

Original Research Article

Impact of an enhanced homestead food production program on household food production and dietary intake of women aged 15-49 years and children aged 6-59 months: a pragmatic delayed cluster randomized control trial protocol

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Received: 27 July 2017

Accepted: 06 September 2017

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ABSTRACT

Background: Undernutrition remains a public health problem in Cambodia. To address this, Helen Keller International has implemented an enhanced homestead food production (EHFP) program that provides agricultural inputs and, nutrition, hygiene, and gender empowerment training. This research evaluates the impact of EHFP on dietary intake of women and children and, household food production.

Methods: This two-year pragmatic delayed cluster randomized controlled trial will be conducted in 600 households in Kampot, Cambodia. Half the households will be randomly assigned to the intervention group and administered the EHFP program immediately. The remaining households (control) will be delayed for one year after which they will receive EHFP. In year one in the control group and year two in the intervention group, household data on food production and income generation will be collected using monthly surveys and, dietary data will be collected using 24-hour recalls from women 15-49 years and children 6-59 months twice during the year. Primary outcomes are differences between the treatment groups in mean intake of zinc and vitamin A among women and children. Secondary outcomes are differences between the treatment groups for other key nutrients and the incremental net monetary benefit of EHFP. Additional outcomes including household food security, women's empowerment, and hygiene practices from larger project data will also be assessed.

Conclusions: The results of this trial will assess the impact of EHFP on household food production and the dietary intake of women and children.

Keywords: Enhanced homestead food production, Nutrition, Pragmatic delayed cluster randomized controlled trial, Cambodia

INTRODUCTION

In Cambodia undernutrition remains high, especially among the rural poor.¹⁻³ Stunting is over 40% in young

children and underweight is 20% among women of reproductive age (WRA).^{4,5} Undernutrition stems, in part, from a combination of inadequate food intake, lack of dietary diversity and a high reliance on white rice.⁴ To

combat undernutrition and improve food insecurity in Cambodia and elsewhere, Helen Keller International (HKI) has implemented an Enhanced Homestead Food Production (EHFP) program that provides women farmers and their families with inputs for micronutrient rich fruits, vegetables, and animal source foods, technical assistance on improved agricultural techniques, and nutrition and women empowerment training.^{2,3} It is theorized that by equipping women farmers with inputs and educational resources, technical assistance, and behaviour change communication (BCC), families will enjoy year round access to nutritious food thereby improving indicators of nutrition and food security of women and their young children.³

To test this hypothesis in Cambodia and assess the impact of EHFP model at improving food security, nutrition outcomes, and women's empowerment, we conducted a cluster randomized controlled trial (RCT) from 2011 to 2014 known as Fish on Farms (FOF). In FOF, 900 households were randomly assigned to one of three arms: 1) EHFP (gardens only); 2) EHFP+F (gardens plus small pond aquaculture); or 3) control. Among intervention households (n=600), 60 village model farms (VMFs) were also purposively selected to function as demonstration farms and microenterprises providing inputs and technical support to intervention households in each village. After completion of the 22-month trial, intervention households had higher food production, greater income from sale of surplus products, higher household food security, dietary diversity, and significantly higher intakes of key micronutrients in comparison to the control group.^{6,7}

Despite successes, several challenges did arise, including lack of time for farms to reach their full potential; difficulties producing fruit, vegetable, and fish during the dry season; lack of diverse market opportunities; high attrition due to employment related migration; and the persistence of gendered divisions of labour in agriculture with women doing much of the work in the field and in the home.⁷ Furthermore, a single 24-hour dietary recall (with repeat assessments) conducted at end-line could not capture seasonal variation in consumption among women and children as the surveys were conducted during the dry season.⁶ Similarly, an economic evaluation on the cost-effectiveness of EHFP conducted by Lakzadeh highlighted gaps in data on household food production⁸. Specifically, since Lakzadeh's evaluation was conducted alongside the RCT, production data was limited to end-line survey data alone based on respondents' recall and therefore did not reveal an objective comparison of the costs of inputs required for EHFP and the monetized net benefits (dollar value of all EHFP products at market value) throughout the whole agriculture cycle.

