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The Addition of a Feeding Toolkit to a Nutrition Sensitive Agriculture Intervention Significantly Enhanced Complementary Feeding Practices in SNNPR, Ethiopia: Results from a Longitudinal Cluster Randomized Controlled Trial

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A thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
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Abstract

The Addition of a Feeding Toolkit to a Nutrition Sensitive Agriculture Intervention Significantly Enhanced Complementary Feeding Practices in SNNPR, Ethiopia: Results from a Longitudinal Cluster Randomized Controlled Trial

By Euisun Pyo

Background Poor complementary feeding (CF) is a major risk factor for the global burden of childhood undernutrition. Quality Diets for Better Health (QDBH) is an integrative agricultural project that aims to improve vitamin A intake and nutrition quality of young children in Ethiopia through promotion of vitamin A rich and climate-sensitive orange flesh sweet potatoes and community-based nutrition education.

Objective This study aims to evaluate the effects of adding child feeding tools to the QDBH package on CF practices and potential effect modification by household food security.

Methods Twenty kebeles in two districts of SNNPR were randomly allocated to one of three intervention groups: full intervention, received feeding toolkit with OFSP promotion and nutrition education; partial intervention, received OFSP promotion and nutrition education; control, scheduled to receive partial intervention at a later date. Effects of the intervention arms were assessed longitudinally among 605 households from participating kebeles. Intent-to-treat analysis applied adjusted logistic regression to examine CF outcomes by intervention group. For as-treated analyses, we created exposure dose scores based on receipt of specific program components and analyzed associations with CF outcomes using logistic regression. Food security status was assessed using the food insecurity experiences scale, and interactions between intervention and food security for CF outcomes was assessed using the chunk test.

Results Controlling for covariates, the odds of meeting minimum dietary diversity (MDD) and minimum acceptable diet (MAD) for a child 6-13 months of age was each significantly higher in the full compared to the control (aOR MDD: 2.40 [2.01, 2.87]; aOR MAD: 2.63 [2.23, 3.09]). The intervention was not significantly associated with minimum meal frequency (MMF). For every additional intervention component received, the odds of achieving MDD and MAD increased by 28% and 27%, respectively. For child's consumption of vitamin A-rich fruits and vegetables, the odds increased in a dose-response manner to both exposures. There was no significant effect modification by food security status.

Conclusion Receipt of the full intervention and each unit increase in program components were each associated with improvements in achieving adequate dietary diversity and overall diet quality in children aged 6 to 13 months.

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CHAPTER I: LITERATURE REVIEW

1.1 Childhood Undernutrition

Nutrition is pivotal for a child's development and health. Without proper nutrition, children not only experience delays in growth and development, but also face serious risk of infection, noncommunicable diseases, and death from an early stage in life. Globally, 51 million children under 5 are wasted (low weight-for-height) – 17 million of whom are severely wasted and 11 times more likely to die prematurely than healthy children (1) – and 151 million children under 5 are stunted (low height-for-age) by chronic undernutrition (2). Stunting and wasting contributes to 113.3 million disability-adjusted life years (DALYs) and more than 1.2 million deaths in 2015 globally (3). This global impact demonstrates a lasting cost of child undernutrition that continues into adulthood, putting a serious burden on individuals, their families, and their countries.

While past nutrition interventions focused on replenishing the caloric need to resolve child undernutrition, clear evidence has been established over many decades that the hidden hunger of micronutrient deficiency has also been a detrimental factor (2, 4). A lack of micronutrients such as vitamins and iron can lead to serious damage to specific physiological functions. Since children under 2 are dependent on their caregiver for food, the caregiver's feeding practices directly influence the quality and quantity of the child's nutrient intake, especially the intake of micronutrients vital for development and survival. For children in low-income countries where diets are normally dominated by starchy foods with poor micronutrient values and bioavailability, meeting adequate micronutrient intake becomes an even greater challenge (5).

1.2 Vitamin A Deficiency in Children

During infancy and early childhood, vitamin A deficiency (VAD) is especially damaging. Vitamin A is a group of lipid-soluble retinoid acids that is essential to supporting numerous physiological functions, including vision, immunity, and cellular processes for growth, epithelial integrity, red blood cell production, and embryonic/fetal development (6-9). Therefore, lack of vitamin A in early stages of life causes severe visual impairment and preventable childhood blindness due to impaired visual signaling(10). Losing normal tissue functioning due to VAD also impairs the already vulnerable immunity of children to severe illnesses, and even causes premature death from common childhood infections (6, 11). If VAD is comorbid with intestinal infestations and infection, children less effectively absorb nutrients, thus creating a vicious cycle of undernutrition and infection (7, 10, 12).

In 2013, VAD impacted about one third of the children aged 6 to 59 months around the world, most significantly in Sub-Saharan Africa and South Asia (13). Globally, VAD is attributable for over 7.6 million global disability-adjusted life years (DALYs) and an estimated 83,000 global deaths of children 6-59 months of age in 2015 (3). While the numbers of children affected by VAD has gradually decreased worldwide, VAD prevalence and its health burden remain substantial in low-income countries of Sub-Saharan Africa and South Asia (13-15). To treat acute VAD in young children, high-dose vitamin A supplementation has long been the dominant approach (16, 17). However, vitamin A supplementation coverage has dropped by half in countries with the highest under-five mortality, thereby leaving 62 million children in these countries unprotected from the outcomes of VAD (17). This fluctuation in supplementation coverage emphasizes the need for alternative and more sustainable strategies to prevent micronutrient deficiencies like VAD in early childhood.

1.3 Complementary Feeding

Proper feeding during the first 1,000 days of a child's life is critical for normal growth, development, and survival during and beyond childhood and is a key strategy for the prevention of stunting and vitamin A deficiency. Most growth and developmental failures accumulate during this period, and only limited evidence exists that demonstrates meaningful recovery past this critical 24-month window (18-20). Since young children are completely dependent on their caregivers for food, caregiver's failure to provide adequate feeding directly risks the energy and nutrient intake of the child. For this reason, it is essential for intervention strategies to target caregivers and their households to ensure optimal feeding of infants and young children.

For the first 6 months after birth, early initiation and exclusive breastfeeding (EBF) are strongly recommended to provide optimal nutrition and minimal exposure to outside foodborne pathogens (21). However, past 6 months of age, breastmilk is no longer enough to meet the increasing caloric and nutritional needs for an infant's growth and health, and these gaps become greater as children get older. For example, after an average intake of 550 mL of breastmilk, nearly a quarter of the daily need of vitamin A and more than 90% of the daily needs of iron are still lacking for a child at the age of 12-23 months (22). Therefore, in addition to breastmilk, caregivers must provide the remaining energy, protein, and micronutrient needs through solid and semi-solid foods.

This process of introducing adequate solid and semi-solid foods to children between 6 and 23 months of age is defined as complementary feeding.

According to the World Health Organization guidelines, complementary feeding of foods and liquid other than breastmilk should be timely and of adequate amount, frequency, consistency, and nutritional quality. Since children under 2 years of age are not yet able to consume the regular family diet, it is also critical that young children are gradually introduced to diverse foods in appropriate texture, accompanied with sanitary meal preparation and responsive feeding (21).

While these complementary feeding principles have been well established and actively promoted over many decades around the world, young children in LMIC and rural areas are still at high risk of poor complementary feeding and undernutrition due to economic or sociocultural barriers caregivers face (23, 24). Particularly, in low-resource settings, animal-food sources rich in various nutrients such as proteins, zinc, iron, and vitamin A are not readily available. Rather than consuming various food sources, young children in LMIC often receive starchy cereal-based complementary foods that mainly provide energy through carbohydrate intake, but likely lack other required nutrients (25). In resource-restricted conditions, caregivers may also underestimate the meal frequency and consistency for their child's nutritional needs.

Recent estimates show that a little more than two thirds of the children worldwide received solid and semi-solid foods at the age of 6-8 month as recommended in the UNICEF guidelines on complementary feeding. Most LMICs had a similar rate of timely initiation of complementary food (TICF), although for some countries like Somalia and India, more than half of the children suffered from delayed complementary feeding. When considering the quality of complementary feeding, the rates of children meeting the recommendations were drastically sparse in low-resource settings**.** In rural areas of low- and LMICs, only 14% of children aged 6 to 23 months were fed the minimum number of meals and the minimum number of food groups (26). In such low-resource settings, delayed and nutritionally poor complementary feeding can easily occur due to factors including but not restricted to poverty, societal violence, food insecurity, caregiver's lack of awareness, and lack of governmental investments (27).

1.4 Improving Child Nutrition with Complementary Feeding

Since the ages of 6 to 24 months are a vulnerable period of growth faltering and micronutrient deficiencies, many efforts are made to reduce the risk of malnutrition for children in this age range. Among many interventions, three strategies are used most extensively: supplementation, food fortification, and diet diversification. Of these three, supplementation and food fortification are considered cost-effective strategies for large-scale impact (28, 29); however, these strategies do not address the root cause of undernutrition in the communities (29-31). With supplementation, the beneficiaries are solely dependent on external supply, making universal coverage challenging to maintain or expand to hard-to-reach populations . Similarly, the success of food fortification is highly dependent on strong public-private partnership (PPP) and long-term political commitment to enforce and regulate fortification (31).

