

Social Behavior Changes Communication Intervention for Stunting Prevention: A Systematic Review

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Social Behavior Changes Communication Intervention for Stunting Prevention: A Systematic Review

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Abstract

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BACKGROUND: Interpersonal communication, media, and community/social mobilization were the most commonly used social and behavior change approaches.

AIM: The present review sought to review and synthesize the present literature regarding social behavior changes communication intervention for stunting prevention.

METHODS: We searched Medline, PsychINFO, and PubMed (January 2000 and December 2020) and conducted ancestral and online searches in peer-reviewed and English language journals for eligible studies. The search parameters included the following search terms: "Complementary feeding" OR "child feeding" OR "infant feeding" AND "behavior change" or "behavior change communication" OR "nutrition education" OR "social marketing" OR "social and behavior change" AND "behaviors" or "practices" OR "stunting" OR "underweight" OR "wasting."

RESULTS: Our overall search yielded 1119 studies and 56 full-texts were assessed for eligibility, resulted in five articles included in review. All studies reported that SBCC was feasible to increased expenditures on eggs and flesh foods, minimum dietary diversity, early initiation of breastfeeding, exclusive breastfeeding, knowledge and practices towards infant and youth complementary feeding, and reduced stunting prevalence.

CONCLUSION: Social and behavior communication change interventions using multiple platforms were feasible and effective. This study provided an approach for prevention of stunting that can be basic evidence for health-care policy to improve prevention programs on stunting with the local community and widely provide culturally training for all community trough cadre as a first line of the health-care system.

Introduction

Stunting is a global public health problem for children, but also an obstacle to advancement in income and growth of the countries. Stunting is defined when the height below minus two standard deviations ($<-2SD$) from the WHO child growth level nutritional status table or below the international reference mean population length or height and is an indicator of success in health, education, and public development [1]. Despite the fact that stunting rates have been declining for decades, an estimated 21.3% (144 million) of children under the age of five worldwide experienced stunted growth in 2019 [2]. The global prevalence ranges from 34.5% in Eastern Africa to 4.5% in Eastern Asia in 2019 (UNICEF, 2020). These estimates indicate that about 17% of mortality in children <5 years of age is attributed to stunting [3]. Indonesia is among the countries with the highest prevalence of stunting. Indonesia is a country

with a high prevalence of malnutrition in children under five. The results of Basic Health Research in 2010 and 2013 and Nutrition Status Monitoring in 2015 and 2017 showed that the prevalence of stunting is still high and does not decrease reaching the WHO threshold (Indonesian Ministry of Health, 2019). Stunting in 2010 reached 35.6% and in 2013 reached 37.2%, nutrition status monitoring in 2015 was 29.0% and in 2017 was 29.6%. This means that there are three stunting toddlers out of ten children born in Indonesia (Indonesian Ministry of Health, 2019).

Stunting is a multidimensional disease that happens not only in children from poor families but also in welfare families [4]. Long-term employment, job capacity potential, income generation capacity and susceptibility to obesity, and chronic disorders can be affected by malnutrition. Stunting can take many forms, but the best ways to avoid it are to breastfeed exclusively during the first 2 years of life, eat a diverse and nutritious diet during childhood, live in a safe setting, have access

to basic services such as water, hygiene, fitness, and sanitation and have adequate maternal nutrition before, during, and after pregnancy [5]. The highest proportion of stunting occurs during the supplementary feeding era (6–23 months), the transition period from exclusive breastfeeding (EBF) in the first 6 months of life, to eating a wide range of family foods when breastfeeding continues [3]. Children who were stunted were more likely to die from pneumonia or diarrhea [6]. Early childhood stunting is related to greater cognitive impairment and lower intelligence quotient levels, which decrease schooling output by a year and adult income by 5–53% [7], [8].