To address these gaps in research and build on the strengths of fof, the scale up study, known as family farms for the future (FF4F), was conceived. In FF4F, we will test the scalability of ehfp across diverse ethnic

(KHMER, Chinese, and Vietnamese), religious (e.g. Buddhist and Muslim), and agro-ecological zones (e.g. Coastal, lowland, highland, and Mekong delta) in Cambodia, and assess the feasibility of a cost-sharing model in which beneficiaries self-select and financially contribute to an EHFP model of their choice (home gardens only, home gardens plus aquaculture, or home gardens plus poultry). We hypothesise the cost-sharing component and choice in intervention will minimize attrition and ensure stronger beneficiary buy-in and project sustainability. Furthermore, to establish evidence base of the impact of EHFP on food production throughout the agricultural cycle and capture seasonal variation in dietary intake, we will conduct a pragmatic delayed cluster randomized controlled trial (PDCRCT) within a sub-sample of the larger study population. When compared with RCTS, pragmatic research designs have the benefits of flexibility in design mimicking real world conditions, while maintaining rigor with respect to internal and external validity.⁹⁻¹⁰ here we describe the study design and protocol of the PDCRCT.

METHODS

FF4F program overview

The PDCRCT, nested within the larger FF4F scale up study, will assess the impact of an EHFP program in contributing to improvements in agricultural productivity and dietary intake of women and children. To do this, a non-probability sampling method will be used to obtain a sample of 4600 households for the scale up study in four target regions: Kampot, Kampong Cham, Prey Veng and, Khan Meanchey, a peri-urban district of Phnom Penh. These regions have been selected to capture the range of social, economic, and agro-ecological zones that exist within Cambodia and seek findings that mimic the wider population. Additionally, as a critical component of the scale up, we will target households for EHFP based on interest, available resources and willingness to cost-share through personal savings, loans from families and/or microcredit.

Targeting of households

Once project areas are identified for scaling up, a formative research piece will be conducted to ensure the feasibility of the proposed study. Specifically, the situational assessment will document existing agricultural and nutrition practices, household preferences, and willingness to participate in EHFP in each area. Gender dynamics in the target areas will also be evaluated through key informant interviews with provincial and district authorities and potential beneficiaries. To avoid duplication and ensure underserved villages are included, initial steps in the targeting of households will consist of a series of meetings with provincial agriculture and health officials and key non-governmental organizations. These meetings will allow us to generate a preliminary list of

existing household food production and nutrition programs in each of the target areas and their geographic scope. This mapping exercise will then be repeated with district, commune, and village level officials for accuracy until a shortlist of villages that would benefit from the FF4F project will be generated. Based on our findings from the situational assessment and mapping exercises, a preliminary list of (n=~270) villages will be generated for recruitment.

After the villages are identified, HKI staff will hold meetings with chiefs of selected villages to inform them about the project objectives, strategy, and selection criteria for households and village model farms (VMFs)—demonstration farms that function as microenterprises supplying inputs and providing technical support to households in each village. Following these meetings, a list of potential households

and VMFs in each village will be generated. HKI staff, with support from village chiefs who will organize community consultations, will then discuss the various EHFP models, the cost-sharing requirements, and eligibility criteria for enrolment in the project with selected villages. These recruitment activities will be repeated until a total sample of 4600 households and one VMF per village are enrolled in the study (see Figure 1). The sample size for the overall scale up study was therefore not calculated to detect a change in any outcome variables, rather it was chosen pragmatically to assess program uptake, scalability, and the sustainability of a cost sharing EHFP model.

To be eligible for participation in FF4F, target villages, VMFs, and households must meet the selection criteria outlined in Table 1.

Table 1: Selection criteria for participation in FF4F.

Selection criteria for Villages participating in FF4F	Selection criteria for village model farms in FF4F	Selection criteria for households participating in FF4F
<ul style="list-style-type: none"> • Not currently involved with other food production or nutrition activities by other NGOs • Have a suitable climate for production of vegetables/fruits and/or poultry and/or fish • Household interest in commercial, medium and small-scale food production activities • Available resources including family labour and interest for microcredit • Willingness to invest in EFHP activities • Produce a final list consisting of information on: district name, village name, commune name, and number of households in the locality. 	<ul style="list-style-type: none"> • Own at least 1,200 square meters of land that can be used to establish the model farm excluding fishpond and poultry area • Be willing to include all three EHFP components in model farms: 1) gardens; 2) aquaculture and; 3) poultry • Be willing to adjust to circumstantial changes to farming and new ideas as offered by HKI and NGO staffs, and willing to offer technical assistance to other households in the village • Establish regular communication with the households under the VMF • Be able and willing to maintain the VMF throughout project lifecycle • Be well accepted by the group members • Be interested in providing input and marketing support to group members • Be willing to share at least 85% of agricultural input cost. 	<ul style="list-style-type: none"> • Available access to homestead land for home garden and/or fishpond and/or poultry production • Available access to labor to undertake the homestead production activities • Be able and willing to maintain the homestead food production activities throughout project lifecycle • Willingness to share 50% of cost for agriculture inputs; • Has a woman of reproductive age (15-49 years) and/or a child under 5 years of age.

