IntHout, Ioannidis, Rovers, & Goeman, 2016; Riley et al., 2011).

Evidence synthesis

Included articles have been synthesized, and reported narratively and in tables following PRISMA guidelines. Meta-analysis using Stata Version 14.2 was conducted for randomised studies only for the a priori main analyses and then for all study types as secondary analysis. High heterogeneity was explored through pre-specified sub-group analyses for the primary outcome by intervention characteristics –context, mode of delivery, type of intervention, timing, intensity, provider of the intervention, and target of intervention; this was done for RCTs as this review focuses on high quality studies which are likely to give more precise results. We have also undertaken sub-group analyses for all study types combined to enable comparison with other published systematic reviews. Meta-regression was conducted to calculate p-values for differences observed in sub-group analysis. Sensitivity analysis was also conducted for the primary outcome by study size and bias judgement.

Ethical approval

Ethical approval was not required for this systematic review.

RESULTS

Study selection

The search identified 7698 titles; after removal of duplicates 6947 underwent title/abstract screening, 183 full text articles were assessed for eligibility, and 67 studies were eligible for inclusion, comprising 79 comparisons between intervention and control (Figure 1).The meta-analysis includes 64 studies with 76 comparisons. No study was excluded for having a breastfeeding initiation rate below 80%. References of included studies are in Appendix II.

Study characteristics

Study design

This review includes 44 RCTs (of which 23 were cluster-RCTs), seven quasi-experimental studies, 12 non-randomised intervention studies, and four observational studies (Appendix III). Table 1 summarises characteristics of included randomised trials; characteristics of non-RCTs are contained in Appendix IV.

Location, setting, and participants

Studies were undertaken in 30 LMICs (Table 1). Of studies reporting setting, ten were in rural settings, 27 in urban areas, four in peri-urban/sub-urban settings and one in a combination of settings.

Interventions were directed primarily at mothers and/or pregnant women in 61 intervention arms, mother plus a significant family member in four arms, and health workers in ten arms. Four study arms provided their intervention to married women in the community.

Characteristics of usual care

Usual care varies both within and between countries and geographical regions. For example, usual care consisted of in-hospital care and follow-up by a community nurse after discharge in Wuhan, China [study 69]; breastfeeding health talk at immunization clinic, health education leaflets during antenatal or postnatal visits, and advice from healthcare workers under the framework of BFHI in Malaysia [study 56]; session on breastfeeding promotion as part of standard nutrition education in a slum in Kenya [study 46], and a facility-based six-week post-natal visit for support and follow-up in Jordan [study 33]. However, for each included study, the intervention(s) provided services above/beyond the usual care for the study context, in quality, coverage, and/or intensity.

Context and type (nature) of intervention

More than 70% of interventions were delivered within a single context – health systems and services, home and family, or the community (56 study arms), with the rest (23 study arms) delivered in multiple contexts (any combination). Three-quarters (75.9%) of interventions employed both education and breastfeeding support (60 study arms).

Personnel delivering interventions and mode of delivery

Interventions were delivered face-to-face (55 studies); by phone/ SMS (three studies); and by a combination of face-to-face and telephone (nine studies).

Interventions were delivered by a range of personnel, including doctors, nurses, midwives, nutritionists, lactation counsellors, community health workers, traditional birth attendants, peer educators/counsellors, religious leaders, and other lay persons (details in Table 1).

Timing and intensity of interventions

Interventions ranged from a single session to over 20 sessions, spanning pregnancy up to the end of the first year. Of the interventions which specified planned contacts, 21 offered three or less, 26 had four to eight contacts, and 19 at least nine contacts.

More details on included studies and characteristics of interventions are in Table 2.

Risk of bias:

Among randomised trials, nine (36%) were assessed to be low risk for bias. (Summary of risk of bias assessment in Appendices V&VI)

Primary outcome: Exclusive breastfeeding until six months

a. RCTs only

This outcome includes 25 comparisons from 18 RCTs involving 29,483 participants, and compared all forms of interventions with standard care. Pooled results showed that infants receiving an intervention had more than a two-fold increase in EBF rates (RR=2.19, 95%CI 1.73 to 2.77; I^2 =78.4%, 95%PI 0.81 to 5.94) compared with controls (Figure 2).

b. All study types

This outcome includes 35 comparisons from 29 studies involving 33,684 participants, comparing all forms of interventions with usual care. The results followed a similar pattern as that for RCTs only, as infants receiving an intervention also had more than a two-fold increase in EBF rates (RR=2.27, 95%CI 1.88 to 2.76; I^2 =83.1%, 95%PI 0.89 to 5.79) compared with controls (Figure 3).

Subgroup analyses of exclusive breastfeeding until six months

a. RCTs only

Table 3 summarises effect estimates for EBF until six months from sub-group analyses. Interventions delivered in a single context more than doubled EBF rates compared to controls, whether conducted in the health facility (RR=2.25, 95%CI 1.01 to 4.99) or home/family context (RR=2.20, 95%CI 1.43 to 3.37). No RCTs were conducted solely in the community context.

Interventions delivered in a combination of health services and home/family contexts more than doubled EBF rates (RR=2.38, 95% CI 1.68 to 3.39), while interventions in a combination of home/family and community contexts increased EBF rates by nearly 50% (RR=1.49, 95%CI 1.19 to 1.87) compared with controls (Table 3, Suppl. Fig. 1). There was no evidence of a difference between the effect of interventions in single versus multiple contexts (p=0.95).

Table 3 and supplementary figures 1- 4 report subgroup analyses by personnel delivering the intervention, timing and intensity of contacts, mode of delivery and study type. Meta-regression analyses found no significant differences between different delivery characteristics. The largest effect sizes were for interventions delivered by a combination of professional/para-professional and lay persons (RR=3.90, 95%CI 1.25 to 12.21); those delivered by a combination of face-to-face and telephone methods (RR=2.33, 95%CI 1.42 to 3.84); interventions combining education and support (RR=2.29, 95%CI 1.77 to 2.98); and those delivered across antenatal and postnatal periods (RR=2.40, 95%CI 1.70 to 3.38).

Prediction intervals were calculated for each effect estimate; the prediction interval reports the range in which 95% of the distribution of the effects lies. The majority of the intervals are greater than zero and thus mainly in favour of the breastfeeding interventions; however, they mainly overlap zero indicating that the interventions may not always be effective. The strongest prediction intervals were found for interventions delivered by lay-persons (95% PI

1.00 to 7.80), and for interventions with four to eight contacts (95% PI 1.35 to 7.59). This implies that there is a high level of certainty that future interventions deploying these characteristic will yield positive results.

b. All study types

The results by context and delivery characteristics for all study designs are similar to those for RCTs only and are reported in Table 3.

Sensitivity Analysis

A sensitivity analysis by study size (>500 participants) gave a similar effect estimate to that for all RCTs with wider confidence interval (RR2.43, 95% CI 1.64 to 3.61); a similar effect size was also obtained from a sensitivity analysis by bias judgement (low risk) with RR 2.23 (95% CI 1.54 to 3.22).

There was no evidence of a small study effect such as publication bias (supplementary figure 5).

Secondary outcomes

Secondary outcomes are in Table 4 and supplementary figures 6-11. Breastfeeding rates at all secondary endpoints for the interventions were significantly higher than usual care for all study designs combined for all outcomes, compared to the findings for RCTs only. The largest effect sizes for EBF (RCTs only) were at two to three months (RR=1.91, 95%CI 1.33 to 2.73, with PI of 0.40 to 9.17) and four to five months (RR=1.76, 95%CI 1.41 to 2.19 with PI of 0.81 to 3.81). For the pooled RCTs the effects of interventions on early initiation of breastfeeding and EBF in populations below six months were not significantly higher than controls.

DISCUSSION

This systematic review has clearly established that a wide range of different interventions, in different settings and by different types of providers significantly improves exclusive breastfeeding in LMICs with high breastfeeding initiation. The estimate of the average effect of the interventions ranged from a two to three fold increase in the proportion of women breastfeeding exclusively until six months: this was robust to study type, and exclusive of studies with a high risk of bias.

Principal findings

Pooled results for all types of interventions showed more than a doubling in EBF rates at six months for RCTs and all study types (RR 2.19 and 2.27 respectively). This effect is of a greater magnitude than estimates found in reviews that included studies from LMICs and high income countries combined, which ranged from 44% increase in EBF rates (RR 1.44; 95% CI 1.38 to 1.51) (Sinha et al., 2015) to 22% reduction in likelihood of stopping EBF before six months (McFadden et al., 2017).This difference could be due in part to the effect of large differences in control arm breastfeeding rates between LMICs and HICs on treatment effects calculated on the relative risk scale. Sinha et al (Sinha et al., 2015) obtained a pooled estimate for interventions in LMICs (57 studies) with relative risk of 1.69 (95% CI 1.54 to 1.86), however their analysis pooled outcomes from studies capturing EBF rates from any age between 0-5 months, so studies may have had the final outcome measure at any time prior to 6 months. Therefore, this is not comparable to our primary outcome, which captured EBF rates *at 24 to 26 weeks (six months) only*. Sinha's more recent review (Sinha et al., 2017) reported an odds ratio for EBF rates between 1-5 months in LMICs of 3.08 (95%CI 2.57 to 3.68) for all study designs, in 61 studies reported in English. Haroon et al also reviewed breastfeeding interventions, reporting that in combination these had a large and

significant effect on EBF rates in infants across ages 1-5 months old in developing countries (RR=2.88, 95% CI 2.11 to 3.93), while effects were non-significant in developed countries (Haroon et al., 2013). McFadden et al also combined EBF at all ages up to 6 months and showed significant effects across low/middle and high income settings (McFadden et al., 2017).

Most of the high-burden countries for neonatal and maternal mortality are LMICs, particularly sub-Saharan Africa and south Asia, which generally have weak health-care systems and low levels of community participation; these have been identified as important determinants of breastfeeding practices, as described in a conceptual model on breastfeeding (Rollins et al., 2016).What is provided as standard maternity care in most high income countries may only be delivered as part of a funded intervention in an LMIC and not usually available routinely from the health service due to lack of capacity. For example, many interventions in this review would be usual care within the UK context [studies 5, 6, 10, 36]. Breastfeeding patterns differ distinctively along country income category lines, with high income countries generally having shorter breastfeeding durations overall, while LMICs tend towards later initiation but high overall initiation rates with low levels of breastfeeding exclusivity (Victora et al., 2016).

Our review fills the major gap from previous reviews by exploring effectiveness of various different interventions by context, setting, and intervention characteristics (e.g. duration and intensity)solely in LMICs and for the key WHO target of EBF until six months. Hitherto this had only been done with the outcome measured at any time point prior to six months (McFadden et al., 2017; Sinha et al., 2017),or for high and low/middle income countries combined (Haroon et al., 2013; McFadden et al., 2017; Sinha et al., 2015),with meta-analysis including all study designs (Sinha et al., 2017), despite the substantial differences in services, maternal attitudes and practices between high and low/middle income countries.

Interventions delivered in health systems and services, and in home and family contexts each more than doubled EBF rates until six months, which is consistent with the combined LMIC and HIC findings from Sinha et al (Sinha et al., 2015). Among RCTs only, two intervention delivery modes had prediction intervals consistent with high level certainty that future interventions with these features would yield positive results: delivery by lay-persons and interventions with four to eight planned contacts. Similar to other reviews (McFadden et al., 2017; Sinha et al., 2015, 2017), our effect estimates were associated with high heterogeneity thus should be interpreted with caution. We did not find convincing statistical evidence of differences between subgroups in meta-regression analyses, which contrasts with findings of McFadden et al.(McFadden et al., 2017).The McFadden review reported significantly greater effects on cessation of EBF before six months for: lay support versus professionals, four to eight postnatal contacts versus fewer or larger numbers of contacts, and face-to-face versus telephone alone or other delivery modes (McFadden et al., 2017).We found no evidence from RCTs that interventions using telephone alone affected EBF rates however the pooled estimate of one RCT and one non-RCT [32, 56] was 1.58, though not statistically significant (95%CI 0.70 to 3.56); this is an area that should be explored in future LMIC studies. In addition, we did not find a significantly greater effect in the RR of EBF at 6 months in trials with interventions in multiple contexts, rather than just single contexts. Other authors have reported higher odds ratios of EBF at any time between 1 and 5 months for interventions in multiple contexts, but consistent with our findings, these were not statistically significant on meta-regression (Sinha et al., 2015, Sinha et al., 2017).