Increasing public awareness of the importance of maternal nutrition from conception to 2 years old is a major task for local and national governments [9]. Adequate supplementary feeding is important in promoting maximum physical growth and growing brain in infants and to avoid stunting. This suggests that providing information about proper and varied nutrition to pregnant and postnatal women is a significant endeavor. Pregnant and postpartum women require a sufficient and varied intake of nutrients. Mother's limited knowledge can endanger the child's health and growth, both in the womb and in its development. This is supported by the previous study which suggested that young mothers whose infants suffer stunting have poor nutrition awareness [9]. Several specific behaviors or practices impact nutritional status during the critical first 1000 days (pregnancy to age two), while complex and contextual determinants also influence individual decisions to consider, test, adapt, and sustain a given behavior or practice [10].

The research by Saaka *et al.* [11] was performed in Northern Japan evaluated the three measures of effective complementary feeding (CF), but not the mothers' awareness or attitudes about infant and young child feeding guidelines [12] looked into mothers' awareness of prescribed infant and young child feeding practices and their association with CF practices, but did not look into mothers' attitudes toward CF practices [13] used the Ghana Multiple Indicator Cluster Survey for 2011 to look into dietary diversity and malnutrition in children, but they did not look into other CF indicators including meal frequency or an appropriate diet. As a result, there is a scarcity of information on mothers' awareness and attitudes about infant and young child feeding guidelines, as well as how these are linked to CF practices.

There is a growing body of research on the effects of different approaches to accomplishing these suggested [14], [15], [16]. Recent impact assessments of large-scale social and behavioral changes in communication interventions to improve CF practices for infants and young people in several countries have shown that intensive interpersonal counseling combined with mass media (MM) (e.g., TV spots and radio campaigns) and community

mobilization (CM) activities (e.g., community group meetings, cooking demonstrations, and CM activities) has positive impacts on breastfeeding [17], [18] and CF practices [14], [17], [18]. Combined intensive initiatives in Bangladesh resulted in significant changes in EBF, early breastfeeding initiation, minimum dietary diversity, minimum meal frequency, minimum acceptable diet, and iron-rich food intake [17], [18]. Improvements in CF practices have been found to be difficult to achieve; however, large improvements and widespread impacts are more frequently reported in the subjects such as this has been found in recent reviews [14], [19], [20], [21], [22], [23]. Sustainable behavior changes are initiated and maintained to improve supplementary nutrition and nutrition practices for children.

The social and behavior change approach most used, and the only one used without other communication interventions was interpersonal communication (IPC) and media and community/social mobilization [18]. SBCC implemented to encourage three key behavioral traits: Pregnant and lactating women to eat well and bottle-feeding new mothers to continue the routine. SBCC interventions are broadly classified into three categories: IPC, media use, and community/social mobilization. IPC, media, and community/social mobilization are generally used to address social and behavioral issues, respectively [17], [24].

The previous study showed that prenatal counseling had greater impacts on breastfeeding rates at 4–6 weeks, while the combined prenatal and postnatal promotion was important for breastfeeding rates at 6 months [25]. Fofren *et al.* [26] found no effect of SBCC on timely support during the antenatal or postnatal visit. While, Jolly *et al.* [27] found that combined antenatal and postnatal peer support was not associated with a significant improvement in not breastfeeding at last study follow-up, whereas postnatal only interventions did significantly reduce not breastfeeding. Likewise, Aidam *et al.* [28] found that women who received two prenatal counseling sessions, one counseling session 48 h postpartum, and six postpartum home visits were just as likely to EBF at 6 months as those who received only postpartum counseling. However, the previous studies were lack of follow-up and using small sample size. In addition, the majority of the previous studies only used two or three SBCC strategies. There has not been much research done to compare the impact of differences in delivery science, particularly when scaled up. Despite hospital and community initiatives, concerns about the current strategy of delivering against stunting persist. Behavioral change has not only been tried in various locations, but has also applied to various interventions and regimes. There is thus far only limited research on social change interventions. The aim of this research was to review the medical literature on community-based social behavior change strategies, summarize

treatment models and success measures, and analyze the evidence.

Methods

Searching strategy

We used Medline, PsychInfo, and PubMed (available in both the library and on the internet) to research possible resources and followed the results to remove duplicate hits, then searched reference databases to help broaden the results; we found in peer-acquired and professional publications. The search parameters included the following search terms: "CF" OR "child feeding" OR "infant feeding" AND "behavior change" or "behavior change communication" OR "nutrition education" OR "social marketing" OR "social and behavior change" AND "behaviors" or "practices" OR "stunting" OR "underweight" OR "wasting."