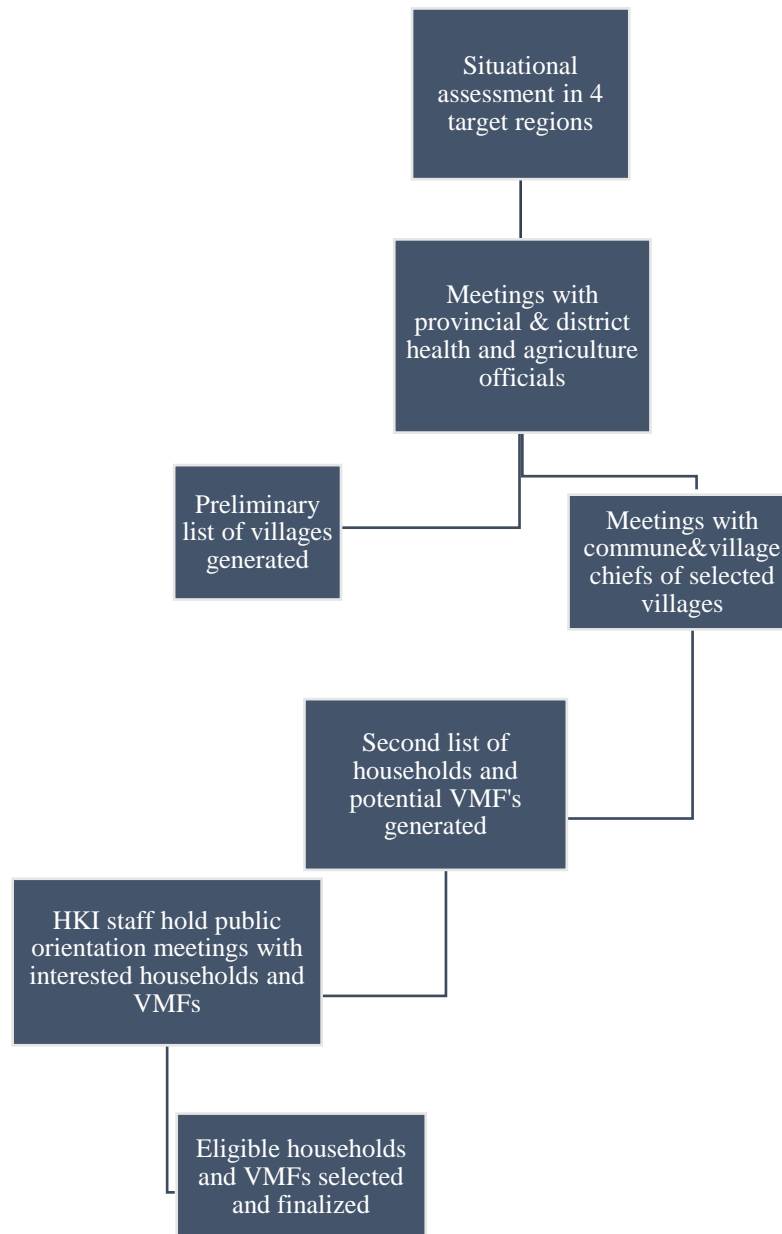


Figure 1: FF4F targeting and recruitment flowchart.