Strengths and weaknesses of the study and in relation to other studies

This systematic review was conducted robustly according to standard protocols, with study selection and data extraction independently in duplicate. Unlike other reviews we provide detail of risk of bias of individual studies and detail the interventions delivered. Sinha et al

(Sinha et al., 2017) reported an attenuation in effect in low quality studies and studies that did not take confounding into account. We focused on RCTs and cluster RCTs in the meta-analyses of the subgroups of intervention characteristics of delivery and we provide a comprehensive range of pre-specified subgroup analyses. To enable comparison with other systematic reviews and to include the full range of evidence about interventions that may be more feasible to implement outside of an RCT, we also reported subgroup analyses for all study designs. Limitations resulted from poor quality of reporting of some studies. There were also issues in harmonizing outcome measures due to varying recall criteria and follow-up periods between studies (even after including secondary outcomes to accommodate some of the variations), and in adjusting for clustering in cluster trials that did not provide values for the intra-class correlation coefficient (ICC) and design effect. The high heterogeneity in many of the effect estimates even after sub-group analysis is likely due to the wide variety of interventions and contexts included in this review; thus some caution is needed in interpretation of results. To help summarise the heterogeneity more clearly, when three or more studies were included in the meta-analysis we calculated prediction intervals to help ascertain whether the intervention would likely work in the majority of settings, or whether due to unexplained heterogeneity would work well in some settings but less effectively, or not at all, in others.

The meta-analysis had insufficient studies conducted solely in the community context for a robust sub-group analysis of this setting, and there were also no studies from the work environment or policy context from LMICs that met our inclusion criteria. Our review also did not include sufficient number of randomised studies targeted at significant ‘others’ such as fathers and mothers-in-law to determine their influence on EBF interventions; the few studies that were included were either non-RCTs [studies 53, 55b] or did not have data that could be used in meta-analysis [study 13].

Conclusions

This review, based on high quality study designs, has conclusively established that interventions to improve breastfeeding exclusivity in LMICs on average resulted in a two-fold increase in rates of EBF until six months of age: all interventions, except telephone alone, were effective. We concur with calls for scaling up of effective national breastfeeding programmes (Pérez-Escamilla & Hall Moran., 2016). Stakeholders in countries, regions and communities should therefore identify and implement interventions that best suit their resources, cultural context, and health service delivery system, to reduce infant and under-five mortality.

Key messages

- This systematic review has filled the gap from previous reviews by including studies from LMICs only and measuring EBF up until six months; with sub-group analysis undertaken to determine the effectiveness of interventions by various intervention characteristics, in RCTs only and all study types.
- It has clearly demonstrated that in LMICs, a wide range of different interventions, in different settings and by different types of providers significantly improved EBF rates by around two-fold compared with controls. All interventions, except use of telephone calls, were effective in increasing EBF rates.
- More research is needed to determine how EBF rates are affected by telephone-based interventions, interventions targeting significant others (father, mother-in-law, etc), and interventions conducted solely in the community, work place or policy contexts.

REFERENCES

Fantom, N. (2016). *The World Bank ' s Classification of Countries by Income* (7528).

Haroon, S., Das, J., Salam, R., Imdad, A., & Bhutta, Z. (2013). Breastfeeding promotion interventions and breastfeeding practices: A systematic review. *BMC Public Health*, *13*(Suppl 3), S20. https://doi.org/10.1186/1471-2458-13-S3-S20

Higgins JPT, Altman DG, Sterne JAC (editors). (2011). Chapter 8: Assessing risk of bias in included studies. In *Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration, 2011. Retrieved from www.handbook.cochrane.org.

Higgins JPT, Deeks JJ, A. D. (editors). (2011). Chapter 16: Special topics in statistics. In *Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0*. The Cochrane Collaboration, 2011. Retrieved from www.handbook.cochrane.org.

IntHout, J., Ioannidis, J. P. A., Rovers, M. M., & Goeman, J. J. (2016). Plea for routinely presenting prediction intervals in meta-analysis. *BMJ Open*, *6*(7), e010247. https://doi.org/10.1136/bmjopen-2015-010247

Jolly, K., Ingram, L., Khan, K. S., Deeks, J. J., Freemantle, N., & MacArthur, C. (2012). Systematic review of peer support for breastfeeding continuation: metaregression analysis of the effect of setting, intensity, and timing. *BMJ*. https://doi.org/10.1136/bmj.d8287

McFadden, A., Gavine, A., Renfrew, M. J., Wade, A., Buchanan, P., Taylor, J. L., … Macgillivray, S. (2017). Support for healthy breastfeeding mothers with healthy term babies (Review). *Cochrane Database of Systematic Reviews*, (2). https://doi.org/10.1002/14651858.CD001141.pub5

Pérez-Escamilla R., Hall Moran V. (2016). Scaling up breastfeeding programmes in a complex adaptive world. MCN, 12(3):375-380.

Renfrew, M. J., McCormick, F. M., Wade, A., Quinn, B., & Dowswell, T. (2012). Support for healthy breastfeeding mothers with healthy term babies (Review). *The Cochrane Library*, (5). https://doi.org/10.1002/14651858.CD001141.pub4

Riley, R. D., Higgins, J. P. T., & Deeks, J. J. (2011). Interpretation of random effects meta-analyses. *BMJ*, *342*. https://doi.org/10.1136/bmj.d549

Rollins, N. C., Bhandari, N., Hajeebhoy, N., Horton, S., Lutter, C. K., Martines, J. C., … Victora, C. G. (2016). Why invest, and what it will take to improve breastfeeding practices? *The Lancet*, *387*(10017). https://doi.org/10.1016/S0140-6736(15)01044-2

Sankar, M. J., Sinha, B., Chowdhury, R., Bhandari, N., Taneja, S., Martines, J., … Mari Jeeva Sankar, C. (2015). Optimal breastfeeding practices and infant and child mortality: a systematic review and meta-analysis. *Acta Paediatrica*, *104*, 3–13. https://doi.org/10.1111/apa.13147

Sinha, B., Chowdhury, R., Sankar, M. J., Martines, J., Taneja, S., Mazumder, S., … Bhandari, N. (2015). Interventions to improve breastfeeding outcomes: a systematic

review and meta-analysis. *Acta Paediatrica (Oslo, Norway : 1992)*, *104*(467), 114–134. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=prem&NEWS=N&AN=26183031

Sinha, B., Chowdhury, R., Upadhyay, R. P., Taneja, S., Martines, J., Bahl, R., & Sankar, M. J. (2017). Integrated Interventions Delivered in Health Systems, Home, and Community Have the Highest Impact on Breastfeeding Outcomes in Low- and Middle-Income Countries. *The Journal of Nutrition*, *147(Suppl)*, 2179S–87S. https://doi.org/10.3945/jn.116.242321

UNICEF. (2013). *Improving child nutrition: the achievable imperative for global progress*. New York: UNICEF.

UNICEF and WHO. (2015). A decade of tracking progress for maternal, newborn and child survival : The 2015 report (pp. 5–26). Geneva: WHO.

Victora, C. G., Bahl, R., Barros, A. J. D., Franca, G. V. A., Horton, S., Krasevec, J., … Richter, L. (2016). Breastfeeding in the 21st century: Epidemiology, mechanisms, and lifelong effect. *The Lancet*. https://doi.org/10.1016/S0140-6736(15)01024-7

WHO. (2001). Report of The Expert Consultation on The Optimal Duration of Exclusive Breastfeeding. *The Optimal Duration Exclusive Breastfeeding*, *65*(13), 1311–1313. https://doi.org/10.1016/j.jacc.2015.02.004

World Health Organization. (2008). Part 1: Definitions. In *Indicators for assessing infant and young child feeding practices*. Geneva: WHO Press. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK148959/

World Health Organization. (2009). The importance of infant and young child feeding and recommended practices. In *Infant and young child feeding: Model chapter for textbooks for medical students and allied health professionals* (pp. 3–8). Geneva: WHO Press.

LEGEND OF FIGURES

Figure 1:

CABI	Centre for Agriculture and Biosciences International
ICTRP	International Clinical Trials Registry Platform
Inc.	inclusion

Figure 2:

nIG	number in intervention group
nCG	number in control group
EBF	exclusive breast feeding
%EBF CG	percent of EBF in control group
ES	Effect size
RR	relative risk
RCT	randomised controlled trial

Figure 3:

nIG	number in intervention group
nCG	number in control group
EBF	exclusive breast feeding
%EBF CG	percent of EBF in control group
ES	Effect size
RR	relative risk

Figure 1 PRISMA Flow Diagram

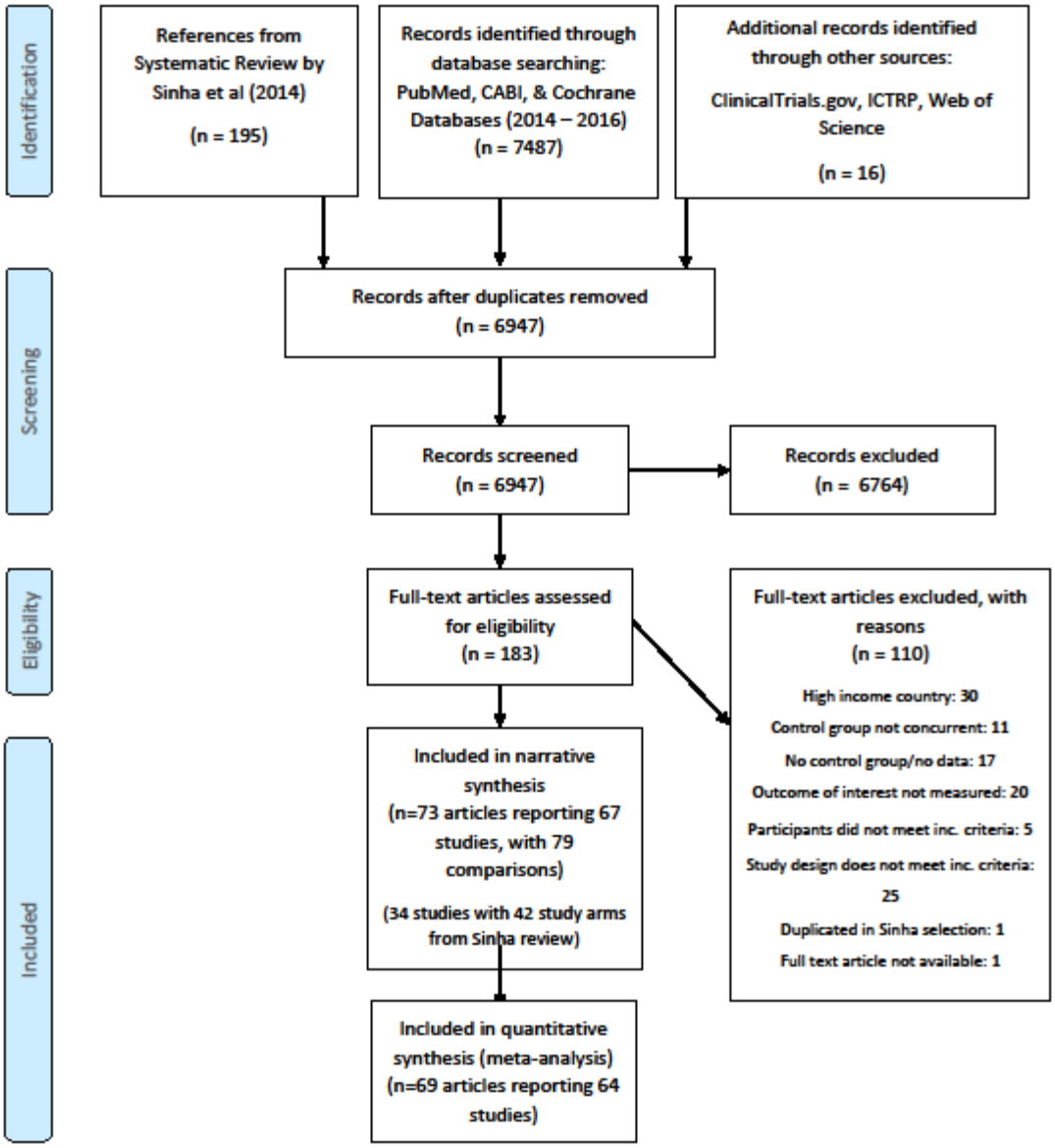

Figure 2: Exclusive breastfeeding at 6-months (RCTs): all interventions versus standard care