Inclusion/exclusion criteria

Studies and programs were eligible for inclusion if they used social and behavior communication change (SBCC) strategies to shift CF behaviors in children aged 6–24 months. NSCs (improving agriculture and female self-efficacy or promoting CF) were also permitted, but had to be planned and applied to educate the populace about nutrition and make dietary changes in conjunction with SBCC to target this population.

For eligibility, nutrition training/SBCC activities required at least monthly and for at least 3 months, as well as experimental design. Only English-language studies/programs published between January 2000 and August 2021 were considered. The research into the interventions necessary to alleviate poverty and sickness in the global South left also failed to find a study in which used concise and explicit information, instead requiring a detailed examination of numerous research abstracts to which had none available.

Data extraction

Both full-text studies and publications that met the inclusion/exclusion requirements had their data extracted into a structured format. We extracted key variables such as research identifiers and context, study design, intervention information, and measured outcomes. Outcomes were divided into two categories: Behavioral/practice outcomes and health outcomes. Data were abstracted at the programmatic level; the data were compiled and reported as one program in several articles describing the same program.

All data collected during the analysis process were double-coded by the research team. The data

were double-entered, allowing for the calculation of percent agreement. Coder agreement reached 89% (range 80–99%) above the 80% acceptable standard recommended for quantitative research synthesis. To ensure further the precision of the inter-relator analysis, we have reached consensus in all areas of discrepancies.

Quality of assessment

Quality assessments were carried out in accordance with CHERG systematic examination guidelines [29]. The initial score for "high" and CBA studies was "low" randomized controlled studies. Every research was given a grade of "high," "moderate," "poor," or "very low," based on the strengths and limitations of the study design and methods." All results were removed from studies with a "very poor" score.

Results

Searching results

Our overall search yielded 1119 studies from 2015 onward (Figure 1). Of these, 243 were removed after duplicates. About 657 studies have been ruled out. About 56 full-texts assessed for eligibility. Twenty were removed due to lack of or incompatible outcomes of interest per our methods, 21 were removed due to intervention and did not include SBCC, and ten were not clinical trial. Finally, a total of five articles were included in review (Figure 1).

Characteristics of included studies

The methodological characteristics of all of the articles analyzed are shown in Table 1. All studies were published between 2015 and 2020. Two studies were conducted in Bangladesh, one study in Ethiopia, one study in Burkina Faso, and one study conducted in two countries (Bangladesh and Viet Nam). Total Sample sizes were generally varying between studies, ranged from 900 to 865. All studies were conducted using cluster randomized trial and non-blinded. The outcome measures also varying between studies, such as food and non-food expenditures, maternal dietary diversity, CF practices, maternal knowledge of infant and young child feeding (IYCF) practices, early initiation of breastfeeding (EIBF), EBF, and prevalence of stunting (Figure 1).

Quality of evidence

The quality of evidence was also determined for each study and outcome using the CHERG