Meanwhile, diet diversification is a more sustainable and community-based alternative that allows long-term changes. Diet diversification is a community-based strategy that promotes adequate consumption of nutrient rich foods by introducing new nutrient-rich food sources, improving access to diverse foods, and increasing nutrition literacy to promote individual and community-level behavioral change. Since these diet-based interventions target the underlying determinants of malnutrition and embed behavioral changes in the communities, diet diversification has powerful potential for a sustainable impact which is then more cost-effective long-term (32).

Diet diversification strategies are the key approaches of complementary feeding interventions targeting children aged 6 to 24 months. Several educational strategies such as caregiver education and nutritional counseling were designed to promote healthy feeding practices. However, in food-insecure settings, caregivers may have limited resources to put the learned recommendations into practice (33). In response to the limitations of nutrition education as the sole intervention, more integrative approaches are used to enhance both knowledge and access to affordable nutrient-rich foods (34, 35).

1.5 Child Feeding Tools

As part of the strategies to promote optimal complementary feeding practices, IYCF tools of various forms are used in community-based interventions. Many of these tools are based on the Health Belief behavior change model, which is grounded in the notion that people will engage and adhere to behaviors depending on the perceived severity and risk of health outcomes, and the perceived benefits versus barriers to adopting the behaviors. In this model, cues to action are pivotal in driving an individual's actions to reflect what has been promoted through interventions (36-38). Based on this concept, many external complementary feeding tools have been developed to help reinforce key messages and trigger actions towards TICF, diet diversity, and frequent meals for children under two years.

As an example, counseling cards have been widely used to visually deliver snapshots of the major IYCF messages and stories on scenarios that are relatable to the communities (39). These cards often focus on graphic illustrations and minimize text descriptions to accommodate for low literacy which is widely prevalent in target communities. Previous studies have shown that these cards were well accepted; both community facilitators and beneficiaries stated that the cards encouraged interactive dialogues and acted as a visual reinforcement of previous messages shared during community educational sessions (40, 41).

Innovative designs for child feeding bowls and spoons have also been used as a cue-to-action tool for optimal diet of pregnant women and complementary feeding of children aged 6 to 23 months. The Manoff Group developed simple low-cost bowls marked with age-specific measurement lines that indicate the recommended volume and frequency of meals for pregnant women and children. This demarcation is an intuitive trigger, particularly useful for feeding young children by helping caregivers to determine if the amount of meal fed is adequate for their child's age. Therefore, the bowls serve as an effective tool to help overcome challenges in communicating and reinforcing correct and consistent guidelines on complementary feeding (42).

Along with the child feeding bowl design, the feeding spoon was developed to promote thicker food consistency, which naturally increases the density of the nutrients. This spoon is slotted so that only meals of thick consistency can be held on the spoon, hence cuing caregivers if the child's meal drips through the slots. When implemented in communities, the two feeding tools have been found acceptable and perceived as beneficial by families in many different countries such as Kenya, India, Malawi, Nicaragua, and El Savador (43-46). While acceptance among communities has proven positive, few studies have directly associated the child feeding bowls and spoons with improvements in feeding practices, growth and morbidity (43, 47). More evidence is needed to better understand the benefits of these tools and their effect on complementary feeding, nutrient intake, and subsequent health outcomes such as growth and morbidity.

1.6 Agricultural Intervention

Nutrition-sensitive agricultural intervention is a major example of a food-based approach that uses biofortification of staple crops to promote dietary diversity for both household diets and complementary feeding practices. Biofortification is the process of breeding crops that have a higher micronutrient content. This approach is a sustainable and cost-effective strategy of delivering micronutrients to rural populations that may have limited access to diverse food sources and other nutrition-specific interventions, such as supplementation and food fortification. Therefore, agricultural activities have been integrated into many IYCF projects worldwide in order to alleviate food security in the households and subsequently promote dietary diversity in complementary feeding of young children (48).

Among the biofortified crops currently developed, there has been a large interest in biofortified orange-fleshed sweet potatoes (OFSP) to combat the global VAD crisis. Sweet potatoes are one of the staple starchy foods most produced and consumed around the globe, including in populations most affected by micronutrient deficiencies (48).

While there is little agreement on the efficacy of other biofortified crops, OFSPs have been recognized as the single most successful example of biofortification (49-52).

Looking solely at the nutritional content of OFSP, studies have shown that OFSP from a wide range of geographical sites included *trans*-β-carotene between 5,091 and 16,456 μg/100 g fresh weight (53, 54). This means that, assuming a standard conversion rate of 12 μg beta-carotene to 1 retinol activity equivalents (RAE), an average sized OFSP contains 0.5 to 1.6 mg RAE which meets the Recommended Dietary Allowances (RDAs) of all children up to 8 years of age (54). Even after cooking or large-scale processing, OFSP retained enough carotenoids to meet the RDA of children under five years of age (55-60).

In several studies, biofortified OFSP have proven to be a sustainable, acceptable, efficacious, and cost-effective vehicle to increase vitamin A intake in young children and pregnant women while simultaneously being a calorie-dense food source (51, 52, 61-66). Intervention studies that incorporated OFSP homestead production or school meal plans showed widespread acceptability of OFSP in everyday diets as well as the successful increase in vitamin A intake and serum retinol levels (51, 61, 67-69).

1.7 Challenges in Ethiopia: Undernutrition and Complementary Feeding

Undernutrition in children is disproportionately prevalent and severe in low-income countries. While only about 60% of the children in the world live in low- or middle-income countries (LMIC), 91% of stunted and 82% of wasted children live in these countries (2). East African countries have the highest rate of stunting worldwide.

Ethiopia is one country that suffers from a high prevalence of child malnutrition despite significant interventions.

According to the Ethiopian Demographic and Health Survey in 2016, 38% of children under 5 years of age were stunted, and 10% of the age group were wasted – a prevalence of wasting that is considered a nutritional emergency based on the global acute malnutrition criteria (70, 71). Severity of child undernutrition in Ethiopia varies by rural/urban settings and by regional units. For instance, in 2016, 38.6% of children under 5 years were stunted in the Southern Nations, Nationalities, and Peoples' Region (SNNPR) which is largely rural, whereas stunting in urban Addis Ababa is as low as 15% (70). Given the existing disparities, it is critical to understand the region-specific risk factors as efforts are made in response to this nutritional crisis in Ethiopia.

Ethiopia, despite its achievement in consistently decreasing overall child morbidity and mortality over the past 2 decades, is not an exception to the urgency of VAD (70). Reported national surveys estimated the national prevalence of VAD is 13.9% in Ethiopia (72). Regarding dietary intake, only 38% of children age 6-23 months consumed vitamin-A rich foods. Not only is the overall consumption level low, but the infant consumption varies greatly between regions, ranging from 11.3% (Affar Region) to 69.0% (Addis Ababa). In SNNPR, 48.2% of children aged 6 to 23 months ate vitamin A rich foods in the previous 24 hours of the survey (70). While the infant vitamin A consumption in SNNPR is not the lowest within Ethiopia, the region still requires committed interventions to improve vitamin A intake.

Complementary feeding in Ethiopia also remains a significant challenge. Nationally, 74% of infants under 1 month are exclusively breastfed but gradually declines to 36% by age 4-5 months. Although many infants are prematurely introduced to complementary feeding contrary to the recommended age of 6 months, Ethiopia has seen an overall improvement in TICF at age 6-8 months, increasing from 49% in 2011 to 60% in 2016. However, TICF varies by region and is especially severely lacking in rural areas. Based on a meta-analysis of studies from the past 10 years, prevalence of TICF was reported as highest (86.2%) in the Amhara region while the lowest prevalence (29.3%) was reported in SNNPR. Furthermore, in SNNPR, the introduction of appropriate, nutrient dense complementary foods often occurs later than the recommended window (70). In addition, responsive and active feeding practices are lacking, and portion sizes are generally small. These factors lead to substantially low intake of both calories and necessary micronutrients. Many studies have shown that these suboptimal feeding practices in rural Ethiopian regions are closely associated with stunting and elevated morbidity in young children (73, 74).

1.8 The Quality Diets for Better Health Project

Quality Diets for Better Health (QDBH) is a 54-month nutrition-sensitive agriculture project that aims to enhance the quality of dietary intake among women and children under 2 years of age in SNNPR, Ethiopia. The QDBH project activities are categorized into three components (Appendix Figure A1): homestead production of vitamin A-rich OFSP, community nutrition education on dietary diversity and young child feeding, and an innovative feeding toolkit that promotes higher energy density and adequate serving size. The International Potato Center (CIP) collaborated with People in Need (PIN), Emory University, local health centers, and local agricultural facilities to establish OFSP multiplication sites and facilitate intervention communities called the Healthy Living Clubs (HLC).

As a major component of the program activities, HLC participants receive OFSP vines for home gardening once they are trained on OFSP farming and cooking practices as part of their HLC education sessions. In addition to the HLC session on OFSP agriculture, seven additional HLC sessions were organized monthly to focus on infant and young child feeding and diet diversity for pregnant/lactating women. Based on the barriers and boosters of IYCF practices identified during formative research, Emory University and PIN developed the HLC nutrition curriculum by using the COM-B model of behavior change as its intervention framework (46). Diet Diversity Wheel and goal cards were also disseminated to each HLC household as a visual reminder and to reinforce knowledge and behavior change. A child feeding tool called the Healthy Baby Toolkit was another unique component distributed by the project to optimize household IYCF practices. The toolkit included a demarcated bowl, a slotted spoon, and a counseling card (Appendix Figure A2; toolkit description in Section 1.6). Mothers received the materials during their HLC sessions and practiced using the toolkit as part of the HLC nutrition education curriculum.