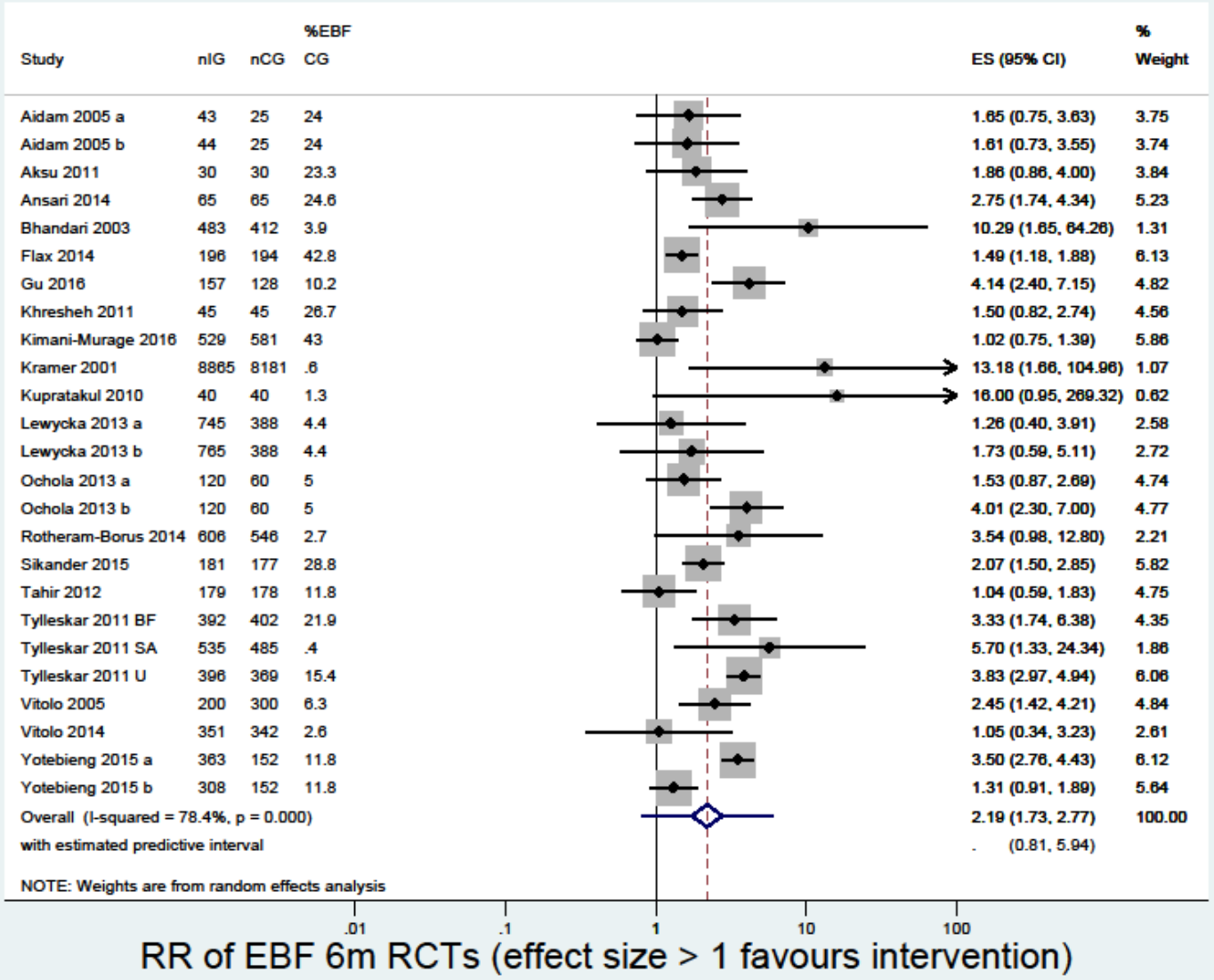

Figure 3:Exclusive breastfeeding at 6-months (all study types): all interventions versus standard care

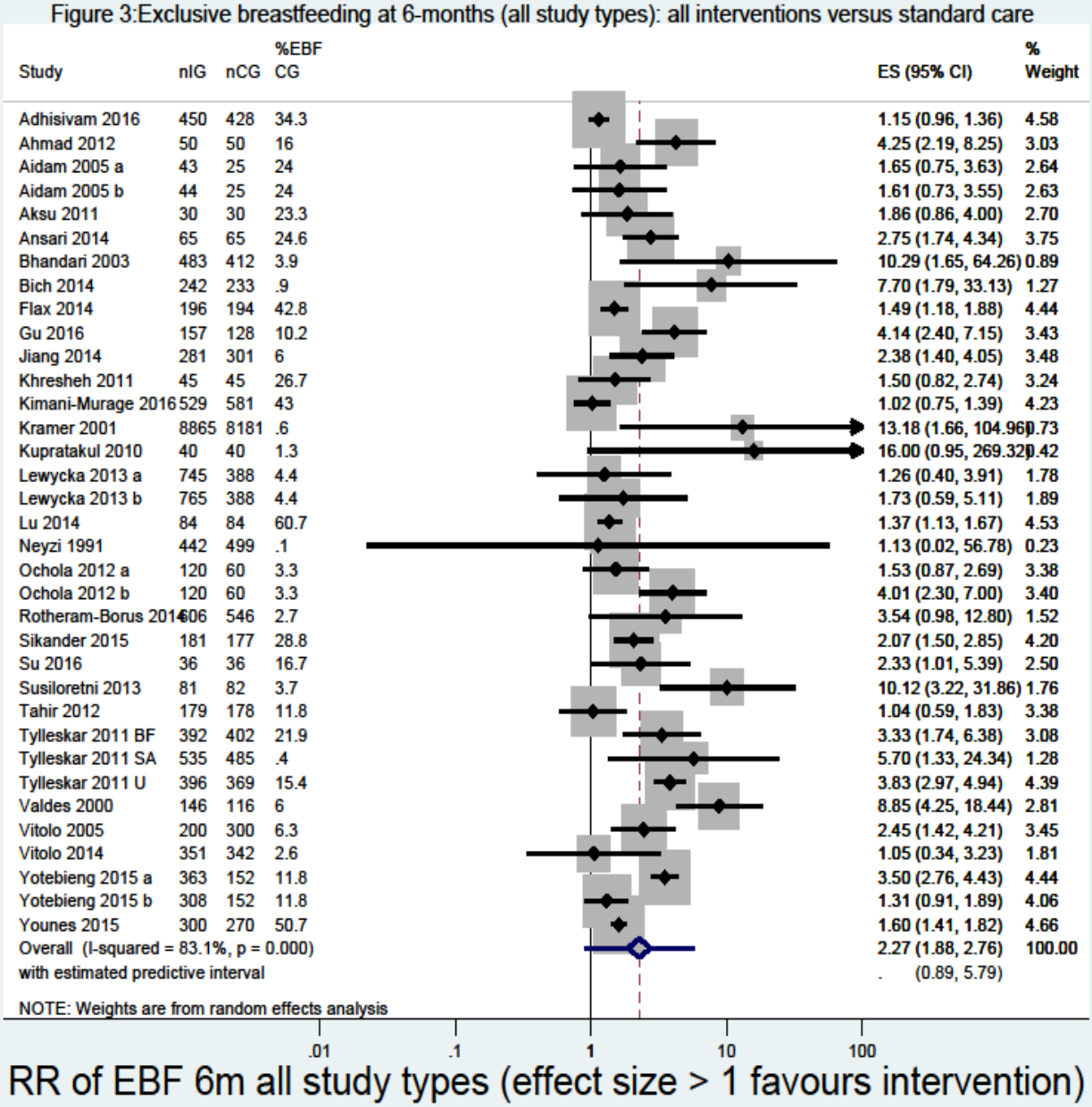

TABLE 1: SUMMARY TABLE OF STUDY CHARACTERISTICS

Characteristic	Number of studies	Number of articles	Reference numbers
Study design			
RCT	21	23	3, 4, 5, 6, 7, 10, 13-15, 19, 22,25, 28, 33, 37, 38, 39, 43, 47, 51, 56, 66, 69
Cluster RCT	23	26	8, 9, 11, 12, 18, 23, 26, 29 & 58, 30, 34, 35, 36, 40, 44, 46, 48 & 73, 50, 52, 57, 60 & 61, 67, 68, 70
Quasi-experimental	7	7	24, 31, 32, 42, 45, 53, 71
Non-randomised study of intervention	12	13	1, 16 & 17, 20, 21, 27, 41, 54, 55, 59, 62, 65, 72
Observational	4	4	2, 49, 63, 64
WHO region			
African region	16	19	3, 20, 23, 29&58, 30, 34, 35, 40, 46, 48&73, 49, 50, 60&61, 65, 68, 70
Americas	16	18	7, 13-15, 19, 21, 22, 38, 39, 43, 44, 47, 55, 62, 63, 64, 66, 67
South East Asia	13	13	1, 6, 8, 9, 11, 26, 27, 31, 37, 51, 54, 57, 71
Eastern Mediterranean (including Egypt)	10	10	2, 4, 10, 12, 18, 24, 28, 33, 52, 72
Western Pacific region & China	8	9	16, 17, 25, 32, 41, 42, 53, 56, 69
European region	4	4	5, 36, 45, 59
Intervention context (code)	**Number of studies**	**Number of study arms[1]**	
health systems/services	N/A	23	1, 2, 6, 27, 30, 31, 36, 38, 46a, 49, 51a, 51b, 53, 55a, 55b, 62, 63, 64, 65, 67, 70a, 70b, 72
home/family context		27	5, 10a, 10b, 19, 22, 26, 29&58, 32, 34, 39, 40b, 43, 44a, 44b, 46b, 48, 50, 52, 56, 57a, 57b, 60-61BF, 60-61U, 60-61SA, 66, 68, 73
community interventions		6	9, 20, 23, 40a, 59, 71
Context Combinations			
Context 1 + 2		15	3, 4, 7, 13-15a, 13-15b, 24, 25, 28, 33, 37, 41, 42, 45, 47, 69

[1] Multiple entries were allowed for studies with more than one study arm

Context 2 + 3		5	12, 18, 21, 35, 54
Context 1 + 3		Nil	
Context 1 + 2 + 3		3	8, 11, 16-17
Setting		N/A	
Rural	10		12, 16&17, 20, 23, 35, 40, 48&73, 52, 54, 68,
Urban	27		3, 6, 7, 13-15, 19, 22, 24, 25, 26, 27, 28, 29&58, 31, 33, 34, 38, 42, 43, 45, 46, 50, 55, 59, 62, 63, 67, 70,
Peri-urban/sub-urban	4		21, 30, 44, 60&61
Rural & urban/sub-urban	1		36
Not specified	25		1, 2, 4, 5, 8, 9, 10, 11, 18, 32, 37, 39, 41, 47, 49, 51, 53, 56, 57, 64, 65, 66, 69, 71, 72
Intervention directed at:	N/A		
Mothers/pregnant women		61	1, 2, 3a, 3b, 4, 5, 6, 7, 10a, 10b, 11, 12, 16-17, 18, 19, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 37, 38, 39, 40b, 41, 42, 43, 44, 45, 46a, 46b, 47, 48&73, 50, 51a, 51b, 52, 55a, 56, 57a, 57b, 58, 59, 60-61BF, 60-61U, 60-61SA, 62, 66, 68, 69, 71, 72
Mother + father/other family member		4	13-15a, 13-15b, 53, 55b
Health workers		10	20, 21, 36, 49, 63, 64, 65, 67, 70a, 70b
Combined/other groups		4	8, 9, 40a, 54
Type of intervention	N/A		
Education		16	2, 6, 9, 22, 23, 27, 30, 32, 40a, 51b, 55a, 55b, 59, 64, 66, 67
Support		1	31
Combination		60	1, 3a, 3b, 4, 5, 7, 10a, 10b, 11, 12, 13-15a, 13-15b, 16-17, 18, 19, 20, 21, 24, 25, 26, 28, 29&58, 33, 34, 35, 36, 37, 38, 39, 40b, 41, 42, 43, 44a, 44b, 45, 46a, 46b, 47, 48&73, 49, 50, 51a, 52, 53, 54, 56, 57a, 57b, 60-61BF, 60-61U, 60-61SA, 62, 63, 68, 69, 70a, 70b, 71, 72
Not specified/not applicable		2	8, 65