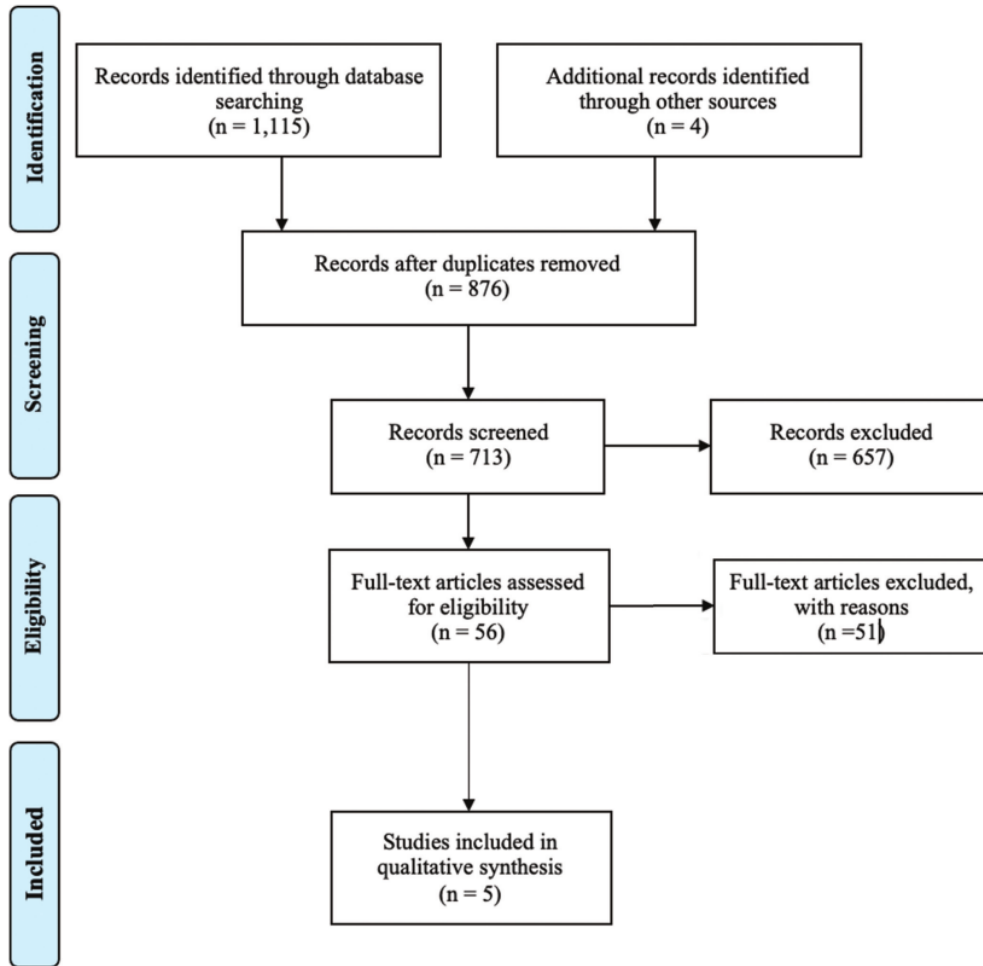


Figure 1. PRISMA flow chart

criteria. There were three studies with high-quality evidence [17], [18], [30] and two studies with moderate-quality evidence [8], [31] (Table 1).

Summary of findings

All studies reported that SBCC could increase expenditures on eggs and flesh foods [30], minimum dietary diversity [8], [17], EIBF [18], EBF [17], knowledge and practices toward IYCF [8], [31], and stunting prevalence [17], [31] (Table 2).

Discussion

SBCC program that focused on integrating intensified IPC, MM, and CM had a greater impact

on IYCF, breastfeeding practices, and prevalence of stunting, within the context of national advocacy to create a supportive environment for optimal feeding practices. SBCC approaches consist of IPC, the use of media, and community/social mobilization. Within each approach, further identified sub-approaches or activities were identified. The SBCC approaches and activities outlined are consistent with those referenced in the C-Change/FHI360 Learning Package for Social and Behavior Change Communication (2010), the Bill and Melinda Gates Foundation "Social and Behavior Change Intervention Landscaping Study: A Global Review" [24], the USAID Infant and Young Child Nutrition (IYCN) Project "IYCN Social and Behavior Change Communication Approach" (2011), the USAID "Community Interventions to Promote Optimal Breastfeeding: Evidence on Early Initiation, Any Breastfeeding, EBF, and Continued Breastfeeding" (2012), the USAID "Behavior Change Interventions and Child Nutritional Status: Evidence from the Promotion