A cluster-randomized controlled trial of the QDBH project was conducted during the first phase of implementation to test the enhanced effect of the project by the Healthy Baby Toolkit and to evaluate dose-response effect of the multiple intervention activities. Household dietary surveys were conducted in three phases (approximate months after the start of project implementation): baseline (0 months), midline (7 months), and endline (13 months). The proposed thesis focuses on evaluating the added benefit of the Healthy

Baby Toolkit on the IYCF practices, dose-response effect of multiple levels of intervention exposure, and possible effect measure modification by household food security.

CHAPTER II: MANUSCRIPT

2.1 Title

The addition of a feeding toolkit to a nutrition sensitive agriculture intervention significantly enhanced complementary feeding practices in SNNPR, Ethiopia: results from a longitudinal cluster randomized controlled trial.

2.2 Contribution of the Student

The student led the formulation of thesis research questions, supported data collection and cleaning, led data analyses, and drafted the thesis and manuscript with guidance from the thesis faculty advisor and a doctoral candidate in the Doctoral Program in Nutrition and Health Sciences.

2.3 Abstract

Background Poor complementary feeding (CF) is a major risk factor for the global burden of childhood undernutrition. Quality Diets for Better Health (QDBH) is an integrative agricultural project that aims to improve vitamin A intake and nutrition quality of young children in Ethiopia through promotion of vitamin A rich and climate-sensitive orange flesh sweet potatoes and community-based nutrition education.

Objective This study aims to evaluate the effects of adding child feeding tools to the QDBH package on CF practices and potential effect modification by household food security.

Methods Twenty kebeles in two districts of SNNPR were randomly allocated to one of three intervention groups: full intervention, received feeding toolkit with OFSP promotion and nutrition education; partial intervention, received OFSP promotion and nutrition education; control, scheduled to receive partial intervention at a later date. Effects of the intervention arms were assessed longitudinally among 605 households from participating kebeles. Intent-to-treat analysis applied adjusted logistic regression to examine CF outcomes by intervention group. For as-treated analyses, we created exposure dose scores based on receipt of specific program components and analyzed associations with CF outcomes using logistic regression. Food security status was assessed using the food insecurity experiences scale, and interactions between intervention and food security for CF outcomes was assessed using the chunk test.

Results Controlling for covariates, the odds of meeting minimum dietary diversity (MDD) and minimum acceptable diet (MAD) for a child 6-13 months of age was each significantly higher in the full compared to the control (aOR MDD: 2.40, [2.01, 2.87]; aOR MAD: 2.63, [2.23, 3.09]). The intervention was not significantly associated with minimum meal frequency (MMF). For every additional intervention component received, the odds of achieving MDD and MAD increased by 28% and 27%, respectively. For child's consumption of vitamin A-rich fruits and vegetables, the odds increased in a dose-response manner to both exposures. There was no significant effect modification by food security status.

Conclusion Receipt of the full intervention and each unit increase in program components were each associated with improvements in achieving adequate dietary diversity and overall diet quality in children aged 6 to 13 months.

2.4 Introduction

Complementary feeding is a process of gradually introducing solid and semi-solid foods into the diets of children aged 6-23 months. This transition from exclusive breastfeeding is a critical and vulnerable process that impacts the overall health, growth, and development of children (75). A delay in complementary feeding or a lack of adequate nutrients during this process increases a child's risk of undernutrition, which not only impairs the child's growth but also increases the risk of childhood morbidity and premature death (3, 76, 77).

The burden of childhood undernutrition is especially great for low and middle-income countries (2). As such, caregivers in low-income settings face practical challenges to adhere to infant and young child feeding (IYCF) recommendations (18, 23, 24). In 2017, only one in six children received a minimum acceptable diet in low- and middle-income countries. Since diverse foods are not readily accessible or affordable for poor and rural households, caregivers often feed young children starchy, cereal-based complementary foods and underestimate the meal frequency and consistency for their child's nutritional needs (25). With the challenges of food fortification and national initiatives reaching rural areas of LMIC, comprehensive community-based approaches rather than nutrition-specific interventions are vital to effectively and sustainably address poor complementary feeding practices (5, 24).

In Ethiopia, 38% of children under 5 years of age were stunted (low height-for-age), and 10% of under-5 children were wasted (low weight-for-height) (70). While Ethiopia Ministry of Health (EMH) has been committed to promoting optimal complementary feeding since 2004, Ethiopia's level of adequate infant and young child feeding (IYCF) has remained low over the past decade (70, 78). Ethiopia has seen an overall improvement in timely initiation of complementary feeding (TICF) at age 6-8 months, increasing from 49% in 2011 to 60% in 2016. However, TICF varies by region and is severely lacking in rural areas. Based on a meta-analysis of studies from the past 10 years, prevalence of TICF was reported the highest (86.2%) in the Amhara region while the lowest prevalence (29.3%) was reported in Southern Nations, Nationalities, and People's Region (SNNPR). Also, in SNNPR, the introduction of appropriate, nutrient dense complementary foods often occurs later than the recommended window (70).

Quality Diets for Better Health (QDBH) is a 54-month proof-of-concept, integrative nutrition-sensitive project implemented in the Southern Nations, Nationalities, and Peoples' Region, Ethiopia. The project aims to promote optimal infant and young child feeding practices with three major components: homestead production of vitamin A-rich OFSP, community nutrition education on dietary diversity and young child feeding, and an innovative feeding toolkit called the Healthy Baby Toolkit that promotes higher energy density and adequate serving size.

Based on similar OFSP-focused projects, the QDBH project was expected to achieve elevated production and household intake of OFSP, and subsequently enhance a child’s diet (51, 61, 64, 79). With an integrative educational curriculum and child feeding tools, the project anticipates more effective outcomes in complementary feeding practices and a child’s diet quality (43, 44). However, with many intervention components in place, further investigation is required to understand how the intervention components and intervention exposure levels are associated with the effect obtained post implementation. Particularly, while the QDBH project introduces a child feeding toolkit in addition to the OFSP activities, limited number of studies have directly associated the feeding toolkit with changes in complementary feeding practices and morbidity (43, 47). Therefore, more rigorous evidence is needed to determine the added effect of the toolkit when it is incorporated into a comprehensive nutrition intervention.

To evaluate the impact of the project, a longitudinal cluster-randomized controlled trial (cRCT) was conducted during the first year of the intervention. The intervention groups were divided into two group, one with the Healthy Baby Toolkit and the other without the Toolkit. As part of the cRCT, the objective of the present study was to evaluate the effect of the Healthy Baby toolkit provided by the QDBH project and exposure dose levels on complementary feeding practices for children 6 to 13 months of age. Modified effects of the intervention were also investigated based on different household food insecurity levels.

2.5 Methods

Study site and intervention activities. Quality Diets for Better Health (QDBH) is an integrative agricultural project that aims to improve vitamin A intake and nutrition quality of young children in Ethiopia through homestead production of vitamin A-enriched OFSP and community-based nutrition education.

Since November 2017, Emory University, the International Potato Center (CIP), and People in Need (PIN) has collaboratively implemented program development, dissemination, and evaluation in the Sidama and Gedeo zones within the Southern Nations, Nationalities, and Peoples' Region (SNNPR) of Ethiopia. The project enrolled 13 eligible kebeles to start the implementation of the program during the first year (phase I of the intervention spans from November 2017 to December 2018). By the fourth year, the program will be scaled up to 41 kebeles from three woredas in SNNPR – the Aleta Chuko woreda in Sidama zone and the Wonago and Dila Zuria woredas in the Gedeo zone. All kebeles of these woredas were enrolled in the QDBH project if the kebele had moderate to high potential for OFSP production and did not have current nutrition programs operating.

In each community, Healthy Living Clubs (HLC) were formed with thirty eligible households. To be considered for participation in the Healthy Living Club, households must have: a pregnant woman or child under 2 years of age, approximately 30 m^2 of land for OFSP production, agree to plant OFSP vines, and to participate in education sessions. The project formed two HLCs per kebele, enrolling 780 households in the first year of the project.

Once the HLC participants were recruited, each HLC household received OFSP vines, participated in acceptability tests and cooking demonstrations, and attended an education session that promoted homestead production and consumption of OFSP roots and leaves. Nine varieties of The OFSP vines were distributed to the year-1 HLC cohort (CIP and International Livestock Research Institute; Appendix Table A1). In addition, the HLC participants of both intervention arms attended 8 monthly HLC sessions on nutrition and complementary feeding. CIP and PIN staff trained Health Extension Workers and volunteer leaders of the selected kebeles to facilitate these HLC sessions by using the QDBH participatory learning curriculum which included facilitator discussion guides and audio stories, and provided families with resources for home use including a Diet Diversity Wheel to assist in selecting diverse diets and family diet goal card to support goal setting and goal monitoring around family, maternal and child nutrition. The topics of these HLC sessions focused on infant and young child feeding (IYCF) practices, nutritional benefits of dietary diversity, the importance of VA in maternal and child nutrition, and OFSP as an exemplary VA-rich food source.