Mode of delivery of intervention	Number of studies	Number of study arms	
Face to face	54	66	1, 2, 3a, 3b, 5, 6, 7,9, 10a, 10b, 11, 12, 13-15a, 13-15b, 16-17, 18, 19, 20, 21, 22, 24, 26, 27, 29&58, 30, 31, 34, 35, 36, 38, 39, 40a, 40b, 41, 44a, 44b, 45, 46a, 46b, 47, 48&73, 49, 50, 51a, 51b, 52, 53, 54, 55a, 55b, 57a, 57b, 59, 60-61BF, 60-61U, 60-61SA, 63, 64, 65, 66, 67, 68, 70a, 70b, 71, 72
Telephone (voice/sms)	3	3	32, 43, 56
Combination	9	9	4, 23, 25, 28, 33, 37, 42, 62, 69
Not specified/not applicable	1	1	8
Timing of intervention	N/A		
Antenatal		6	2, 4, 6, 46a, 53, 59,
Postnatal		27	1, 5, 7, 10a, 10b, 11, 13-15a, 13-15b, 19, 22, 24, 25, 27, 31, 33, 39, 43, 45, 47, 51a, 51b, 55a, 55b, 56, 62, 66, 69
Both		34	3a, 3b, 12, 16-17, 18, 21, 26, 28, 29&58, 30, 32, 34, 35, 37, 38, 40b, 41, 42, 44a, 44b, 46b, 48&73, 49, 50, 52, 54, 57a, 57b, 60&61BF, 60&61U, 60&61SA, 68, 70a, 70b
Not specified/not applicable		12	8, 9, 20, 23, 36, 40a, 63, 64, 65, 67, 71, 72
Intensity (number of sessions)	N/A		
≤3		21	1, 2, 4, 5, 10b, 28, 31, 33, 38, 43, 44b, 45, 46a, 47, 51a, 51b, 53, 55a, 55b, 67, 72
4-8		26	6, 7, 10a, 11, 12, 13-15a, 13-15b, 16-17, 24, 29&58, 30, 35, 39, 40b, 44a, 46b, 48&73, 52, 54, 59, 60&61BF, 60&61U, 60&61SA, 62, 68, 69
≥9		19	3a, 3b, 9, 18, 19, 22, 23, 25, 26, 27, 32, 34, 37, 40a, 50, 56, 57a, 57b, 66
Not specified/not applicable		13	8, 20, 21, 36, 41, 42, 49, 63, 64, 65, 70a, 70b, 71
Intervention delivered by:			
Professional	40	47	1, 3a, 3b, 6, 7, 10a, 10b, 13-15a, 13-15b, 16-17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29&58, 31, 34, 36, 37, 38, 41, 42, 43, 45, 46a, 47, 49, 50, 51a, 51b, 53, 55a, 55b, 56, 62, 63, 66, 67, 69, 70a, 70b, 72
Para-professional	5	5	8, 12, 30, 35, 52
Lay	10	14	9, 26, 39, 40a, 40b, 44a, 44b, 46b, 48, 60&61BF, 60&61U, 60&61SA, 68, 71
Lay + professional/ para-professional	6	7	4, 11, 54, 57a, 57b, 59, 65
Not specified/not applicable	5	5	2, 5, 32, 33, 64

TABLE 2: CHARACTERISTICS OF STUDIES AND INTERVENTION – RANDOMISED CONTROLLED TRIALS

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
03	Aidam 2005 Ghana	RCT	Pregnant women in 3rd trimester, with FT singleton delivery, n = 137	*Health systems/services & home/family setting* BF education given prenatally (IG1) or perinatally (IG2) with home visits postpartum by trained staff CG: education on other health-related topics	Yes	24 hour recall
04	Ansari 2014 Iran	RCT	Primips> 36 weeks GA attending public health centres, with intention to BF; n = 120	*Health systems/services & home/family setting* Group training sessions prenatally on benefits of BF + peer education + phone counselling + standard care CG: standard care	Yes	Not specified
05	Aksu 2011 Turkey	RCT	Primips with FT vaginal delivery at study hospital; n = 60	*Home/family setting* Single postpartum education session during home visit + standard care CG: standard care	Yes	Not specified
06	Akter 2012 Bangladesh	RCT	Pregnant women in 7th month of pregnancy attending govt. facility, n = 115	*Health systems & services* Group antenatal nutrition education between 7th & 9thmonths of pregnancy CG: standard care	No	24 hour recall
07	Albernaz 2003, Brazil	RCT	Women at 37-42 weeks GA with singleton birth, resident in area & intending to BF; n = 167	*Health systems/services & home/family setting* Postnatal lactation counselling video session in hospital; + home visits & 24-hour telephone hotline CG: standard care	No	Not stated
08	Arifeen 2009, Bangladesh	c- RCT	All women ever married 15-49 years & children < 5 yrs; n = 3115	*Health systems/services, home/family& community setting* Implementation of facility & community components of IMCI, involving VHW & community leaders CG: standard care	No	Not stated

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
09	Azad 2010, Bangladesh	c-RCT with factorial design	Married WRA + other female members; n = 30,952	*Community setting* Women's group participatory learning & action meetings (20 cycles) with peer educators.	No	Not stated
10	Bashour 2008. Syria	RCT	Women with FT healthy infant, resident in study area; n = 877	*Home/family setting* Four (IG1) or one (IG2) home visits postpartum providing information, education and support. CG: standard care	No	Not stated
11	Bhandari 2003, India	c-RCT	All infants born & residing in study communities during recruitment period; n = 895	*Health systems/services, home/family& community setting* Repeated EBF counselling at multiple opportunities through existing PHC services, home visits & community meetings	Yes	24 hour recall, since birth recall
12	Bhutta 2011, Pakistan	c-RCT	All pregnant women in study areas; n = 4474	*Home/family &Community environment* Home visits by Lady Health Workers; ante + postnatal + Community Health Committee group education sessions; training of TBAs (*Dais*)	No	Not stated
13, 14, 15	de Oliveira[†]2014, Brazil (with Bica 2014 & da Silva 2016)	RCT	Adolescent mothers living with or without maternal grandmothers; n = 320	*Health systems/services &Home/family setting* Single postnatal counselling session at maternity + home visits CG: standard care at BFI facility	Yes	Previous month recall

[†]Not included in meta-analysis

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
18	Brasington 2016, Egypt	c-RCT	Pregnant women & women with child(ren) < 2 years; n = 3445	*Home/family & community setting* Monthly antenatal & postnatal home visits with individual & family counselling sessions + further sessions for children at risk	No	24 hour recall
19	Coutinho 2005 Brazil	RCT	Mothers of FT normal delivery with birth weight >2500g; n = 350	*Health systems & services/home& family setting* Postnatal home visits up to 6m + BFHI training of maternity staff CG: BFHI training of maternity staff	No	24 hour recall
22	Feldens 2006, Brazil	RCT	Mothers with healthy FT in public health facility; n = 372	*Home/family setting* Home visits post-natally for nutrition counselling by trained fieldworkers until 12 months	No	Since birth recall
23	Flax 2014, Nigeria	c-RCT	Microcredit clients, pregnant & aged 15-45 yrs; n = 390	*Community setting* BF learning sessions during microcredit meetings + Cell phone sms& voice messages + participant-generated songs & drama.	Yes	Since birth recall
25	Gu 2016[‡] China	RCT	Healthy primipara, with husband or grandmother able to attend intervention activities; n = 285	*Health systems/services & Home/family setting* Individual, group, & telephone counselling sessions held postpartum in hospital & home until 6m CG: standard care	Yes	Not specified
26	Haider 2000, Bangladesh	c-RCT	Pregnant women 16-35 years resident in study area; n = 653	*Home/family setting* Home-based peer counselling (10 -15 visits) in antenatal & postnatal period up to 5th month. CG: standard care	No	24 hour recall, previous month recall

[‡]A very similar article with the same study results, Wan 2016, was not included in the review, since it did not contribute any additional results. It is cited as an additional reference

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
28	Heidari 2016 Iran	RCT	Primipara> 18 yrs with singleton pregnancy; n = 70	*Health systems/services & Home/family setting* Two prenatal & one postnatal group BF counselling session with key family members + regular SMS messages CG: standard care	No	Not stated
29 & 58	Ijumba 2015 S. Africa (with Tomlinson 2014)	c-RCT	Pregnant women ≥ 17 years, resident in study area; n = 3656	*Home/family setting* Ante- & Postnatal home visits by CHWs providing education using motivational interviewing techniques. CG: 3 home visits from CHW, focusing on social welfare.	No	24 hour recall
30	Jakobsen 1999 Guinea Bissau	c-RCT	Mothers of FTND registered during pregnancy; n = 963	*Health systems and services* Ante- & post-natal health education sessions during routine clinic visits, until 9m postpartum	No	Not stated
33	Khresheh 2011, Jordan	RCT	Primiparous women with vaginal delivery at study hospitals; n = 90	*Health systems/services& Home/family setting* Individual BF education session post-natally + follow-up phone calls CG: standard care	Yes	Not specified
34	Kimani-Murage 2016, Kenya	c-RCT	Pregnant women 12-49 years old, resident in study communities; n = 1110	*Home/family setting* Regular, comprehensive, home-based nutritional counselling by trained CHWs, from pregnancy until 1st birthday. CG: standard care, including counselling by CHWs not specially trained	Yes	3 day recall, since birth recall
35	Kirkwood 2013, Ghana	c-RCT	All pregnant women and newborns resident in intervention zones; n=15,594	*Home/family and community setting* Ante- & post-natal home visits by community-based surveillance volunteers CG: standard care	No	24 hour recall
36	Kramer 2001,	c-RCT	Mothers of healthy FT infants, intending to BF; n = 17,046	*Health systems and services* BFHI training, emphasizing health worker support for BF initiation and	Yes	Since birth

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
	Republic of Belarus			maintenance. CG: standard care		recall
37	Kupratakul 2010, Thailand	RCT	Pregnant women < 32 weeks GA attending ANC, & having a telephone; n = 80	*Health systems/services & Home/family setting* Single KSPES session antenatally, + telephone follow up ± home visits where necessary. CG: standard education program	Yes	Not specified
38	Langer 1998, Mexico	RCT	Women with single pregnancy in labour (<6cm dilated), no prev. vaginal delivery or indication for elective C/S; n = 724	*Health systems and services* Support from a *Doula* during delivery and immediate postpartum period, CG: standard care	No	Not stated
39	Leite 2005, Brazil	RCT	Mothers of healthy singletons weighing< 3000g; n = 1003	*Home/family setting* Home visits post-partum by lay counsellors until 4m after delivery CG: standard care	No	Not stated
40	Lewycka 2013, Malawi	c-RCT with factorial design	Women 10-49 yrs in study community (IG1) All pregnant women (IG2); n = 2286	*Home/family &Community setting* IG1: Women's group intervention: – community mobilization action cycle of 20 meetings IG2: Volunteer peer counselling ante- & post-natally (5 visits). CG: standard care	Yes	Not stated
43	Malowsky 2016, Ecuador	RCT	Mothers ≥ 15 years, Spanish-speaking, recruited after delivery from study facilities; n = 135	*Home/family setting* 48 hr post-discharge counselling session via telephone+ telephone support in neonatal period CG: standard care	No	Not specified
44	Morrow 1999, Mexico	c-RCT	All pregnant women residing in study area; n = 130	*Home/family setting* Six (IG1) or three (IG2) home visits by peer counsellors ante- & post-	No	7 day recall

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
				natally. CG: standard care		
46	Ochola, 2012, Kenya	c- RCT	Pregnant HIV-negative women accessing antenatal services; n = 360	*Health systems/services & home/family setting* IG1: Single, one-on-one BF counselling session prenatally at health facility IG2: intensive, home-based counselling sessions pre- & post-natally by peer counsellors until 5 months post-partum CG: standard care	Yes	24 hour recall, since-birth recall
47	de Oliveira 2006, Brazil	RCT	Mothers of healthy singletons weighing >2500g in the study hospital; n = 211	*Health systems/services& Home/family setting* Postnatal BF counselling session prior to discharge, + 2 home visits in 1st month. CG: standard care	No	Since-birth recall
48, 73	Penfold 2014, Tanzania (with Hanson 2015)	c-RCT	All pregnant women in study communities; n = 512 (n = 14, 295 for Hanson 2015)	*Home/family setting* Home visits during pregnancy & early neonatal period by lay community volunteers CG: standard care	No	Not stated
50	Rotheram-Borus 2014, South Africa	c-RCT	Pregnant women ≥ 18 years, living in study clusters; n = 1152	*Home/family setting* Home visits by trained CHWs, ante- & post-natally, to deliver health messages including EBF CG: standard care	Yes	Not stated
51	Sharma 2013, India	RCT	Pregnant women who delivered at term in study facility; n = 1412	*Health systems and services* IG1: Postnatal counselling session IG2: Video demonstration on BF CG: standard care	No	Not stated