Table 1: Methodological characteristics of included studies

Author, years (country)	Sample	Design	Outcomes	Quality of study
Warren et al., 2020 (Bangladesh)	4281 households receiving the intensive intervention and 4284 households receiving the no intensive intervention	A cluster randomized and non-blinded	<ul style="list-style-type: none"> • Food and non-food expenditures • Maternal dietary diversity 	High
Kim et al., 2019 (Ethiopia)	Households were having produced chickens for 2 years, having <50 birds, having ≥1 woman of reproductive age (18–49 years at enrollment). Intensive intervention=1328 No intensive intervention=1318	Cluster randomized trial and non-blinded	<ul style="list-style-type: none"> • CF practices • Maternal knowledge about CF • Stunting prevalence 	High
Hoddinot et al., 2017 (Bangladesh)	• BCC neighbor households: 300 • Non-BCC neighbor households: 600	Cluster randomized trial and non-blinded	<ul style="list-style-type: none"> • Maternal knowledge of IYCF practices 	Moderate
Menon et al., 2016 (Bangladesh and Viet Nam)	Households with infants less 6 months N=980 (490/group)	Cluster randomized trial and non-blinded	<ul style="list-style-type: none"> • Early initiation of breastfeeding • Exclusive breastfeeding 	High
Olney et al., 2015 (Burkina Faso)	All women with children 3–12.9 months of age Intervention group=1481 Control=597	Cluster randomized trial control	<ul style="list-style-type: none"> • Household dietary diversity and health • Nutrition knowledge (maternal recall) • IYCF practices • Stunting was defined as length-forage z score or HAZ<2.2 SD 	Moderate

CF: Complementary feeding, IYCF: Infant and young child feeding

of Improved Complementary Feeding Practices” (2011), and the USAID Maternal and Child Health Integrated Program publication “Technical Reference Materials: Behavior Change Interventions” (2010).

EIBF and EBF were increased after SBCC program. These results are consistent with the sustainability literature that shows diminution of activities and effects almost immediately after initial project termination or external support expires; partial sustainability or continuation of some parts of a program

or interventions and benefits is often noted [17]. Most IYCF indicators decreased at follow-up in the intensive areas compared with endline. SBCC approaches consist of IPC, the use of media, and community/social mobilization. Within each approach, further identified sub-approaches or activities were identified [32]. Meta-analysis found a statistically significant increase in the consumption of women’s protein as a result of individual counseling and community education (pooled mean difference of 6.99 g/day), but no increase in energy

Table 2: Social behavior changes communication intervention

Author, years (country)	Intervention	Main finding
Warren et al., 2020 (Bangladesh)	<ul style="list-style-type: none"> • Intensive intervention package of interpersonal counseling and CM <ul style="list-style-type: none"> – Interpersonal counseling that was delivered by a new cadre of frontline workers focused on infant and young child feeding – Mass media campaign consisting of seven nationally televised spots, and video materials on infant and young child feeding • No intensive intervention: Home visits and interpersonal counseling • Duration of intervention: 4 years 	<ul style="list-style-type: none"> • Expenditures on eggs and flesh foods increased more in intensive areas than in no intensive areas by 53 (p<0.01) and 471 (p<0.01) taka/month, respectively • Household food expenditures increased more in intensive areas by 832 taka (p=0.02), whereas changes in non-food expenditures did not differ.
Hoddinot et al., 2017 (Bangladesh)	<ul style="list-style-type: none"> • Intervention group consists of four treatment arms: <ul style="list-style-type: none"> – Beneficiaries receiving a cash transfer (Cash) – A food ration (Food) – Combination of cash transfer and a food ration – Cash transfer plus nutrition BCC • Control group: Non-BCC neighbor households • Duration of intervention: 2 years 	<ul style="list-style-type: none"> • Having a neighboring mother participate in a nutrition BCC intervention increased non-participant mothers’ IYCF knowledge • Children of non-participant mothers who had a neighboring mother participate in a nutrition BCC intervention were 13.8% points more likely to meet WHO guidelines for minimum diet diversity • Children aged 0–6 months of non-participant mothers who are neighbors of mothers receiving BCC were 7.1% points less likely to have ever consumed water-based liquids.
Menon et al., 2016 (Bangladesh and Viet Nam)	<ul style="list-style-type: none"> • Intensive intervention: <ul style="list-style-type: none"> – IPC was based on multiple age-targeted IYCF-focused visits to households with pregnant women and mothers of children up to 2 years of age. – The MM component consisted of the national broadcast of seven TV spots that targeted mothers, family members, health workers, and local doctors with messages on various aspects of IYCF, and air the TV spots, and other IYCF films produced by the project, through local video screenings – CM: Sensitization of community leaders to IYCF, and community theater shows focused on IYCF – PA: Workshops to share data, engagement of journalists to broaden reporting on IYCF in the media, creation of an IYCF alliance. • No intensive intervention: standard nutrition counseling • Duration of intervention: 4 years 	<ul style="list-style-type: none"> • Improvements were significantly greater in the intensive compared to the non-intensive group for the proportion of women who reported practicing IYCF • Prevalence in intensive group rose from 48.5% to 87.6% and engaging in EIBF. • EBF increases were greater in the intensive compared to the non-intensive group (57.4–40.6%).
Olney et al., 2015 (Burkina Faso)	<ul style="list-style-type: none"> • HKI 2-y integrated agriculture (HFP) and nutrition and BCC program. • Treatment group that received the agricultural production intervention with the BCC strategy implemented. <ul style="list-style-type: none"> – Women’s nutrition – Anemia prevention and control (e.g., intake of iron-rich foods and use of bed nets to prevent malaria) – Iodine intake – Prevention of vitamin A deficiency – Breastfeeding practices – Complementary feeding practices – Nutritional care for sick and severely malnourished children • Control group that received no interventions • Duration of intervention: 2 years 	<ul style="list-style-type: none"> • Integrated HFP+BCC program (HC group) no significant impacts on stunting or underweight prevalence. • Later improvements in women’s agricultural production and maternal infant and young child feeding and care knowledge and practices in HC compared with control villages.