Cluster randomized, longitudinal sub-study of the Healthy Baby Toolkit. Additionally, among the 26 kebeles eligible for year 1 of the QDBH project, 20 kebeles were selected for the longitudinal evaluation of the Healthy Baby feeding toolkit as a strategy to enhance project impacts. The Healthy Baby Toolkit consists of a demarcated bowl, a slotted spoon, and a counseling card (Appendix Figure A2). The purpose of the demarcated bowl was to guide caregivers to serve age-specific optimal meal size and frequency for pregnant women and children. The slotted spoon was designed to promote thicker food consistency (thereby higher nutrient density) by cuing caregivers that the food consistency is below optimal energy density (below approximately 1 kcal/g) if the food drips through the slotted holes on the spoon. The counseling card provides pictorial instructions on how to use the card.

These 20 kebeles were randomly allocate to full (n = 7), partial (n = 6) intervention groups and controls (n = 7). The full intervention group received the QDBH nutrition and agriculture activities and the healthy baby toolkit; the partial intervention received the QDBH nutrition and agriculture activities without the toolkit. The control groups did not participate in any intervention activities during the cRCT period; however, they will crossover into intervention activities after year one. The Healthy Baby Toolkit was distributed one kit per household during an HLC, during which the HLC facilitators demonstrated the use with a counseling card. All other aspects of the nutrition education followed the QDBH curriculum.

A total of 605 eligible children and their caregivers were recruited as dyads (full intervention = 182, partial intervention = 154, control = 269) from participating kebeles randomly sampled from the QDBH project (Figure 1). Eligibility criteria included having a child aged 0 to 5.9 months of age at recruitment, participation in a Healthy Living Club for those in the full or partial intervention arms, and consent from primary caregiver and head of household (if applicable) for the survey. Given kebele populations, all eligible households from each kebele were recruited, and if consented, enrolled.

If the household had twin children that met the eligibility criteria, we recruited only one of the twins to form an eligible dyad for data collection. Households were excluded from the study if the child of eligible age had a serious comorbidity such as HIV/AIDS or congenital defects. Dyads were followed up 6 months following enrollment when infants were below 6 months and again 6 months following midline when infants were 6 to 12 months. This manuscript presents findings from the first follow up period.

Data collection. Trained investigators administered standardized questionnaires to collect data on household demographic characteristics and food security, household and women's diet diversity, maternal nutrition knowledge, breastfeeding (enrollment), infant and young child complementary feeding practices (midline), and uptake of QDBH intervention activities (midline). The collected survey questionnaire and anthropometric data were double entered into the Census and Survey Processing System, CS Pro version 7.2 (United States Census Bureau).

Cluster sampling. A total of 20 clusters (kebeles) were selected from the target regions of SNNPR and were randomly assigned to intervention groups. All eligible households from each kebele were enrolled in the study as the target population. Based on the baseline household survey data on maternal dietary diversity scores and the length/height-for-age z-score in the three intervention arms of the QDBH cRCT study, the intraclass correlation coefficient (ICC) for the maternal dietary diversity score was 0.073 and 0.102, respectively.

Ethics. All research protocols were approved by the institutional review board at Emory University and the SNNPR Health Bureau. All study participants provided written informed consent both before project participation and at the start of each survey period. This clinical trial is approved under ClinicalTrials.gov identifier (NCT number): NCT03423472.

Variable specification. A household wealth index was derived from self-reported responses collected at baseline regarding ownership of household assets and livestock, housing characteristics, and access to drinking water and sanitation facilities using principle component analysis to assign indicator weights. The continuous wealth index was then categorized by quintiles. Household food security status was assessed by using the Food Insecurity Experience Scale (80) with a 1-year recall at baseline and a 1-month recall at midline. FIES scores were categorized into 4 levels (food secure, some presence of food insecurity, moderate insecurity, and severe insecurity) when considered as a covariate (81).

Household dietary diversity was assessed during both baseline and midline data collection by using FANTA (Food and Nutrition Technical Assistance III) Household Dietary Diversity Scale (HDDS) (82). At baseline, HDDS scores were generated from the dietary diversity of anyone in the household in the previous 24 hours of 26 food categories. Midline HDDS and women's dietary diversity score were estimated from baseline and midline were tabulated with a similar approach described above.

Infant and young child feeding practices was assessed during midline at which the participating children's ages were between 6 and 13 months. The midline survey asked the child's consumption of 27 foods during the previous 24 hours. These food groups were then merged into 7 major food groups used to tabulate the child's dietary diversity scores based on the WHO guidelines (83). By using the child's dietary diversity score he three major IYCF indicators were generated as described by the WHO guidelines: minimum dietary diversity (MDD; child's diet diversity score ≥ 4), minimum meal frequency (MMF; child consumed at least 2 meals with solids during the previous 24 hours if the child is 6 to 9 months old, and at least 3 meals if older than 9 months), and minimum acceptable diet (MAD; both MDD and MMF were achieved). Child's consumption of vitamin-A rich fruits and vegetables were investigated separately from the 7 food groups used for the child's diet diversity score and MDD. In addition, the number of children who consumed OFSP at least one day during the past 7 days was calculated as a separate variable from the MMF survey questions.

An exposure dose score was developed to investigate the effect of intervention components. Exposure dose score was calculated by summing each score assigned to the receipt of each specific intervention component – HBT bowl and spoon, HBT training, HBT counseling card, HLC diet diversity wheel, HLC goal card, and OFSP vines (Appendix Table A2). Attendance for the HLC sessions was scored by tertiles: scored 0 if the caregiver did not attend any HLC session in the past year, 1 if attended 1 to 6 sessions in the past year, and 2 if attended over 7 sessions in the past year. Receiving each of the intervention resources were scored as 1. Responses stating that they received either counseling card or diet diversity wheel, or both, were scored as 1 since the material on the two handouts was similar. The sum of all six score criteria thus ranges from 0 to 7.

Statistical analysis. Differences in demographic characteristics, potential risk factors, and outcomes of interest were compared across the three treatment groups (control, partial, and full intervention) by performing F tests with regression models; the analyses were also controlled for woreda due to a disproportionate assignment of treatment groups among the three woredas during the cluster randomization process. For continuous variables, linear regression was performed to test association between intervention groups and continuous variables with approximately normal distribution. Logistic regression was used for categorical variables. We similarly examined bias due to loss to follow-up by comparing select baseline characteristics between households followed at midline and those lost to follow-up.

Logistic regression models were used to evaluate the impact of the intervention on dichotomous IYCF outcomes (MAD, MDD, and MMF) and on child feeding of vitamin

A-rich fruits and vegetables. The intervention effect was investigated by three different exposure factors: intervention groups, exposure dose score, and intervention components. The intervention groups were 3-level groups of full intervention, partial intervention, and control. Within a subpopulation of partial and full intervention groups, exposure dose score was evaluated as either a continuous predictor or in tertile levels.

For all exposures, crude odds ratios (cOR) were first estimated without any covariate adjustment. Adjusted odds ratio (aOR) were estimated for logistic regression models controlling for woreda, child's age at midline, child's sex, parents' education and occupation, parents' nutrition knowledge, total household size, household wealth index, and food security at midline. The woredas in this study have geographical and sociocultural differences that may affect the implementation and effectiveness of the intervention, and thereby added *a priori* as a confounder for all models. Child's sex and age at midline were also added as *a priori* confounders to adjust for their biological influence. Confounding assessments on all other covariates were performed for the second models by comparing the 10% range of the estimated OR of the full model (gold standard) with the OR estimates of models with variable(s) of interest dropped from the full model. The final variables included in the regression models to estimate the adjusted OR is summarized in Appendix Table A3.

Household food insecurity is an important risk factor that can adversely affect the food available for child's meals and deter caregiver's adherence to complementary feeding interventions (84, 85). To understand whether household food security status modified the effect of the intervention activities, effect measure modification by household food security status was tested by using chunk test (likelihood ratio test) for the interaction term between exposure variables and midline FIES scores. While FIES scores were treated as a continuous variable for the chunk test, the OR estimates were stratified by FIES categorized into two groups with the median as the cutoff point. Here, the FIES was dichotomized by the median to prevent low or zero cell counts when exposure groups were further stratified by food security status.

SAS 9.4 (SAS Institute, Cary NC) was used for all statistical analyses. To account for the cluster sampling design, PROC SURVEY procedures were used in this software. Significance level of 0.10 was used to assess the significance for interaction; for all other hypothesis tests, p-values below 0.05 were considered statistically significant.

2.6 Results

Baseline characteristics and loss to follow-up. Sociodemographic characteristics of 605 households enrolled at baseline are presented in Table 1. At enrollment, the distribution of woredas assigned to each intervention arm was statistically different when full and partial intervention groups were each compared to the control ($p < 0.01$).

The average maternal age was 26.0 ± 1.5 years. Parental education and occupation did not differ significantly between full intervention and control groups, while significant differences were observed between partial and control groups. Mean household dietary diversity score (HDDS) at baseline was 5.6 ± 0.7 for 605 households and did not differ significantly between intervention arms.

The overall prevalence of moderate to severe household food insecurity among the study participants was 73.7% at the time of enrollment. The distribution of food insecurity levels at enrollment was significantly different between the full intervention group and the control ($p = 0.02$) but not between partial intervention and control groups ($p = 0.07$). However, at midline, the distribution of food insecurity experience scale scores was significantly different for both full and partial intervention groups when compared to the control group ($p < 0.0001$).