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
52	Sikander 2015, Pakistan	RCT	Married women 17 – 40 yrs in 3rd trimester, resident in study area; n = 358	*Home/family setting* Psycho-educational sessions integrated into routine LHW home visits, ante-& post-natally CG: home visits from routinely-trained LHW	Yes	24 hour recall
56	Tahir 2013, Malaysia	RCT	Pregnant women who received at least 1 prenatal BF education session, with telephone access; n = 357	*Home/family setting* Postnatal lactation counselling by phone twice monthly until 6 months CG: standard care.	Yes	24 hour recall, since-birth recall
57	Talukder 2016, Bangladesh	c-RCT	Pregnant women in 2nd& 3rd trimester & mothers of children 0-6 months; n=1147	*Home/family setting* Home visits (ante- & post-natal) by trained TBAs & community volunteers (IG1), + support from field supervisors (IG2), until 6m	No	24 hour recall
60, 61	Tylleskar, 2011 Burkina Faso, Uganda, & South Africa (with Engebretsen 2014)	c-RCT	Visibly pregnant women intending to BF, with singleton live birth & resident in study area; n = 2579 (nBF = 794, nUG = 765, nSA = 1020).	*Home/family setting* Ante- & postnatal home visits by trained peer *counsellors* Control group: received standard care in Burkina Faso & Uganda; in S. Africa peer supporters helped with vital registration and benefits	Yes	24 hour recall, 7 day recall
66	Vitolo 2005, Brazil	RCT	Mothers of healthy FT infants with birth wt>2500g; n = 500	*Home/family setting* Postnatal home visits (10 sessions) until 12 months.	Yes	Not stated
67	Vitolo 2014, Brazil	c-RCT	Pregnant women in 3rd trimester attending health facilities; n = 693	*Health systems and services* Single session update for health professionals focused on improving infant feeding practices	Yes	Since-birth recall
68	Waiswa 2015,	c-RCT	All pregnant women and their newborns identified in study	Home/family setting Home visits (5 sessions) in antenatal and early post-natal period by	No	Not stated

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME (EBF until 6m) ASSESSED?	METHOD OF OUTCOME ASSESSMENT
	Uganda		communities; n = 1787	volunteer CHWs + health facility strengthening CG: standard care + health facility strengthening		
69	Wu 2014,[§] China	RCT	Primipara ≥18 years, healthy FT infant & intention to BF; n = 74	*Health systems/services & Home/family setting* 3 individualized self-efficacy enhancing sessions early postpartum; 3rd session by telephone CG – standard care	No	Not stated
70	Yotebieng 2015, Democratic Republic of Congo	c-RCT	Mothers delivering healthy singleton at study facilities & intending to attend well-baby clinics; n = 975	*Health systems and services* Training of health staff in Steps 1-9 (IG1) & Steps 1-10 (IG2) of successful BF CG – standard care	Yes	24 hour recall 7 day recall

c-RCT, cluster randomised controlled trial; RCT, randomised controlled trial; IG, intervention group; CG, control group; BF, breastfeeding; EBF, exclusive breastfeeding; FT, full term; FTND, normal delivery; GA, gestational age; IMCI, Integrated management of childhood illnesses; KSPES, Knowledge Sharing Practices with Empowerment Strategic program; VHW/CHW, village/community health worker; WRA, women of reproductive age; PHC, primary health care; TBA, traditional birth attendant; BFI/BFHI, baby friendly (hospital) initiative; sms, short message service.

[§]Not included in meta-analysis

TABLE 3: SUMMARY OF EFFECT ESTIMATES FOR EBF UNTIL 6 MONTHS

VARIABLE	No. OF ESTIMATES	No. OF PARTICIPANTS	POOLED ES	LOWER LIMIT 95% CI	UPPER LIMIT 95% CI	I^2 (%)	LOWER LIMIT PI	UPPER LIMIT PI	P value	Meta- reg p value
ALL INTERVENTIONS BY STUDY TYPE										0.493
RCTs	25	29,483	2.188	1.731	2.766	78.4	0.81	5.94	0.000	
non RCTs	10	4,211	2.429	1.752	3.368	85.5	0.90	6.97	0.000	
All studies	35	33,694	2.274	1.877	2.755	83.1	0.89	5.79	0.000	
SUB-GROUP ANALYSIS (RCTs only)										
By intervention context:										0.981
Health systems & services	4	18,714	2.246	1.011	4.990	87.7	0.07	67.57	0.000	
Home & family	9	6,116	2.197	1.433	3.368	84.8	0.53	9.09	0.000	
Community	N/A	-	N/A				-	-		
Combined context:										
Health systems & services/home & family	8	1,082	2.384	1.678	3.386	55.6	0.89	6.42	0.027	
Home & family/community settings	3	2,676	1.490	1.190	1.866	0.0	0.35	6.40	0.923	
Health systems & services/home & family/ community	1	895	10.289	1.648	64.261	N/A	-	-	-	
Single vs combined context:										0.949
Single context	13	24,830	2.191	1.547	3.103	84.9	0.64	7.51	0.000	
Combined context	12	4,653	2.187	1.606	2.977	61.6	0.86	5.54	0.003	
Mode of delivery of intervention										0.936
Face to face	19	28,151	2.255	1.704	2.983	78.2	0.78	6.56	0.000	
Telephone (voice/sms)	1	357	1.042	0.595	1.825	0.0	-	-	-	
Face to face + telephone	5	975	2.333	1.419	3.837	76.7	0.44	12.30	0.002	
Type/nature of intervention										0.363
Education	3	1,583	1.670	1.148	2.427	38.4	0.04	64.03	0.197	
Education + support	22	27,900	2.292	1.765	2.976	79.2	0.79	6.63	0.000	

VARIABLE	No. OF ESTIMATES	No. OF PARTICIPANTS	POOLED ES	LOWER LIMIT 95% CI	UPPER LIMIT 95% CI	I^2 (%)	LOWER LIMIT PI	UPPER LIMIT PI	P value	Meta- reg p value
Intervention delivered by:										
Professional/para-professional	13	22,693	2.019	1.416	2.878	81.6	0.59	6.86	0.000	0.900
Lay person	7	5,225	2.800	1.924	4.074	55.9	1.00	7.80	0.035	
Lay + professional/para-professional	2	1,025	3.900	1.246	12.208	46.7	-	-	0.171	
Other group/not specified/not applicable	3	540	1.517	1.229	1.871	0.0	0.39	5.92	0.865	
Timing of intervention										0.784
Antenatal	2	310	2.101	1.185	3.725	60.2	-	-	0.113	
Postnatal	6	2,187	2.179	1.319	3.599	69.5	0.45	10.45	0.006	
Antenatal + postnatal (combined)	13	7,724	2.395	1.697	3.380	83.6	0.72	7.94	0.000	
Not specified/not applicable	4	19,262	1.569	0.891	2.763	36.2	0.21	11.51	0.195	
Intensity of intervention (number of contacts)										0.992
≤ 3	5	1,153	1.852	1.362	2.518	15.7	0.95	3.62	0.314	
4-8	7	5,165	3.199	2.299	4.450	53.8	1.35	7.59	0.043	
≥ 9	10	5,144	1.755	1.256	2.452	68.4	0.65	4.76	0.001	
Not specified/not applicable	3	18,021	2.761	1.111	6.861	90.9	0.00	105726.73	0.000	
Intervention targeted at:										0.996
Mothers/pregnant women	21	10,769	2.185	1.701	2.807	75.8	0.81	5.90	0.000	
Health care provider	4	18,714	2.246	1.011	4.990	87.7	0.07	67.57	0.000	
Mother + other family member	N/A		N/A							
Combined group/other	N/A		N/A							
Sensitivity analysis:										
By bias judgement										
Low risk	9	4,673	2.226	1.541	3.215	80.4	0.73	6.75	0.000	
All RCTs	25	29,483	2.188	1.731	2.766	78.4	0.81	5.94	0.000	
By study size:										
≥500 participants	13	27,236	2.429	1.637	3.605	83.7	0.64	9.27	0.000	
All RCTs	25	29,483	2.188	1.731	2.766	78.4	0.81	5.94	0.000	
All RCTs	25	29,483	2.188	1.731	2.766	78.4	0.81	5.94	0.000	

VARIABLE	No. OF ESTIMATES	No. OF PARTICIPANTS	POOLED ES	LOWER LIMIT 95% CI	UPPER LIMIT 95% CI	I^2 (%)	LOWER LIMIT PI	UPPER LIMIT PI	P value	Meta- reg p value
SUB-GROUP ANALYSIS (All studies)										0.739
By intervention context:										
Health systems & services	8	20,026	2.631	1.502	4.611	92.1	0.41	17.09	0.000	
Home & family	10	6,698	2.207	1.503	3.242	83.0	0.60	8.06	0.000	
Community	1	570	1.603	1.408	1.824	N/A	N/A	N/A	N/A	
Combined context:										
Health systems & services/home & family	10	2,191	2.159	1.518	3.072	70.5	0.74	6.29	0.000	
Home & family/community settings	3	2,676	1.490	1.190	1.866	0.0	0.35	6.40	0.923	
Health systems & services/home & family/ community	3	1,533	9.337	4.159	20.964	0.0	0.05	1767.51	0.953	
Single vs combined context:										0.880
Single context	19	27,294	2.268	1.740	2.955	88.1	0.77	6.65	0.000	
Combined context	16	6,400	2.289	1.715	3.055	69.5	0.89	5.87	0.000	
Mode of delivery of intervention										0.875
Face to face	26	31,350	2.307	1.819	2.925	83.7	0.84	6.33	0.000	
Telephone (voice/sms)	2	939	1.583	0.704	3.557	77.2	N/A	N/A	0.036	
Face-to-face + telephone	7	1,405	2.513	1.626	3.886	85.8	0.62	10.13	0.000	
Type/nature of intervention										0.771
Education	5	2,265	2.134	1.407	3.237	67.0	0.55	8.31	0.017	
Education + support	30	31,429	2.317	1.863	2.881	84.7	0.86	6.27	0.000	
Intervention delivered by:										0.621
Professional/para-professional	19	25,489	2.104	1.575	2.810	85.1	0.69	6.42	0.000	
Lay person	8	5,795	2.476	1.610	3.808	85.4	0.64	9.60	0.000	
Lay + professional/para-professional	3	1,188	5.440	1.926	15.362	64.9	0.00	509515.44	0.058	
Other/not specified/not applicable	5	1,222	2.014	1.389	2.920	60.9	0.62	6.58	0.037	0.480
Timing of intervention										
Antenatal	4	482	2.517	1.662	3.812	46.2	0.54	11.65	0.134	
Postnatal	9	4,268	2.356	1.396	3.977	85.2	0.43	13.00	0.000	
Antenatal + postnatal (combined)	17	9,112	2.502	1.843	3.397	85.1	0.78	7.98	0.000	

VARIABLE	No. OF ESTIMATES	No. OF PARTICIPANTS	POOLED ES	LOWER LIMIT 95% CI	UPPER LIMIT 95% CI	I^2 (%)	LOWER LIMIT PI	UPPER LIMIT PI	P value	Meta- reg p value
Not specified/not applicable	5	19,832	1.563	1.317	1.855	19.4	1.05	2.33	0.291	
Intensity of intervention (number of contacts)										0.545
≤ 3	9	3,144	1.843	1.277	2.659	69.9	0.62	5.49	0.001	
4-8	10	6,065	4.085	2.852	5.850	63.9	1.47	11.36	0.03	
≥ 9	11	5,726	1.813	1.329	2.472	67.7	0.70	4.68	0.001	
Not specified/not applicable	5	18,759	1.912	1.278	2.860	91.4	0.46	7.98	0.000	
Intervention targeted at:										0.364
Mothers/pregnant women	29	14,745	2.197	1.802	2.678	81.6	0.91	5.31	0.000	
Health care provider	4	18,714	2.246	1.011	4.990	87.7	0.07	67.57	0.000	
Mother and/or other family member	1	72	2.333	1.010	5.391	N/A	N/A	N/A	N/A	
Combined group/other	1	163	10.123	3.217	31.857	N/A	N/A	N/A	N/A	
By study size:										0.547
< 500 participants	18	3,487	2.422	1.858	3.157	77.2	0.88	6.63	0.000	
≥500 participants	17	30,207	2.135	1.586	2.875	87.3	0.73	6.29	0.000	