IPC: Interpersonal communication, AG: Agricultural activities, CM: Community mobilization, MM: Mass media, WHO: World Health Organization, EBF: Early initiation of breastfeeding, HKI: Helen Keller International’s, HFP: Homestead food production, BCC: Behavior change communication

intake. In addition, two other studies recorded significant outcomes related to the influence of IPC approaches on protein/energy consumption, four reported significant outcomes related to improved diet efficiency, three reported significant outcomes concerning iron intake, and one reported a significant impact on workload during pregnancy. However, the sustained impacts in the primary outcomes between baseline and follow-up lend evidence that there are continued benefits in the intensive interventions, because the IYCF practices improved over time in the intensive areas and above the difference over time in control group, where we had observed no change in intervention exposure.

Many reports have used more than one SBCC operation and many have used more than one [22]. The target audience is a particularly important aspect of implementing the SBCC initiatives. Several people can affect whether a person adopts a promoted behavior or does not. Successful SBCC approaches to address a range of audiences and often more than one audience or sphere of influence, including: Self-caregivers, such as pregnant and lactating women, as well as other immediate caregivers of children under two; indirect influencers, including partners/fathers, mothers-in-law, parents, other family members, and peers; local community performers, including commanders, including community members, leaders, social groups, and providers; and an actors within the enabling environment, including the government (national, sub-regional, district, and/or municipal), business, faith, and movement leaders [22].

SBCC strategies are grouped into three main categories or methods of SBCC activities: Interpersonal contact, media, and community/social mobilization. Such strategies are defined in the introductory chapter and the specific activities associated with each. In this chapter, the studies examined included a wide range of approaches to promoting optimal dietary intake among pregnant and lactating women. Many involved more than one specific activity of the SBCC and many used more than one strategy [32]. Analysis include several studies involving IPC methods explicitly for individual counseling and social education to encourage the consumption of women's energy and protein. All included IPC strategies, seven included some form of media, and two included community/social mobilization, among the nine other studies reporting statistically significant results. One-on-one therapy (in the time) was the most widely used IPC solution, and the most commonly used marketing approach was the small media (such as posters, leaflets, and stickers). However, The scope of evidence regarding SBCC's effectiveness in improving dietary habits is limited.

There is some evidence of IPC strategies' success in increasing protein/energy intake, improving diet consistency and increasing the intake of micronutrient supplements. The Ota *et al.* [32] meta-analysis found a statistically significant increase

in the consumption of women's protein as a result of individual counseling and community education (pooled mean difference of 6.99 g/day), but no increase in energy intake. Gogia and Sachdev [33] recorded a positive effect of IPC on early breastfeeding (Relative Risk [RR] = 3.35), while Imdad *et al.* [25] documented a six-fold increase in EBF levels in developing countries at 6 months of breastfeeding promotion (RR = 1.37 overall). Renfrew *et al.* [26] found that additional support resulted in a lower risk of stopping exclusive breast feeding at 6 months (RR = 0.86), Hall [34] and Jolly *et al.* [27] reported similar results linked to EBF at other times, and Imdad *et al.* [25] reported positive effects on continuing breastfeeding at 6 months (RR = 1.12). Lassi *et al.* [35] recorded an RR of 1.94 as regards early breast initiation.