Between enrollment and at midline, 57 caregiver-child dyads (9.42%) were lost to follow-up (Table 2). Woredas, maternal age, maternal education, and household dietary diversity scores were not significantly different between participants lost to follow-up and those followed at midline. However, significant differences between the two groups were found in intervention assignment, paternal education, household wealth quintile, household food insecurity, caregiver's dietary diversity scale score, and participating child's sex.

Complementary Feeding by Intervention Group. In adjusted models, the odds of meeting MAD and MDD in the full intervention group were more than two folds that of the controls (aOR MAD: 2.63 [95% CI 2.23, 3.09]; aOR MDD: 2.40 [2.01, 2.87], Table 3). There were no significant effects observed for partial intervention compared to control for MAD (aOR = 1.04 [0.82, 1.31]) or MMD. (aOR = 0.84 [0.66, 1.07]).

When looking at child's consumption of vitamin A-rich fruits and vegetables during the previous 24 hours, both partial and full intervention group showed higher odds of consumption than the control by 24% and 64%, respectively (aOR Partial: 1.24 [1.14, 1.34]; aOR Full: 1.64 [1.46, 1.85]). Neither full intervention nor partial intervention were associated with MMF.

Effect by Dose of Exposure to QDBH Activities. For each unit increase in the exposure dose score, the odds of achieving both MAD and MDD increased by 27% and 28%, respectively (aOR MAD: 1.27 [(1.11, 1.45)]; aOR MDD: 1.28 [1.11, 1.46]). There were no significant associations between MMF and exposure dose score (0.98 [0.90, 1.08]).

When categorized into tertiles, the odds of meeting MDD was 2.9 times higher in the high exposure dose group compared to the low exposure (3.90 [2.35, 6.48]), and three-fold higher in achieving MAD (4.00 [2.34, 6.84]). The odds of achieving MAD for participants with intermediate level of exposure to the intervention was 3.43 times the odds of low exposure (3.43 [2.26, 5.19]), and 3.84 times the odds of participants with low exposure meeting MDD (3.84 [2.52, 5.85]). The odds of meeting MMF remained unchanged between tertile levels of the exposure dose score.

Modified Effect by Household Food Insecurity Interaction of FIES at midline was not statistically significant for any of the three IYCF indicators (Appendix Table A4).

2.7 Discussion

Previous studies have shown promising results in promoting community-based OFSP production to improve maternal and child vitamin A intake and status (63, 64, 68). However, limited evidence exists that explores the added effects of integrating child feeding tools with these agricultural approaches to improve the overall complementary feeding practices. Formative studies in Kenya have found that the feeding toolkits were positively perceived by caregivers (43) and that the tools improve child food intakes, and some studies in Malawi have shown reduction in child morbidity (44, 47). Based on these findings, our study aimed to evaluate the added value of a child feeding toolkit to a nutrition sensitive intervention by means of a rigorous cluster-randomized controlled trial setting. In this study, adding the child feeding toolkit to a nutrition-sensitive agricultural project significantly improved IYCF practices, and there was a dose-response increase in the odds of achieving optimal complementary feeding when household members were exposed to more intervention components.

For the integrative OFSP intervention without the Healthy Baby Toolkit, limited improvement was found in the odds of meeting any of the complementary feeding indicators. However, those receiving the OSFP and nutrition education in the absence of the toolkit had significantly improved odds of VA rich food consumption. This finding is consistent with previous studies in which OFSP interventions were associated with significant increase in vitamin A intake (in retinol activity equivalent) and status (in serum retinol levels) in young children (64).

When the Healthy Baby Toolkit was added to the integrative OFSP intervention, we found significant and large improvements in the odds of meeting the IYCF standards for diet diversity and subsequently for minimum acceptable diet. This finding supports the hypothesis that caregiver's perceived benefits are translated into actual behavioral change (43, 44). Controlling for confounding household and child characteristics, caregivers who received the feeding toolkit had significantly higher odds of feeding 2 or more major food groups as well as meeting the overall minimum acceptable diet. While the toolkit alone aims to specifically improve the meal frequency, no change in the odds of meeting the minimum meal frequency was observed in this study. Rather, the study suggests that child dietary diversity was the main driver for the greater improvement of complementary feeding practices observed when the feeding toolkit was added to the intervention.

The second objective of this study was to determine whether the participant's exposure to more intervention activities was associated with changes in complementary feeding practices. The significant dose-response effect of the intervention components on the minimum dietary diversity suggests that the intervention components form a combined effect on the dietary diversity of the child's diet. This finding highlights previous recommendations on taking comprehensive approaches to improve complementary feeding practices in LMIC (5, 24), suggesting that the recommendations that integrating various modes of nutrition-sensitive interventions may lead to great odds of achieving adequate dietary diversity in a child's diet.

Study Strength and Limitations. The QDBH project design, intervention activities, and evaluation strategy were informed through previous studies in other geographical settings (43, 44, 47, 61, 64) and through extensive formative research of the study area (46). This study, with its rigorous longitudinal cRCT study design, is the first to evaluate the added effects of the child feeding toolkit on complementary feeding practices. The study also enrolled all eligible households from the selected kebeles for the longitudinal study, thereby creating stronger internal validity of the study. While there was a higher rate of loss to follow-up in the control group, less than 10% of the total participants were lost to follow-up at midline. Since the control group have not yet received any benefit from the intervention, people in the control group could have been less motivated to adhere to the study past enrollment.

When kebeles were assigned to the three treatment groups of the study, more than half of the kebeles in the partial and full intervention groups were from Aleta Chuko woreda in the Sidama Zone, while more than half of the kebeles in the control group were from Dila Zuria woreda in the Gedeo Zone. Woredas in the Gedeo zones are known to have poorer and more densely populated kebeles, and recently, many ethnic conflicts in the area caused a large migration of internally displaced people near the border of the Gedeo zone (86). Furthermore, Dila Zuria is geographically near the conflict areas and more likely to be affected by the crisis compared to Aleta Chuko. Therefore, to minimize the confounding effect by woredas, all adjusted odds ratio estimates were controlled for woredas.

While unit increase of the exposure dose score showed significant improvement in complementary feeding, further investigation is needed to understand the relative contribution of each intervention component to the effect. The exposure dose score used in this study has been tabulated by giving equal weights of 1 for all component except for HLC attendance. This weighting scheme does not reflect the actual contribution of the components to the overall effect of the intervention on complementary feeding. Since intervention activities were distributed differently by intervention groups, there is high potential for multicollinearity among intervention activities. Also, there may be a different quality of implementation between the two intervention groups, especially since the HLC attendance varied significantly by intervention arm (Table 4). Considering the potential multicollinearity and difference in implementation, logistic regression analysis approach used in this study is greatly limited in evaluating the components as individual predictors rather than as a tabulated exposure dose score. Therefore, different statistical approaches are needed to investigate the relative effect of each component.

Further understanding of the effects is also needed in the context of household food insecurity. Household food insecurity is an important risk factor of poor complementary feeding (25, 87). As part of the impact pathway of OFSP intervention, the OFSP production is expected to provide additional provision of food sources to either eat within the household or to sell for economic gains. Either action taken after OFSP production would lead to increased household food security. Meanwhile, adherence and effectiveness to the behavioral change curriculum are known to be affected by food insecurity, and the relationship between food insecurity and feeding tools is unclear. Therefore, for an integrative intervention, the role of household food insecurity becomes complex. In a preliminary investigation of this study, household food security status did not significantly modify the effect of the feeding toolkit or the intervention exposure dose (Appendix Table A4). Further analysis is needed to identify the role of household food security in the impact pathway of this integrative intervention.

Conclusions. The results of this study, when considering existing evidence and global guidelines (5, 21, 43, 44, 47), support the child feeding toolkit as an effective tool that offers added benefit to nutrition-sensitive interventions. When toolkits were distributed, the OFSP intervention showed greater improvement in complementary feeding practices, particularly in child dietary diversity and consumption of vitamin A-rich fruits and vegetables. Considering all intervention components of the integrative nutrition-sensitive intervention, higher exposure to various forms of intervention activities can also significantly increase the effectiveness of promoting optimal complementary feeding. Additional research is needed to better understand the effect of the child feeding toolkit and the comprehensive intervention approach in the context of food insecurity.