TABLE 4: SUMMARY OF EFFECT ESTIMATES FOR SECONDARY OUTCOMES

VARIABLE	No. of estimates	No. of Participants	Pooled ES	Lower Limit 95% CI	Upper Limit 95% CI	I^2 (%)
Exclusive breastfeeding at 0 -1 month						
RCTs	19	53,034	1.268	1.163	1.382	78.3
All studies	27	57,642	1.315	1.220	1.418	87.5
Exclusive breastfeeding at 2-3 months						
RCTs	17	28,161	1.910	1.335	2.733	97.8
All studies	25	31,031	1.891	1.421	2.517	97.7
Exclusive breastfeeding at 4-5 months						
RCTs	15	6,982	1.757	1.411	2.187	72.9
All studies	26	10,345	1.842	1.538	2.207	79.5
Exclusive breastfeeding of infants less than 6 months (0 – 5 months)						
RCTs	5	8,057	1.604	0.677	3.802	84.4
All studies	7	8,961	1.503	1.028	2.197	80.1
Early initiation of breastfeeding						
RCTs	20	48,003	1.113	0.997	1.242	76.1
All studies	26	50,629	1.176	1.041	1.329	88.1
Continued breastfeeding at 12 months						
RCTs	3	820	1.463	1.029	2.079	68.8
All studies	4	1,402	1.367	1.039	1.800	62.2

APPENDIX 1: ELECTRONIC SEARCH STRATEGY

String of search terms utilized:

1. Breast Feeding OR Breastfeeding OR (Exclusive AND Breastfeeding [All fields]) OR (Any AND Breastfeeding [All fields]) OR (Continued AND Breast feeding [All Fields]) OR Breastfeeding, early initiation, OR Lactation, Human OR Breast Milk [Index terms])
2. (Counseling OR education, peer OR Social media OR mass media OR health promotion OR health education OR community participation OR (intervention[All Fields]) OR family practice OR support, breastfeeding OR health worker OR physician OR workplace OR Policy OR Legislations OR law [Index Terms])
3. (BFHI [All Fields] OR (Baby Friendly Hospital Initiative [All Fields]) OR Baby Friendly Initiative [All Fields]) OR Baby friendly Hospital [All Fields]) OR Baby Friendly Community Initiative OR Rooming in OR Perinatal care OR Postnatal care OR health services OR hospital OR health facility OR health system OR healthcare system OR health program[Index Terms]
4. #1 AND (#2 OR #3)
5. Autobiography[Publication Type]) OR Biography[Publication Type]) OR Case report[Publication Type]) OR Editorial[Publication Type]) OR Guideline[Publication Type]) OR Interview[Publication Type]) OR Letter[Publication Type]) OR Legal case[Publication Type]) OR News[Publication Type]) OR Newspaper article[Publication Type]) OR Personal Narratives[Publication Type]) OR Video-audio media[Publication Type]
6. #4 NOT #5

APPENDIX II: REFERENCES OF STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

1. Adhisivam B, Vishnu Bhat B, Poorna R, Thulasingam M, Pournami F, Joy R. Postnatal counseling on exclusive breastfeeding using video–experience from a tertiary care teaching hospital, south India. *The Journal of Maternal-Fetal& Neonatal Medicine*2016; DOI: 10.1080/14767058.2016.1188379.
2. Ahmad MO, Sughra U, Kalsoom U, Imran M, Hadi U. Effect of antenatal counselling on exclusive breastfeeding. *J Ayub Med Coll Abbottabad* 2012; **24**: 116–9.
3. Aidam BA, Perez-Escamilla R, Lartey A. Lactation counseling increases exclusive breast-feeding rates in Ghana. *J Nutr* 2005; **135**: 1691–5.
4. Ansari S, Abedi P, Hasanpoor S, Bani S. The Effect of Interventional Program on Breastfeeding Self-Efficacy and Duration of Exclusive Breastfeeding in Pregnant Women in Ahvaz, Iran. *International Scholarly Research Notices* 2014, Article ID 510793 http://dx.doi.org/10.1155/2014/510793.
5. Aksu H, Küçük M, Düzgün G. The effect of postnatal breastfeeding education/support offered at home 3 days after delivery on breastfeeding duration and knowledge: a randomized trial. *J MaternFetal Neonatal Med* 2011; **24**: 354– 61.
6. Akter SM, Roy SK, Thakur SK, Sultana M, Khatun W, Rahman R, et al. Effects of third trimester counseling on pregnancy weight gain, birthweight, and breastfeeding among urban poor women in Bangladesh. *Food Nutr Bull* 2012; **33**: 194–201.
7. Albernaz E, Victora CG, Haisma H, Wright A, Coward WA. Lactation counseling increases breast-feeding duration but not breast milk intake as measured by isotopic methods. *J Nutr* 2003; **133**: 205–10.
8. Arifeen SE, Hoque DM, Akter T, Rahman M, Hoque ME, Begum K, et al. Effect of the Integrated Management of Childhood Illness strategy on childhood mortality and nutrition in a rural area in Bangladesh: a cluster randomised trial. *Lancet* 2009; **374**: 393–403.
9. Azad K, Barnett S, Banerjee B, Shaha S, Khan K, Rego AR, Barua S, Flatman D, Pagel C, Prost A, Ellis M. Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial. *Lancet* 2010;**375**(9721):1193-202.
10. Bashour HN, Kharouf MH, Abdulsalam AA, Asmar K, Tabbaa MA, Cheikha SA. Effect of postnatal home visits on maternal/ infant outcomes in Syria: a randomized controlled trial. *Public Health Nurs* 2008; **25**: 115–25.
11. Bhandari N, Bahl R, Mazumdar S, Martines J, Black RE, Bhan MK. Effect of community-based promotion of exclusive breastfeeding on diarrhoeal illness and growth: a cluster randomised controlled trial. *Lancet* 2003; **361**: 1418–23.
12. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J. Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bull World Health Organ* 2008; **86**: 452–9.
13. Bica OC, Giugliani ER. Influence of counseling sessions on the prevalence of breastfeeding in the first year of life: a randomized clinical trial with adolescent mothers and grandmothers. *Birth* 2014;**41**(1):39–45.
14. de Oliveira LD, Giugliani ER, do Espírito Santo LC, Nunes LM. Counselling sessions increased duration of exclusive breastfeeding: a randomized clinical trial with adolescent mothers and grandmothers. *Nutrition Journal* 2014;**13**(1):73.

15. Silva et al. Effect of a pro-breastfeeding intervention on the maintenance of breastfeeding for 2 years or more: randomized clinical trial with adolescent mothers and grandmothers. *BMC Pregnancy and Childbirth*2016;**16**:97. DOI 10.1186/s12884-016-0878-z
16. Bich TH, Hoa DT, Målqvist M. Fathers as supporters for improved exclusive breastfeeding in Viet Nam. *Matern Child Health J* 2014;**18**(6):1444-53.
17. Bich TH, Hoa DT, Ha NT, Vui LT, Nghia DT, Målqvist M. Father's involvement and its effect on early breastfeeding practices in Viet Nam. *Maternal and Child Nutrition* 2016;**12**(4): 768–777.
18. Brasington A, Abdelmegeid A, Dwivedi V, Kols A, Kim YM, Khadka N, Rawlins B, Gibson A. Promoting healthy behaviors among Egyptian mothers: a quasi-experimental study of a health communication package delivered by community organizations. *PloS One*2016;**11**(3):e0151783.
19. Coutinho SB, de Lira PI, de Carvalho Lima M, Ashworth A. Comparison of the effect of two systems for the promotion of exclusive breastfeeding. *Lancet* 2005; **366**: 1094–100.
20. Davies-Adetugbo AA, Adebawa HA. The Ife South Breastfeeding Project: training community health extension workers to promote and manage breastfeeding in rural communities. *Bull World Health Organ* 1997; **75**: 323–32.
21. Dearden K, Altaye M, De Maza I, De Oliva M, Stone-Jimenez M, Burkhalter BR, et al. The impact of mother-to-mother support on optimal breast-feeding: a controlled community intervention trial in peri-urban Guatemala City, Guatemala. *Rev PanamSaludPublica* 2002; **12**: 193–201.
22. Feldens CA, Vitolo MR, DrachlerMde L. A randomized trial of the effectiveness of home visits in preventing early childhood caries. *Community Dent Oral Epidemiol* 2007; **35**: 215–23.
23. Flax VL, Negerie M, Ibrahim AU, Leatherman S, Daza EJ, Bentley ME. Integrating group counseling, cell phone messaging, and participant-generated songs and dramas into a microcredit program increases Nigerian women's adherence to international breastfeeding recommendations. *J Nutr*2014; **144**: 1120–4.
24. Froozani MD, Permehzadeh K, Motlagh AR, Golestan B. Effect of breastfeeding education on the feeding pattern and health of infants in their first 4 months in the Islamic Republic of Iran. *Bull World Health Organ* 1999; **77**: 381–5.
25. Gu Y, Zhu Y, Zhang Z, Wan H. Effectiveness of a theory-based breastfeeding promotion intervention on exclusive breastfeeding in China: A randomised controlled trial. *Midwifery*2016;**42**:93-9.
26. Haider R, Ashworth A, Kabir I, Huttly S. Effects of community-based peer counsellors on exclusive breastfeeding practices in Dhaka, Bangladesh: a randomised controlled trial. Lancet 2000;356:1643–7.
27. Haque MF, Hussain M, Sarkar A, Hoque MM, Ara FA, Sultana S. Breast-feeding counselling and its effect on the prevalence of exclusive breast-feeding. *J Health PopulNutr* 2002; **20**: 312–6.
28. Heidari Z, Keshvari M, Kohan S. Clinical Trial to Comparison the Effect of Family-centered Educational-supportive Program on Mothers' Empowerment in Breast-feeding. *International Journal of Pediatrics* 2016;**4**(3):1445-51.

29. Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Swanevelder S, et al. Effect of an integrated community based package for maternal and newborn care on feeding patterns during the first 12 weeks of life: a cluster randomized trial in a South African township. *Public Health Nutrition* 2015;**18**(14):2660–8.
30. Jakobsen MS, Sodemann M, Molbak K, Alvarenga I, Aaby P. Promoting breastfeeding through health education at the time of immunizations: a randomized trial from Guinea Bissau. *ActaPaediatr* 1999; **88**: 741–7.
31. Jesmin E, Chowdhury RB, Begum S, Shapla NR, Shahida SM. Postnatal Support Strategies for Improving Rates of Exclusive Breastfeeding in Case of Caesarean Baby. *MymensinghMedical Journal* 2015;**24**(4):750-5.
32. Jiang H, Li M, Wen LM, Hu Q, Yang D, He G, Baur LA, Dibley MJ, Qian X. Effect of short message service on infant feeding practice: findings from a community-based study in Shanghai, China. *JAMA Pediatrics* 2014;**168**(5):471-8.
33. Khresheh R, Suhaimat A, Jalamdeh F, Barclay L. The effect of a postnatal education and support program on breastfeeding among primiparous women: a randomized controlled trial. *Int J Nurs Stud* 2011; **48**: 1058–65.
34. Kimani-Murage EW, Norris SA, Mutua MK, Wekesah F, Wanjohi M, Muhia N, Muriuki P, Egondi T, Kyobutungi C, Ezeh AC, Musoke RN. Potential effectiveness of Community Health Strategy to promote exclusive breastfeeding in urban poor settings in Nairobi, Kenya: a quasi-experimental study. *Journal of developmental origins of health and disease* 2016;**7**(2):172-84.
35. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, Danso S, Amenga-Etego S, Tawiah-Agyemang C, Owusu-Agyei S, Hill Z. Effect of the Newhints home-visits intervention on neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial. *Lancet* 2013;**381**(9884):2184-92.
36. Kramer MS, Chalmers B, Hodnett ED, Sevkovskaya Z, Dzikovich I, Shapiro S, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA* 2001; **285**: 413–20.
37. Kupratakul J, Taneepanichskul S, Voramongkol N, Phupong V. A randomized controlled trial of knowledge sharing practice with empowerment strategies in pregnant women to improve exclusive breastfeeding during the first six months postpartum. *J Med Assoc Thai* 2010; **93**: 1009–18.
38. Langer A, Campero L, Garcia C, Reynoso S. Effects of psychosocial support during labour and childbirth on breastfeeding, medical interventions, and mothers' wellbeing in a Mexican public hospital: a randomised clinical trial. *Br J ObstetGynaecol* 1998; **105**: 1056–63.
39. Leite AJ, Puccini RF, Atalah AN, Alves Da Cunha AL, Machado MT. Effectiveness of home-based peer counselling to promote breastfeeding in the northeast of Brazil: a randomized clinical trial. *ActaPaediatr* 2005; **94**: 741–6.
40. LewyckaS.,MwansamboC.,RosatoM.,.,Phiri T., Mganga A. et al. Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (MaiMwana): a factorial, cluster-randomised controlled trial. *Lancet* 2013; **381**:1721-1735.
41. Li Y, Sun G. Study on the correlation between perinatal health education and postpartumbreastfeeding, maternal rehabilitation. Chinese book classification number R173 Document code A Article ID 1001-4411 (2015) 28-4775-04;doi: 10. 7620 / zgfybj. J. Issn. 1001 -4411. 2015. 28. 05.