Nine primary research studies assessing the efficacy of various SBCC strategies for enhancing maternal dietary habits and seven out of the nine reported statistically significant findings. Guyon *et al.* [36] reported a 12% point gap between intervention and control cultures while Ndiaye *et al.* [37] reported a 21% point difference in the consumption of animal products. Sun *et al.* [38] reported a difference of 21–26% points in intake of iron-fortified soy sauce between rural and urban intervention and control populations, and Adhikari *et al.* [39] and Risonar *et al.* [40], both of which reported differences in intake of micronutrients intake of 15 and 22% points, respectively. Omer *et al.* [41] reported a positive, statistically significant effect on reduction in pregnancy workload (OR = 1.48); however, no longitudinal data were obtained, making it difficult to identify the intervention.

In Indonesia, program to eradicate or eliminate stunting was stated in the specific regulation, in Law No. 17 of 2007 on the National Long-term Development Plan 2005–2025, the government has a framework for food and nutrition programs (Indonesian Ministry of Health, 2007). The two stunting intervention frameworks have been planned and implemented by the Government of Indonesia as part of national efforts to prevent and reduce the stunting prevalence. This is an intervention aimed at children in the first 1000 days of life and contributes to a 30% reduction in stunting. First, specific nutrition intervention activities are generally carried out in the health sector. Specific nutrition interventions targeting pregnant women. These interventions include providing supplementary food to pregnant women to overcome chronic energy and protein deficiencies, overcome iron and folic acid deficiencies, overcome iodine deficiency, and overcome intestinal worms in pregnant women and protect pregnant women from Malaria. The second is the sensitive nutrition intervention. This framework is ideally carried out through various development activities outside the health sector and contributes to 70% of stunting interventions. Activities related to sensitive nutrition interventions can be carried out

through several activities that are generally macro and carried out across Ministries and Institutions (Ministry of Health, 2018). However, all that program still resulted in high prevalence of stunting among children aged under 5-years-old.

There are some limitations to the present review. First, selection biases cannot be ruled out in this study, because the inclusion criteria focused on studies published in English and excluded conference papers and offline publications. However, we believe that the included studies give good overview on the effect of SSBC toward stunting prevention. Future meta-analysis should be done to determine the true effect of SSBC toward stunting prevention.

Conclusion

SBCC interventions using multiple platforms were feasible and effective. SBCC could improve knowledge and practices toward IYCF and stunting prevalence. (SBCC) approaches consist of IPC, the use of media, and community/social mobilization. Developing a community-based SBCC intervention on infant and young feeding practice is important to prevent stunting among children under 5 years. This study provided an approach for prevention of stunting that can be basic evidence for health-care policy to improve prevention programs on stunting with the local community and widely provide culturally training for all community through cadre as a first line of the health-care system. The future studies could be re-tested using more sample size in different place or region of others countries with relatively high prevalence of stunting.

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Authors Contribution

Data collection: Ahmad Darajat, Mayasyanti Dewi Amir, Hendri Hadiyanto, and Ernawati Umar. Data analysis and interpretation: Ahmad Darajat, Tukimin bin Sansuwito, Dessy Abdullah, and Nadia Purnama Dewi. Drafting of the article: Ahmad Darajat, Mayasyanti Dewi Amir, Hendri Hadiyanto, and Ernawati Umar. Critical revision of the article: Ahmad Darajat, Tukimin bin Sansuwito, Dessy Abdullah, and Nadia Purnama Dewi.

Data Availability Statement

The datasets generated during and/or analyzed during the present study are available from the corresponding author on reasonable request.

Ethical Consideration

Ethical permission was obtained prior data collection from the Institutional Review Board of the affiliated university.

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