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2.9 Tables and Figures

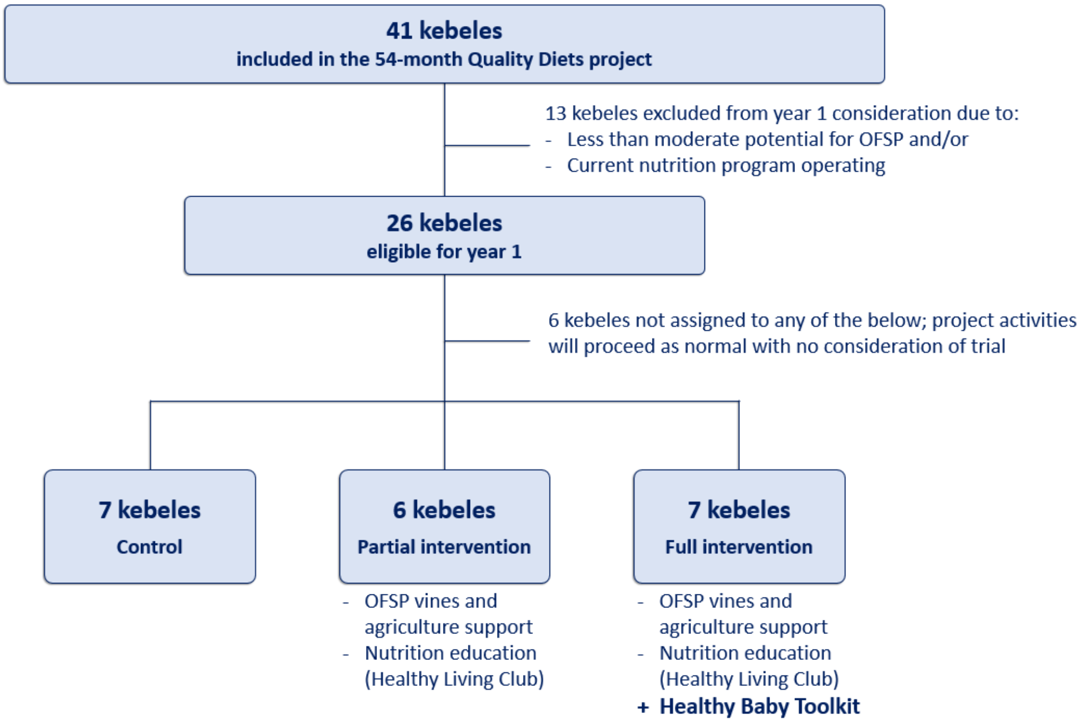

Figure 1. Diagram of randomized assignment of kebeles into full intervention, partial intervention, and control group. Image retrieved from Emory University Institutional Review Board proposal for the Quality Diets for Better Health cluster-randomized controlled trial. OFSP, orange-fleshed sweet potatoes.

Table 1. Descriptive characteristics of the 605 households enrolled in the QDBH longitudinal study in SNNPR, Ethiopia[1]

	Overall	Full	Partial	Control	*P*-difference[2]
Household Characteristics					
n	605	182	154	269	
Woredas					< 0.0001
Aleta Chuko	244 (40.3)	90 (49.5)	96 (62.3)	58 (21.6)	
Dila Zuria	245 (40.5)	62 (34.1)	36 (23.4)	147 (54.7)	
Wonago	19.17 (19.2)	30 (16.5)	22 (14.3)	64 (23.8)	
Maternal age, years	26.04 ± 1.48	26.26 ± 4.99	25.91 ± 3.02	25.97 ± 7.27	< 0.0001
Maternal education, n(%)					0.02
No formal education	185 (30.6)	47 (25.8)	33 (21.4)	105 (39.0)	
1 - 6 y	212 (35.0)	2 (38.5)	68 (44.2)	74 (27.5)	
7 - 12 y	198 (32.7)	64 (35.2)	53 (34.4)	81 (30.1)	
Technical or vocational	8 (1.3)	1 (0.6)	0 (0.0)	7 (2.6)	
University	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.7)	
Maternal occupation, n (%)					< 0.0001
Does not work / housewife	473 (78.2)	141 (77.5)	109 (70.8)	223 (82.9)	
Agriculture	65 (10.7)	22 (12.1)	21 (13.6)	22 (8.2)	
Professional or technical	8 (1.3)	0 (0.0)	4 (2.6)	4 (1.5)	
Other source of income	58 (9.6)	19 (10.4)	20 (13.0)	19 (7.1)	
Missing	1 (0.17)	0 (0.0)	0 (0.0)	1 (0.4)	
Head of household education, n(%)					0.27
No education	48 (7.9)	11 (6.0)	5 (3.3)	32 (11.9)	
1 - 6 y	168 (27.8)	52 (28.6)	53 (34.4)	63 (23.4)	
7 - 12 y	354 (58.5)	115 (63.2)	83 (53.9)	156 (58.0)	
Technical or vocational	22 (3.6)	3 (1.7)	9 (5.8)	10 (3.7)	
University	10 (1.7)	1 (0.6)	3 (2.0)	6 (2.2)	
Missing	3 (0.5)	0 (0.0)	1 (0.7)	2 (0.7)	
Head of household occupation, n (%)					0.01
Does not work	8 (1.3)	2 (1.1)	1 (0.7)	5 (1.9)	
Agriculture	391 (64.7)	126 (69.2)	96 (62.3)	169 (62.8)	
Professional or technical	68 (11.2)	11 (6.04)	23 (14.9)	34 (12.6)	
Other source of income	137 (22.6)	43 (23.6)	34 (22.1)	60 (22.3)	
Missing	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	
Household wealth quintile, n (%)					0.02
Lowest	121 (20.0)	41 (22.5)	20 (13.0)	60 (22.3)	
Second	121 (20.0)	38 (20.9)	37 (24.0)	46 (17.1)	
Middle	121 (20.0)	31 (17.0)	37 (24.0)	53 (19.7)	
Fourth	121 (20.0)	30 (16.5)	33 (21.4)	58 (21.6)	
Highest	121 (20.0)	42 (23.1)	27 (17.53)	52 (19.3)	
Household food insecurity at baseline[3], n (%)					0.05
Food Secure	132 (21.8)	40 (22.0)	33 (21.4)	59 (21.9)	
Some indication of insecurity	172 (28.4)	45 (24.7)	45 (29.2)	82 (30.5)	
Moderate insecurity	139 (23.0)	49 (26.9)	36 (23.4)	54 (20.1)	
Severe insecurity	162 (26.8)	48 (26.4)	40 (26.0)	74 (27.5)	
Household food insecurity at midline[3], n (%)					< 0.0001
Food Secure	67 (12.2)	32 (18.8)	29 (20.3)	6 (2.6)	
Some indication of insecurity	77 (14.1)	25 (14.7)	30 (21.0)	22 (9.4)	
Moderate insecurity	209 (38.1)	65 (38.2)	50 (35.0)	94 (40.0)	
Severe insecurity	195 (35.6)	48 (28.2)	34 (23.8)	113 (48.1)	
Women's Dietary Diversity Scale score	3.16 ± 0.64	3.39 ± 3.21	3.27 ± 2.21	2.94 ± 0.94	< 0.0001
Household Dietary Diversity Scale score	5.59 ± 0.72	5.62 ± 4.18	5.71 ± 2.35	5.51 ± 1.57	0.10
Participatipating child's characteristics					
Child's age, months	2.65 ± 0.41	2.71 ± 1.20	2.87 ± 1.45	2.48 ± 1.32	< 0.0001
Child's sex is female, n (%)	297 (49.1)	87 (47.8)	71 (46.1)	139 (51.7)	< 0.0001
IYCF indicators at midline					
Minimum acceptable diet, n (%)	91 (16.6)	47 (27.7)	25 (17.5)	19 (8.2)	< 0.01
Minimum dietary diversity, n (%)	96 (17.5)	49 (28.8)	25 (17.5)	22 (9.4)	< 0.0001
Minimum meal frequency, n (%)	452 (82.9)	141 (83.4)	125 (87.4)	186 (79.8)	< 0.0001
VA-rich fruits and vegetables consumed yesterday, n (%)	266 (48.6)	92 (54.1)	64 (44.8)	110 (47.0)	0.10
OFSP consumed in the past 7 days, n (%)	32 (5.9)	18 (10.6)	10 (7.0)	4 (1.7)	0.02
OFSP leaves consumed in the past 7 days, n (%)	16 (2.9)	9 (5.29)	5 (3.5)	2 (0.9)	< 0.0001

[1] Values are n(%) or means ± SEs and collected at baseline unless otherwise indicated. For midline, total sample size = 548. Full, full intervention (agriculture activities + nutrition/health education + Healthy Baby Toolkit); Partial, partial intervention group (agriculture activities + nutrition/health education); QDBH, Quality Diets for Better Health; VA, vitamin A; OFSP, orange-fleshed sweet potato. n (%), column percentage is shown for the frequency counts of each follow-

[2] *P*-difference between intervention groups were estimated by performing *F*-tests on cluster-adjusted regression models; all regression models with were

[3] Food Insecurity Experience Score (FIES) at baseline (13-month recall period, N = 605) and at midline (1-month recall period, N = 548). FIES is categorized as follows: FIES score = 0 is categorized as food secure; FIES = 1 to 3 is categorized as milld food insecurity; FIES scores = 4 to 6 is categorized as moderate food

Table 2. Characteristics compared between participants lost to follow-up and followed at mildline evaluation[1]