42. Lu Liu－Xue, Lu Xiao －Ni, Chen Li－Xin, et al. Study on the effect of 3S conception health education pattern on breastfeeding of rural primiparous women in Western Guangxi. *China Maternal and Child Health* 2009; **29**:1824-6.
43. Maslowsky J, Frost S, Hendrick CE, Trujillo Cruz FO, Merajver SD. Effects of postpartum mobile phone-based education on maternal and infant health in Ecuador. *International Journal of Gynaecology& Obstetrics* 2016;**134**(1):93-8.
44. Morrow AL, Guerrero ML, Shults J, Calva JJ, Lutter C, Bravo J, et al. Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial. *Lancet* 1999; **353**: 1226–31.
45. Neyzi O, Olgun P, Kutluay T, Uzel N, Saner G, Gökçay G, Taşdelen E, Akar U. An educational intervention on promotion of breast feeding. *Paediatr Perinat Epidemiol*1991;**5**(3):286-98.
46. Ochola SA, Labadarios D, Nduati RW. Impact of counselling on exclusive breast-feeding practices in a poor urban setting in Kenya: a randomized controlled trial. *Public Health Nutr* 2013; **16**: 1732–40.
47. deOliveira LD, Giugliani ER, do Espırito Santo LC, Franca MC, Weigert EM, Kohler CV, et al. Effect of intervention to improve breastfeeding technique on the frequency of exclusive breastfeeding and lactation-related problems. *J Hum Lact* 2006; **22**: 315–21.
48. Penfold S, Manzi F, Mkumbo E, Temu S, Jaribu J, Shamba DD, et al. Effect of home-based counselling on newborn care practices in southern Tanzania one year after implementation: a cluster-randomised controlled trial. *BMC Pediatrics* 2014;**14**(1):187.
49. Reinsma K, Nkuoh G, Nshom E. The potential effectiveness of the nutrition improvement program on infant and young child feeding and nutritional status in the Northwest and Southwest regions of Cameroon, Central Africa. *BMC Health Services Research*2016;**16**(1):654.
50. Rotheram-Borus MJ, Tomlinson M, Le Roux IM, Harwood JM, Comulada S, O'Connor MJ, Weiss RE, Worthman CM. A cluster randomised controlled effectiveness trial evaluating perinatal home visiting among South African mothers/infants. *PLoS One* 2014;**9**(10):e105934.
51. Sharma K. Comparison of Breast Feeding Counseling and Video Demonstration on Exclusive Breast Feeding Rates at 6 Weeks (unpublished trial results). Available at: www.ClinicalTrials.gov.
52. Sikander S, Maselko J, Zafar S, Haq Z, Ahmad I, Ahmad M, et al. Cognitive-behavioralcounseling for exclusive breastfeeding in rural paediatrics: a cluster RCT. *Pediatrics* 2015;**135**(2):e424–e431.
53. Su M, Ouyang YQ. Father's Role in Breastfeeding Promotion: Lessons from a Quasi-Experimental Trial in China. *Breastfeeding Medicine* 2016;**11**(3):144-9.
54. Susiloretni K.A., Krisnamurni S., Widiyanto S.Y.D., Yazid A. &Wilopo S.A. The effectiveness of multilevel promotion of exclusive breastfeeding in rural Indonesia. *American Journal of Health Promotion* 2013; **28**: E44 –E55.
55. Susin LR, Giugliani ER. Inclusion of fathers in an intervention to promote breastfeeding: impact on breastfeeding rates. *J Hum Lact* 2008; **24**: 386–92; quiz 451–3.
56. Tahir NM, Al-Sadat N. Does telephone lactation counselling improve breastfeeding practices? A randomised controlled trial.*Int J Nurs Stud* 2013; **50**: 16–25.

57. Talukder S, Farhana D, Vitta B, Greiner T. In a rural area of Bangladesh, traditional birth attendant training improved early infant feeding practices: a pragmatic cluster randomized trial. *Maternal & Child Nutrition* 2016;**13**(1): 1-11.
58. Tomlinson M, Doherty T, Ijumba P, Jackson D, Lawn J, Persson LÅ, Lombard C, Sanders D, Daviaud E, Nkonki L, Goga A. Goodstart: a cluster randomised effectiveness trial of an integrated, community-based package for maternal and newborn care, with prevention of mother-to-child transmission of HIV in a South African township. *Tropical Medicine &International Health*2014;**19**(3):256-66.
59. Turan JM, Say L. Community-based antenatal education in Istanbul, Turkey: effects on health behaviours. *Health Policy Plan* 2003; **18**: 391–8.
60. Tylleskar T, Jackson D, Meda N, Engebretsen IM, Chopra M, Diallo AH, et al. Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial. *Lancet* 2011; **378**: 420–7.
61. Engebretsen IM, Nankabirwa V, Doherty T, Diallo AH, Nankunda J, Fadnes LT, Ekström EC, Ramokolo V, Meda N, Sommerfelt H, Jackson D. Early infant feeding practices in three African countries: the PROMISE-EBF trial promoting exclusive breastfeeding by peer counsellors. *International Breastfeeding Journal* 2014;**9**(1):19.
62. Valdes V, Pugin E, Schooley J, Catalan S, Aravena R. Clinical support can make the difference in exclusive breastfeeding success among working women. *J Trop Pediatr* 2000; **46**: 149– 54.
63. Venancio SI, Saldiva SR, Escuder MM, Giugliani ER. The Baby-Friendly Hospital Initiative shows positive effects on breastfeeding indicators in Brazil. *J Epidemiol Community Health* 2012; **66**: 914–8.
64. Venancio SI, Giugliani ER, Silva OL, Stefanello J, Benicio MH, Reis MC, Issler RM, Santo LC, Cardoso MR, Rios GS. Association between the degree of implementation of the Brazilian Breastfeeding Network and breastfeeding indicators. *Cadernos de SaudePublica*2016;**32**(3).http://dx.doi.org/10.1590/0102-311X00010315
65. Villadsen SF, Negussie D, GebreMariam A, Tilahun A, Girma T, Friis H, Rasch V. Antenatal care strengthening for improved health behaviours in Jimma, Ethiopia, 2009–2011: An effectiveness study. *Midwifery*2016;**40**:87-94.
66. Vitolo MR, Bortolini GA, Feldens CA, DrachlerMde L. Impacts of the 10 Steps to Healthy Feeding in Infants: a randomized field trial. *Cad SaudePublica* 2005; **21**:1448–57.
67. Vitolo MR, Louzada ML, Rauber F. Positive impact of child feeding training program for primary care health professionals: a cluster randomized field trial [Atualizacaosobrealimentacao da crianca para profissionais de saude: estudo de campo randomizadoporconglomerados]. *RevistaBrasileira De Epidemiologia* 2014;**17**(4):873–86.
68. Waiswa P, Pariyo G, Kallander K, Akuze J, Namazzi G, Ekirapa-Kiracho E, Kerber K, Sengendo H, Aliganyira P, Lawn JE, Peterson S. Effect of the Uganda Newborn Study on care-seeking and care practices: a cluster-randomised controlled trial. *Global Health Action*2015;**8**(1):24584.

69. Wu DS, Hu J, McCoy TP, Efird JT. The effects of a breastfeeding self-efficacy intervention on short-term breastfeeding outcomes among primiparous mothers in Wuhan, China. *Journal of Advanced Nursing* 2014;**70**(8): 1867–79.
70. Yotebieng M, Labbok M, Soeters HM, Chalachala JL, Lapika B, Vitta BS, et al. Ten steps to successful breastfeeding programme to promote early initiation and exclusive breastfeeding in DR Congo: a cluster-randomised controlled trial. *Lancet Global Health* 2015;**3**(9):e546–55.
71. Younes L, Houweling TA, Azad K, Kuddus A, Shaha S, Haq B, Nahar T, Hossen M, Beard J, Copas A, Prost A. The effect of participatory women's groups on infant feeding and child health knowledge, behaviour and outcomes in rural Bangladesh: a controlled before-and-after study. *J Epidemiol Community Health* 2015;**69**(4):374-381.
72. MohammadiZeidi I, PakpourHajiagha A, MohammadiZeidi B. Effectiveness of educational intervention on exclusive breast feeding in primipara women: application of planned behavior theory. *Razi Journal of Medical Sciences* 2015;**21**(127):12-23.
73. Hanson C, ManziF,Mkumbo E, Shirima K, PenfoldS,Hill Z, et al. Effectiveness of a home-based counselling strategy on neonatal care and survival: a cluster-randomised trial in six districts of rural Southern Tanzania. *PLOS Medicine* 2015;**12**(9):e1001881.

APPENDIX III: LIST OF STUDIES BY STUDY DESIGN

ID #	Study	ID #	Study
	RCT – randomised controlled trial		**Quasi-randomised controlled trials**
3	Aidam 2005	24	Froozani 1999
4	Ansari 2014	31	Jesmin 2015
5	Aksu 2011	32	Jiang 2014
6	Akter 2012	42	Lu 2014
7	Albernaz 2003	45	Neyzi 1991
10	Bashour 2008	53	Su 2016
13	Bica 2014	71	Younes 2015
14	de Oliveira 2014		
15	da Silva 2016		
19	Coutinho 2005		
22	Feldens 2006		
25	Gu 2016		**Non-randomised controlled trials**
28	Heidari 2016		
33	Khresheh 2011	1	Adhisivam 2016
37	Kupratakul 2010	16	Bich 2014
38	Langer 1998	17	Bich 2016 (referred to as 2015 earlier)
39	Leite 2005	20	Davies-Adetugbo 2005
47	de Oliveira 2006	21	Dearden 2002
51	Sharma 2013	27	Haque 2002
56	Tahir 2013	41	Li 2015
66	Vitolo 2005	43	Malowsky 2016
69	Wu 2014	54	Susiloretni 2013
		55	Susin 2008
	Cluster randomised controlled trials	59	Turan 2003
8	Arifeen 2009	62	Valdes 2000
9	Azad 2010	65	Villadsen 2016
11	Bhandari 2003	72	Zeidi 2015
12	Bhutta 2011		
18	Brasington 2016		
23	Flax 2014		**Cross-sectional (observational) studies**
26	Haider 2000	2	Ahmad 2012
29	Ijumba 2015	49	Reinsma 2016
30	Jakobsen 1999	63	Venancio 2012
34	Kimani-Murage 2016	64	Venancio 2016
35	Kirkwood 2013		
36	Kramer 2001		

40	Lewycka 2013		
44	Morrow 1999		
46	Ochola 2012		
48	Penfold 2014		
50	Rotheram-Borus 2014		
52	Sikander 2015		
57	Talukder 2016		
58	Tomlinson 2014		
60	Tylleskar 2011		
61	Engebretsen 2014		
67	Vitolo 2014		
68	Waiswa 2015		
70	Yotebieng 2015		
73	Hanson 2015		