	Loss to follow-up	Follow-up at midline	*P*-difference[2]
Baseline characteristics			
n (%)	57 (9.42)	548 (90.58)	
Woredas, n(%)			
Aleta Chuko	20 (8.20)	224 (91.80)	0.14
Dila Zuria	28 (11.43)	217 (88.57)	
Wonago	9 (7.76)	107 (92.24)	
Intervention groups, n(%)[3]			< 0.0001
Control	34 (12.64)	235 (87.36)	
Partial intervention	11 (7.14)	143 (92.86)	
Full intervention	12 (6.59)	170 (93.41)	
Maternal age, y	26.00 ± 2.42	26.05 ± 1.54	0.80
Maternal education, n(%)			0.05
No formal education	21 (11.35)	164 (88.65)	
1 - 6 y	17 (8.02)	195 (91.98)	
7 - 12 y	17 (8.59)	181 (91.41)	
Technical or vocational	2 (25.00)	6 (75.00)	
University	0 (NA)	0 (NA)	
Missing	0 (0.00)	2 (100.00)	
Head of household education, n(%)			< 0.0001
No education	9 (18.75)	39 (81.25)	
1 - 6 y	15 (8.93)	153 (91.07)	
7 - 12 y	30 (8.47)	324 (91.53)	
Technical or vocational	1 (4.55)	21 (95.45)	
University	2 (20.00)	8 (80.00)	
Missing	0 (0.00)	3 (100.00)	
Household wealth quintile, n (%)			< 0.01
Lowest	17 (14.05)	104 (85.95)	
Second	7 (5.79)	114 (94.21)	
Middle	11 (9.09)	110 (90.91)	
Fourth	10 (8.26)	111 (91.74)	
Highest	12 (9.92)	109 (90.08)	
Household food insecurity[4], n (%)			< 0.01
Food Secure	11 (8.33)	121 (91.67)	
Some indication of insecurity	17 (9.88)	155 (90.12)	
Moderate insecurity	10 (7.19)	129 (92.81)	
Severe insecurity	19 (11.73)	143 (88.27)	
Women's Dietary Diversity Scale Score	3.04 ± 0.60	3.17 ± 0.63	0.04
Household Dietary Diversity Scale score	5.54 ± 0.64	5.60 ± 0.73	0.43
Participating child's sex is female, n (%)	24 (8.08)	273 (91.92)	< 0.0001

[1] Values are means ± SEs and collected at baseline unless otherwise indicated; n (%), row percentage is shown for the frequency counts of each follow-up group.

[2] *P*-difference between participants lost and those followed up at midline were estimated by using cluster-adjusted

[3] Full intervention, agriculture activities + nutrition/health education + Healthy Baby Toolkit; Partial intervention group, agriculture activities + nutrition/health education; Control, no intervention.

[4] 13-month recall Food Insecurity Experience Score (FIES) at enrollment. FIES = 0 is categorized as food secure; FIES = 1 to 3 is categorized as some indication of food insecurity; FIES = 4 to 6 is categorized as moderate food insecurity; FIES 7 to

Table 3. Cluster and confounder-adjected effects of an integrated agriculture, nutrition, and health intervention on the infant and young child feeding (IYCF) indicators of children aged 6 to 13 months[1]

	cOR	(95% CI)	aOR	(95% CI)	*p* -value[2]
Minimum Acceptable Diet (MAD)					
Intervention[3]					
Full intervention	4.32	(3.43, 5.45)	2.63	(2.23, 3.09)	< 0.0001
Partial intervention	2.40	(1.86, 3.10)	1.04	(0.82, 1.31)	0.77
Control					
Exposure dose score[4]	1.17	(1.06, 1.28)	1.27	(1.11, 1.45)	< 0.01
High (5-7)	2.35	(1.34, 4.00)	4.00	(2.34, 6.84)	< 0.0001
Medium (2-4)	2.08	(1.18, 3.66)	3.43	(2.26, 5.19)	< 0.0001
Low (0-1)					
Minimum Dietary Diversity (MDD)					
Intervention					
Full intervention	3.92	(3.15, 4.88)	2.40	(2.01, 2.87)	< 0.0001
Partial intervention	2.05	(1.60, 2.64)	0.84	(0.66, 1.07)	0.15
Control					
Exposure dose score	1.16	(1.06, 1.28)	1.28	(1.11, 1.46)	< 0.01
High (5-7)	2.54	(1.52, 4.25)	3.90	(2.35, 6.48)	< 0.0001
Medium (2-4)	2.57	(1.52, 4.34)	3.84	(2.52, 5.85)	< 0.0001
Low (0-1)					
Minimum Meal Frequency (MMF)					
Intervention					
Full intervention	1.27	(1.46, 2.11)	0.98	(0.85, 1.12)	0.72
Partial intervention	1.76	(0.99, 1.64)	1.10	(0.98, 1.24)	0.10
Control					
Exposure dose score	0.99	(0.20, 1.23)	0.98	(0.90, 1.08)	0.73
High (5-7)	1.09	(0.50, 2.35)	1.04	(0.58, 1.87)	0.64
Medium (2-4)	0.81	(0.38, 1.72)	0.85	(0.43, 1.69)	0.89
Low (0-1)					
Consumption of VA-rich fruits and vegetables					
Intervention					
Full intervention	1.33	(1.15, 1.53)	1.64	(1.46, 1.85)	< 0.0001
Partial intervention	0.91	(0.81, 1.03)	1.24	(1.14, 1.34)	< 0.0001
Control					
Exposure dose score	1.04	(0.97, 1.12)	1.08	(1.02, 1.16)	0.02
High (5-7)	1.30	(0.89, 1.90)	1.57	(1.10, 2.23)	0.02
Medium (2-4)	1.52	(1.08, 2.13)	1.51	(1.17, 1.95)	< 0.01
Low (0-1)					

[1] cOR, crude odds ratio, adjusted only for clusters; aOR, cluster-adjusted odds ratio controlled for confounding: woredas, child's sex, child's age at midline, household food security experience score (FIES) at midline, parental education and

[2] *P* -value were estimated for aOR.

[3] Full intervention, agriculture activities + nutrition/health education + Healthy Baby Toolkit; Partial intervention group, agriculture activities + nutrition/health education; Control, no intervention.

[4] Exposure dose score was tabulated by summing the scores for each participant that (a) attended the Healthy Living Club sessions more than 7 sessions (score 2) or between 1 and 6 sessions (score 1) during the past year, (b) received the Healthy Baby Toolkit spoon and bowl (score 1), (c) received the Healthy Baby Toolkit training (score 1), (d) received a diet diversity wheel or a counseling card, (e) received a goal card, and (f) received orange-fleshed sweet potato vines.

Table 4. Participation of intervention components of the Quality Diets for Better Health project in full and partial intervention groups[1]

	N	Full	Partial	*P*-difference[2]
Intervention Components				
# HLC sessions attended[3]				
0 sessions	165	77 (46.7)	88 (53.3)	0.01
1~6 sessions	48	29 (60.4)	19 (39.6)	
Over 7 sessions	95	60 (63.2)	35 (36.8)	
Healthy Baby Toolkit spoon and bowl	124	124 (100.0)	0 (0.0)	NA
Healthy Baby Toolkit training	116	116 (100.0)	0 (0.0)	NA
Diet diversity wheel / counseling card	173	111 (64.2)	62 (35.8)	0.08
HLC goal card	170	108 (63.5)	62 (36.5)	0.10
OFSP vines	205	116 (56.6)	89 (43.4)	0.39

[1] Values are in row percentages shown as n(%). Total sample size at midline: full intervention = 170, partial intervention = 143. Full, full intervention (agriculture activities + nutrition/health education + Healthy Baby Toolkit); Partial, partial intervention group (agriculture activities + nutrition/health education). HLC, Healthy

[2] *P*-difference between participants lost and those followed up at midline were estimated by using cluster-adjusted regression analyses.

[3] The number of HLC sessions attended were categorized into tertile groups.

<u>CHAPTER III</u>: PUBLIC HEALTH IMPLICATIONS

Poor complementary feeding is known to cause child undernutrition and micronutrient deficiencies. Suboptimal complementary feeding practices are particularly prevalent in low-resource settings in which caregivers face challenges in accessing affordable nutrient rich and diverse food sources. Various community-based interventions promoting infant and young child feeding guidelines are implemented based on behavioral change models. Although significant, behavioral change interventions often generate only small improvements in complementary feeding practices (33).

One of the major limitations of behavioral change and nutrition education intervention for complementary feeding is the socioeconomic barrier of not being able to access or afford the sources, such as diverse foods or animal-source foods, recommended from the promotional messages delivered to the caregivers. Another limitation is the attrition in engaging and adhering to the intervention messages (25).

To address the limitation of community-based intervention of complementary feeding promotions, there is a rising interest for program designs with innovative and comprehensive tools that tackle complex root causes in the target communities (21). However, rigorous studies to evaluate the effectiveness of the comprehensive interventions is still lacking. This study demonstrated that child feeding toolkits have an added effect in enhancing dietary diversity beyond implementation of nutrition sensitive agriculture and nutrition education strategies. Therefore, based on this evidence, future programs should consider incorporating feeding tools such as the Healthy Baby Toolkit as a major action-to-cue material to catalyze behavioral change towards optimal complementary feeding.

Appendix: Supplementary Figures and Tables

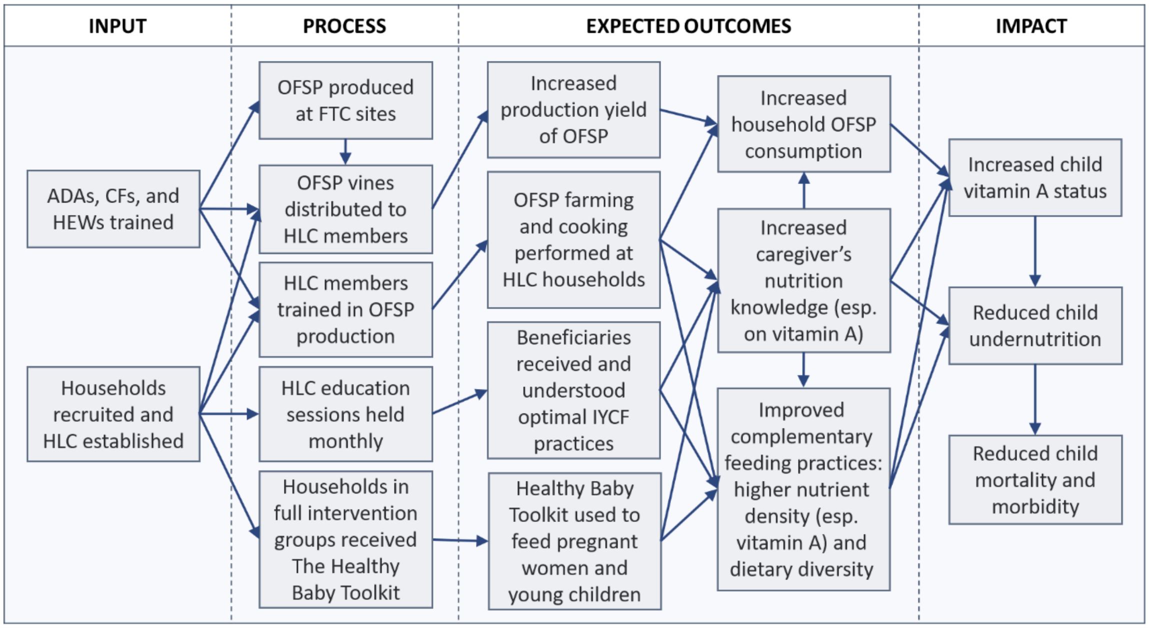

Figure A1. Project impact pathway of the Quality Diets for Better Health (QDBH) project. HLC, Healthy Living Clubs; ADA, agricultural development agents; CF, community facilitators (HLC leaders); HEW, health extension worker; OFSP, orange-fleshed sweet potatoes; FTC, farmer training center; IYCF, infant and young child feeding; MCHN, maternal and child health/nutrition.

Figure A2. Model image of the Healthy Baby Toolkit. The toolkit is a collaborative design of Emory University and Georgia Institute of Technology. The toolkit consists of (1) a feeding bowl demarcated for age-specific meal volume and frequency, (2) a slotted spoon to promote thicker food consistency (and hence nutrient density), and (3) an image-based counseling card to promote diet diversity and hygienic food preparation. Image retrieved from the 2018 Emory University Process Evaluation Presentation of the QDBH project.

Table A1. Orange-fleshed sweet potato varieities received in the full and partial intervention groups of the Quality Diets for Better Health study[1]

	N	Full	Partial	*P*-difference[2]
OFSP Variety Name				
Alamura	68	37 (54.4)	31 (45.6)	0.16
Dilla	67	36 (53.7)	31 (46.3)	0.01
Halaba	53	34 (64.2)	19 (35.8)	0.40
Kabode	48	33 (68.8)	15 (31.3)	0.01
Kulfu	87	46 (52.9)	41 (47.1)	0.27
Naspot12	18	13 (72.2)	5 (27.8)	0.12
Naspot13	19	6 (31.6)	13 (68.4)	0.05
Tule	2	1 (50.0)	1 (50.0)	NA
Vita	23	13 (56.5)	10 (43.5)	0.53
Other	1	0 (0.0)	1 (100.0)	NA

[1] Values are in row percentages shown as n(%). Full, full intervention (agriculture activities + nutrition/health education + Healthy Baby Toolkit); Partial, partial intervention group (agriculture activities + nutrition/health education). OFSP, orange-fleshed sweet potatoes.
[2] *P*-difference between full and partial intervention groups were estimated by using cluster-adjusted regression analyses controlled for woreda.

Table A2. Tabulation plan for the exposure dose score of the Quality Diets for Better Health project. The exposure score represents the level project resources and activities to which the study participants were exposed during the first 6 months of the cluster-randomized controlled trial of the project.

Intervention Categories and Survey Questions	Score AssignmentS
A. Number of Healthy Living Club (HLC) Sessions Attended: number of sessions attended categorized into tertiles *How many HLC sessions have you attended in the past year?*	0 sessions ………… A = 0 1~6 sessions ……… A = 1 Over 7 sessions …… A = 2
B. Healthy Baby Toolkit Bowl and Spoon *Did you receive the Healthy Baby Toolkit spoon and bowl from a Health Development Agent (HDA), Health Extension Worker (HEW), or People in Need Community Facilitator (CIP CF)?*	No …………………… B = 0 Yes …………………… B = 1
C. Health Baby Toolkit Training *Did you receive guidance from an HDA, HEW, or PIN CF on how to use the bowl and spoon?*	No …………………… C = 0 Yes …………………… C = 1
D. Diet Diversity Wheel and Counseling Card *Did you receive the HLC Diet Diversity Wheel or the Healthy Baby Toolkit Counseling Card?*	No …………………… D = 0 Yes …………………… D = 1
E. HLC Goal Card *Did you receive the goal card?*	No …………………… E = 0 Yes …………………… E = 1
F. Orange-Fleshed Sweet Potato Vine Distribution to Households *Did anyone in your household receive sweet potato vines from PIN/CIP within the last year?*	No …………………… F = 0 Yes …………………… F = 1
Exposure dose score (0 – 7) =	sum (A + B + C + D + E + F)

Table A3. Covariate selection for logistic regression models used for estimating the adjusted odds ratio of infant young child feeding indicators. MAD, minimum acceptable diet; MDD, minimum dietary diversity, MMF, minimum meal frequency; VA-rich FV, vitamin A-rich fruits and vegetables (one of the food groups used for tabulating child's dietary diversity score); HHH, head of household; FIES, food insecurity experience scale.

Outcome Variables	Exposure Variables	Covariates included in the regression model
MAD	Intervention groups	woreda, child's age at midline, child's sex, midline FIES, household size, caregiver's occupation, HHH's occupation, wealth index
	Exposure dose scores	woreda, child's age at midline, child's sex, midline FIES, HHH education, HHH occupation, wealth index
MDD	Intervention groups	woreda, child's age at midline, child's sex, midline FIES, household size, caregiver's occupation, wealth index
	Exposure dose scores	woreda, child's age at midline, child's sex, midline FIES, household size, caregiver's education, wealth index
MMF	Intervention groups	woreda, child's age at midline, child's sex, midline FIES,
	Exposure dose scores	woreda, child's age at midline, child's sex, midline FIES
VA-rich FV	Intervention groups	woreda, child's age at midline, child's sex, midline FIES
	Exposure dose scores	woreda, child's age at midline, child's sex, midline FIES

Table A4. Cluster and confounder-adjected effects of an integrated agriculture, nutrition, and health intervention on the infant and young child feeding (IYCF) indicators, stratified by household food insecurity status[1]

	OR_1	(95% CI)	OR_2	(95% CI)	*P*-value[2]
Minimum Acceptable Diet (MAD)					
Intervention[3]					0.93
Full intervention	2.10	(1.66, 2.67)	3.20	(2.65, 3.86)	
Partial intervention	0.87	(0.61, 1.25)	1.19	(0.96, 1.49)	
Control					
Exposure dose score[4]	1.22	(1.07, 1.38)	1.18	(1.06, 1.32)	0.57
High (5-7)	4.05	(0.83, 19.87)	2.76	(1.90, 4.01)	0.21
Medium (2-4)	3.00	(1.08, 8.31)	2.79	(1.75, 4.45)	
Low (0-1)					
Minimum Dietary Diversity (MDD)					
Intervention					0.66
Full intervention	1.77	(1.36, 2.30)	3.41	(2.86, 4.07)	
Partial intervention	0.68	(0.47, 0.97)	1.24	(1.01, 1.53)	
Control					
Exposure dose score	1.21	(1.06, 1.37)	1.18	(1.06, 1.31)	0.60
High (5-7)	2.85	(1.03, 7.88)	2.74	(1.73, 4.34)	0.17
Medium (2-4)	4.95	(1.29, 19.06)	2.95	(2.02, 4.31)	
Low (0-1)					
Minimum Meal Frequency (MMF)					
Intervention					0.14
Full intervention	0.84	(0.76, 0.93)	1.02	(0.80, 1.29)	
Partial intervention	1.76	(1.58, 1.95)	0.62	(0.51, 0.77)	
Control					
Exposure dose score	0.95	(0.84, 1.07)	1.05	(0.97, 1.13)	0.45
High (5-7)					0.66
Medium (2-4)	0.94	(0.34, 2.62)	0.79	(0.40, 1.58)	
Low (0-1)	0.94	(0.43, 2.05)	1.30	(0.84, 2.01)	

[1] The odds ratio estimates were stratified by the median of household Food Insecurity Experience Score (FIES): OR_1, odds ratio for households that are food secure or of mild/moderate food insecurity (FIES below the median, FIES = 1 to 5); OR_2, odds ratio for households with moderate/severe food insecurity (FIES above the median, 6 to 8).

[2] p-value of likelihood ratio test between cluster-adjusted regression models with and without the exposure-food security interaction term.

[3] Full intervention, agriculture activities + nutrition/health education + Healthy Baby Toolkit; Partial intervention group, agriculture activities + nutrition/health education; Control, no intervention.

[4] Exposure dose score was tabulated by summing the scores for each participant that (a) attended the Healthy Living Club sessions more than 7 sessions (score 2) or between 1 and 6 sessions (score 1) during the past year, (b) received the Healthy Baby Toolkit spoon and bowl (score 1), (c) received the Healthy Baby Toolkit training (score 1), (d) received a diet diversity wheel or a counseling card, (e) received a goal card, and (f) received orange-fleshed sweet potato vines.