APPENDIX IV: CHARACTERISTICS OF STUDIES AND INTERVENTION – NON-RANDOMISED CONTROLLED TRIALS AND OBSERVATIONAL STUDIES

STUDY ID	STUDY & LOCATION	STUDY DESIGN	PARTICIPANTS	INTERVENTION CHARACTERISTICS	PRIMARY OUTCOME ASSESSED? (EBF 6M)
01	Adhisivam 2016, India	NRSI	Primiparous mothers in postnatal wards of a tertiary hospital	*Health systems and services.* Single, video-based health education programme postnatally, reinforced by lactation counsellor CG: standard care	Yes
02	Ahmad 2012 Pakistan	Observational (retrospective cohort)	Mothers breastfeeding after delivery, with at least one previous child	*Health systems and services.* Single antenatal counselling conducted in previous pregnancy CG: standard care	Yes
16, 17	Bich 2014, Viet Nam (with Bich 2016)	NRSI	Wives 7 - 30 weeks pregnant & their husbands	*Health systems/services, Home/ family and Community settings* Antenatal & postnatal home visits (4 visits) +fathers' group counselling sessions + Mass media + Community mobilization activities CG: standard care	Yes
20	Davies-Adetugbo2005 Nigeria	NRSI	Pregnant women recruited in 3rd trimester	*Community setting.* Training of health staff + formation of community BF support groups CG: Health staff not trained	No
21	Dearden 2002, Guatemala	NRSI	LLLG BF counsellors. Pregnant women were recruited for LLLG activities	*Home/family &Community setting.* Antenatal & postnatal BF promotion & support activities by La Leche League: mother-to-mother support groups (1°focus), home visits, community education, referrals. Supported by community liaisons. CG: Health staff did not receive special training	No
24	Froozani 1999 Iran	Quasi-experimental	Primipara, or women unsuccessful with BF in previous child, with healthy FT infant	*Health systems/services &Home/family setting.* Postpartum BF education programme, with follow-up visits at home or in hospital till 4 months CG: standard care	No
27	Haque 2002, Bangladesh	NRSI	Pregnant women attending maternity centres for delivery	*Health systems and services.* **R**epeated BF counselling postpartum (8 sessions) till 12m CG: standard care	No

31	Jesmin 2015, Bangladesh	Quasi-experimental	Pregnant, >32 weeks gestation, had full term healthy infant by C/S	*Health systems and services.* Postnatal support in the post-operative period by health professionals. CG: standard care	No
32	Jiang 2014, China	Quasi-experimental	Primipara with singleton fetus, having mobile phone	*Home/family setting.* Weekly SMS on BF from 28th week of pregnancy till 12 months after delivery. CG: standard care	Yes
41	Li 2015, China	NRSI	Primiparous women with singleton delivery	*Health systems/services & Home/family setting* Perinatal health education course for pregnant women through multimedia lectures, video playback, experiential learning & brochures. Postpartum visits in special circumstances. CG: standard care	No
42	Lu 2014, China	Quasi-experimental	Primipara, FT live singleton, intention to BF, + rural household registration	*Health systems/services & Home/family setting* Health education model of support, skill and self-confidence (3S) + weekly telephone follow-up. CG: standard care	Yes
45	Neyzi 1991, Turkey	Quasi-experimental	Primips with vaginal delivery, birth weight > 2500g	*Health systems/services & Home/family setting* Single group BF education session + video on BF practice in hospital post-natally; 2nd session at home on day 5-7 postpartum. CG: Had group session on another topic, + home visit not focused on EBF	Yes
49	Reinsma 2016, Cameroun	Observational	Mothers 18–50yrs& infants 0-8 months residing in study areas	*Health systems and services* Training of nutrition counsellors & integration into existing ante- & post-natal health care services to improve IYCF. CG: standard care	No
53	Su 2016, China	Quasi-experimental	Primiparous females with singleton fetus, + father in intervention group	*Health systems and services.* Single, group education session conducted ante-natally with fathers in intervention group. CG: standard care	Yes
54	Susiloretni 2013, Indonesia	NRSI	Pregnant >28 weeks, willing to deliver with village midwife; + fathers & other family member	*Health systems & services, Home/family &Community setting* Multilevel EBF promotion conducted through home visits, advocacy, training & media CG: Standard care	Yes
55	Susin 2008, Brazil	NRSI	Couples living together with healthy FT infant, have initiated BF & domiciled in study area	*Health systems and services* Single health education session on BF promotion given to mothers in IG1, mothers + fathers in IG2; plus 18-minute video followed by open discussion, & leaflets on BF promotion. CG: standard care	No
59	Turan 2003, Turkey	NRSI	Primiparous women	*Community setting.* Antenatal group participatory education programme; 8 sessions over 1 month. CG: standard care	No
62	Valdes 2000,	NRSI	Women delivered at	*Health systems and services*	Yes

	Chile*		selected facility and exclusively breast feeding on day 30	Postnatal. Monthly counselling & support sessions for working women during well-baby visits. CG: standard care, including BF hospital support till day 30	
63	Venancio 2012, Brazil	Observational	Infants < 1year attending immunization clinics	*Health systems & services* Assessment of effect of BFHI on infant feeding outcomes	No
64	Venancio 2016, Brazil	Observational	Mothers with infants < 6m at clinic visit	*Health systems & services* Evaluation study of BFHI implementation through training & certification of basic health units on infant feeding practices CG: did not receive intervention elements	EBF <6m Continued BF 12m
65	Villadsen 2016, Ethiopia	NRSI	Pregnant women receiving ANC at study facilities	*Health systems & services* Participatory ANC strengthening intervention in public health delivery system within study area. CG: standard care	EBF 1m
71	Younes 2015, Bangladesh	Quasi-experimental	Women 15-49 years & resident in intervention communities	*Community setting* Participatory learning & action cycle, focusing on health issues for under 5s including BF promotion. All clusters received health services strengthening initiatives	Yes
72	Zeidi 2015, Iran	NRSI	Primipara recruited at 7-8 months of pregnancy	*Health systems/services* Three hospital-based group educational sessions CG: standard care	No

*Chile was classified as LMIC until 2013

CG, control group; IG, intervention group; NRSI, non-randomised study of intervention; BFHI, baby-friendly hospital initiative; BF, breastfeeding; EBF, exclusive breastfeeding; ANC, antenatal care; FT, full term; IYCF, infant and young child feeding; C/S, caesarean section; sms, short message service; LLLG, La Leche League Guatemala

APPENDIX V: BIAS SUMMARY TABLE FOR RANDOMISED STUDIES

Study ID	Random sequence generation (Selection Bias)	Allocation concealment (Selection Bias)	Blinding of outcome assessment (Detection Bias)	Incomplete outcome data (Attrition Bias)	Selective reporting (Reporting Bias)	Other sources of bias	Bias judgment
Aidam 2005	Low	High	High	UC	UC	UC	High
Aksu 2011	Low	UC	High	Low	UC	UC	High
Akter 2012	Low	UC	High	UC	UC	UC	High
Albernaz 2003	Low	Low	Low	UC	UC	UC	Low
Ansari 2014	Low	UC	UC	Low	Low	UC	Low
Arifeen 2009	UC	UC	UC	Low	Low	UC	Low
Azad 2010	Low	High	High	UC	UC	UC	High
Bashour 2008	Low	Low	Low	UC	UC	UC	Low
Bhandari 2003	Low	Low	Low	UC	UC	UC	Low
Bhutta 2011	Low	Low	Low	UC	Low	Low	Low
Bica 2014, de Oliveira 2014 & da Silva 2016	Low	High	Low	UC	UC	UC	High
Brasington 2016	UC	UC	UC	UC	UC	UC	Unclear
Coutinho 2005	Low	UC	Low	Low	UC	UC	Low
Feldens 2006	Low	UC	Low	UC	Low	Low	Low
Flax 2014	Low	UC	Low	Low	Low	UC	Low
Gu 2016	Low	UC	UC	High	UC	UC	High
Haider 2000	Low	Low	High	UC	UC	Low	High
Heidari 2016	UC	UC	UC	UC	UC	UC	Unclear
Ijumba 2015 & Tomlinson 2014	Low	High	Low	Low	Low	UC	High
Jakobsen 1999	UC	UC	UC	High	Low	UC	High
Khresheh 2011	Low	Low	High	High	UC	UC	High
Kimani-Murage 2016	Low	High	UC	UC	UC	UC	High
Kirkwood 2013	Low	High	High	Low	Low	UC	High
Kramer 2001	Low	Low	High	Low	Low	Low	High
Kupratakul 2010	Low	Low	UC	Low	Low	Low	Low
Langer 1998	Low	Low	UC	Low	Low	UC	Low
Leite 2005	Low	Low	Low	Low	Low	Low	Low
Lewycka 2013	Low	High	UC	Low	UC	UC	High

Study ID	Random sequence generation (Selection Bias)	Allocation concealment (Selection Bias)	Blinding of outcome assessment (Detection Bias)	Incomplete outcome data (Attrition Bias)	Selective reporting (Reporting Bias)	Other sources of bias	Bias judgment
Malowsky 2016	Low	UC	UC	High	UC	UC	High
Morrow 1999	Low	Low	High	Low	UC	UC	High
Ochola 2012	Low	UC	Low	High	Low	UC	High
De Oliveira 2006	UC	High	Low	Low	Low	UC	High
Penfold 2014 & Hanson 2015	Low	UC	High	Low	Low	Low	High
Rotheram-Borus 2014	UC	UC	UC	Low	Low	UC	Low
Sharma 2013	Low	Low	UC	High	UC	UC	High
Sikander 2015	UC	UC	Low	Low	Low	UC	Low
Tahir 2013	Low	High	Low	Low	UC	UC	High
Talukder 2016	Low	Low	Low	UC	UC	UC	Low
Tylleskar 2011[5]BF	Low	High	Low	Low	Low	UC	High
Tylleskar 2011 U	Low	High	Low	Low	Low	UC	High
Tylleskar 2011 SA	Low	High	Low	High	Low	UC	High
Vitolo 2005	UC	High	High	Low	Low	Low	High
Vitolo 2014	Low	UC	Low	UC	UC	UC	Low
Waiswa 2015	Low	Low	High	UC	Low	UC	High
Wu 2014	UC	UC	High	Low	UC	UC	High
Yotebieng 2015	Low	Low	UC	Low	Low	UC	Low

[5] With Engebretsen 2014

APPENDIX VI: BIAS SUMMARY TABLE FOR NON-RANDOMISED STUDIES OF INTERVENTIONS

Study ID	Bias due to confounding	Bias due to participant selection	Bias in measurement of interventions	Bias due to departures from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Bias judgement
Adhisivam 2016	Serious risk	Low risk	Low risk	No information	Low risk	No information	Low risk	Serious risk
Ahmad 2012	No information	No information	Serious risk	No information	Critical risk	Serious risk	Moderate risk	Critical
Bich 2014/2016	Moderate risk	Low risk	Low risk	Low risk	Low risk	Moderate risk	Low risk	Moderate
D-Adetugbo 1997	No information	No information	Moderate	Moderate	Moderate	Serious	Low	Serious
Dearden 2002	Moderate risk	Moderate risk	Moderate risk	Serious risk	No information	No information	Low risk	Serious
Froozani 1999	Moderate risk	Low risk	Low risk	No information	Low risk	Moderate risk	Moderate risk	Moderate
Haque 2002	No information	Low	Low	No information	Serious	No information	Low	Serious
Jesmin 2015	Moderate risk	Moderate risk	No information	No information	Moderate risk	No information	Low	Serious
Jiang 2014	Moderate risk	Moderate risk	Low risk	Low risk	Low risk	Low risk	Moderate risk	Moderate
Li 2015	Moderate risk	Moderate risk	Low risk	No information	Low risk	Low risk	Low risk	Moderate
Lu 2009	Moderate risk	Low risk	Low risk	No information	Low risk	Low risk	Low risk	Moderate
Neyzi 1991	Low risk	Moderate risk	Low risk	No information	Moderate	Low risk	Moderate risk	Moderate
Reinsma 2016	Moderate risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Moderate
Su 2016	Serious risk	Moderate risk	Low risk	Low risk	Low risk	Moderate risk	Moderate risk	Serious
Susiloretni 2013	Moderate risk	Moderate risk	Low	Low	Low	Moderate	Low	Moderate
Susin 2008	Moderate risk	Moderate risk	Low risk	No information	Low risk	Low risk	Low risk	Moderate
Turan 2003	Moderate risk	Serious risk	Low risk	No information	Moderate risk	Moderate risk	Low risk	Serious
Valdes 2000	Serious risk	Moderate risk	Low risk	No information	No information	Serious risk	Low risk	Serious
Venancio 2012	Moderate risk	Low risk	Low risk	Serious risk	Low risk	Low risk	Low risk	Serious
Venancio 2016	Serious risk	Moderate risk	Moderate risk	No information	Low risk	Low risk	Low risk	Serious
Villadsen 2016	Moderate risk	Low risk	Low risk	Moderate risk	Low risk	Moderate risk	Low risk	Moderate
Younes 2015	Serious risk	Moderate risk	Low risk	Low risk	Moderate risk	Moderate risk	Moderate risk	Serious