EHFP interventions

Households who elect to participate in FF4F will choose from one of three EHFP models: 1) home gardens only; 2) home gardens plus aquaculture; or 3) home gardens plus poultry. Once households have selected their EHFP model, they will receive the corresponding inputs; specifically, fruit and vegetable seeds, fish fingerlings, chicks, and technical training. The costs of inputs will be shared such that the project will contribute 50% and households will contribute 50%. Once inputs are distributed, training on improved agricultural practices will be conducted by project staff twice per year (initial and refresher training). Training will occur at VMF owners' homes, as these individuals have large farms with the capacity to maintain a demonstration plot of all three EHFP models. Counselling on infant and young

child feeding (IYCF) practices, water, sanitation and hygiene (WASH) and, maternal and child nutrition will also be conducted at the VMF by trained village health volunteers using modules from the World Health Organization's Essential Nutrition Actions twice per year (initial and refresher training).¹¹

Seven monthly sessions of gender equity training will be conducted at the village level using an adapted version of the nurturing connections manual.¹² Nurturing connections incorporates various activities such as demonstrations, role playing, games, and peer practice which aims to create a safe space for dialogue and to foster a deeper understanding of power hierarchies, domestic violence, decision making and asset control between men and women.¹²

Finally, to improve women farmers’ value chain participation and sales of surplus products, business and entrepreneurship training will be conducted. Specifically, we will develop and pilot business tools that will allow farmers to track household expenses and profits, improve crop selection, and track market price fluctuation.

Pragmatic delayed cluster randomized controlled trial research design

According to Ford and Norrie, the level of pragmatism in a pragmatic design is evaluated on nine dimensions: eligibility criteria, recruitment process, setting of the trial, resources harnessed by implementing organizations, flexibility in delivery and compliance with the intervention, degree of follow-up, and relevance of outcomes to study participants.¹³ These dimensions are

then compared against usual care, in this case, traditional homestead food production (HFP) for similarity. Where RCTs determine efficacy of an intervention in tightly controlled settings, pragmatic RCTs seek to establish evidence of uptake in real-world settings. Therefore, in this study several elements of pragmatism will be present: neither the investigators nor the participants will be blinded; recruitment will be purposive rather than random selection; participants in the intervention group will self-select their preferred EHFP model; intervention and control groups will be balanced in terms of demographic and socio-economic characteristics; the intervention will be administered by a mix of practitioners with varying degrees of expertise; compliance will be flexible as enrolment will be based on interest and cost-sharing; and the unit of analysis will be at the household (group) level rather than individual level.

Table 2: Timeline of surveillance research activities.

Trial Timeline (months)	0	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Targeting/recruitment for all trial participants	X																								
Random selection of households for surveillance		X																							
Implementation of EHFP (intervention group)		X																							
1 st round of 24 HDR (intervention group)																X									
2 nd round of 24 HDR (intervention group)																								X	
Monthly production survey (intervention group)																X	X	X	X	X	X	X	X	X	X
Monthly market survey (intervention group)																X	X	X	X	X	X	X	X	X	X
Implementation of EHFP (control group)																	X								
1 st round of 24 HDR (control group)					X														X						
2 nd round of 24 HDR (control group)											X									X					
Monthly production survey (control group)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Monthly Market Survey (Control Group)			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

For the PDCRCT, a subset of the larger study population living in one of the scale up study provinces, Kampot, will be followed to assess the impact of the project on household food production and dietary intake of women and children throughout a full agricultural cycle (1 year). In the first year of the trial, EHFP will be delayed for the

control population and data will be collected on production and income generated from agriculture activities, monthly. To capture seasonal fluctuations in prices of agricultural products, a monthly market survey will also be conducted at the district and village level. In addition to this, 24-hour dietary recalls will be conducted

twice in the agricultural cycle, during lean and peak seasons, with women heads of the household (15-49 years of age) and children (6-59 months). After completion of this, control households will be given free inputs for the EHFP model of their choosing. In the second year of the trial, data collection procedures will be repeated in a similar fashion with intervention households after they have completed implementation of EHFP for one year. The trial will be conducted for approximately two years. See Table 2 for the detailed timeline of research activities.

Ethics

The trial is registered at Clinicaltrials.gov (NCT02786368). Ethics approval was obtained from the National Ethics Committee for Health Research (Approval Number: 471NECHR) from the Kingdom of

Cambodia and the University of British Columbia Behavioral Research Ethics Board (Approval Number: H1500720). Written informed consent will be obtained from participants prior to any data collection. In the event participants are illiterate, consent forms will be read aloud by project staff and an ‘x’ will be obtained in place of a signature.

Sampling procedure and sample size

The sample size for the PDCRCT was calculated to detect a difference in zinc and vitamin A intake between any two groups. With 80% power and alpha of 0.05, assuming a 30% attrition, we estimate that 504 participants (252 subjects per group) will be needed to see a 50% increase in vitamin A intake. Likewise, to see a doubling of zinc intake we estimate we would require 325 participants per group.

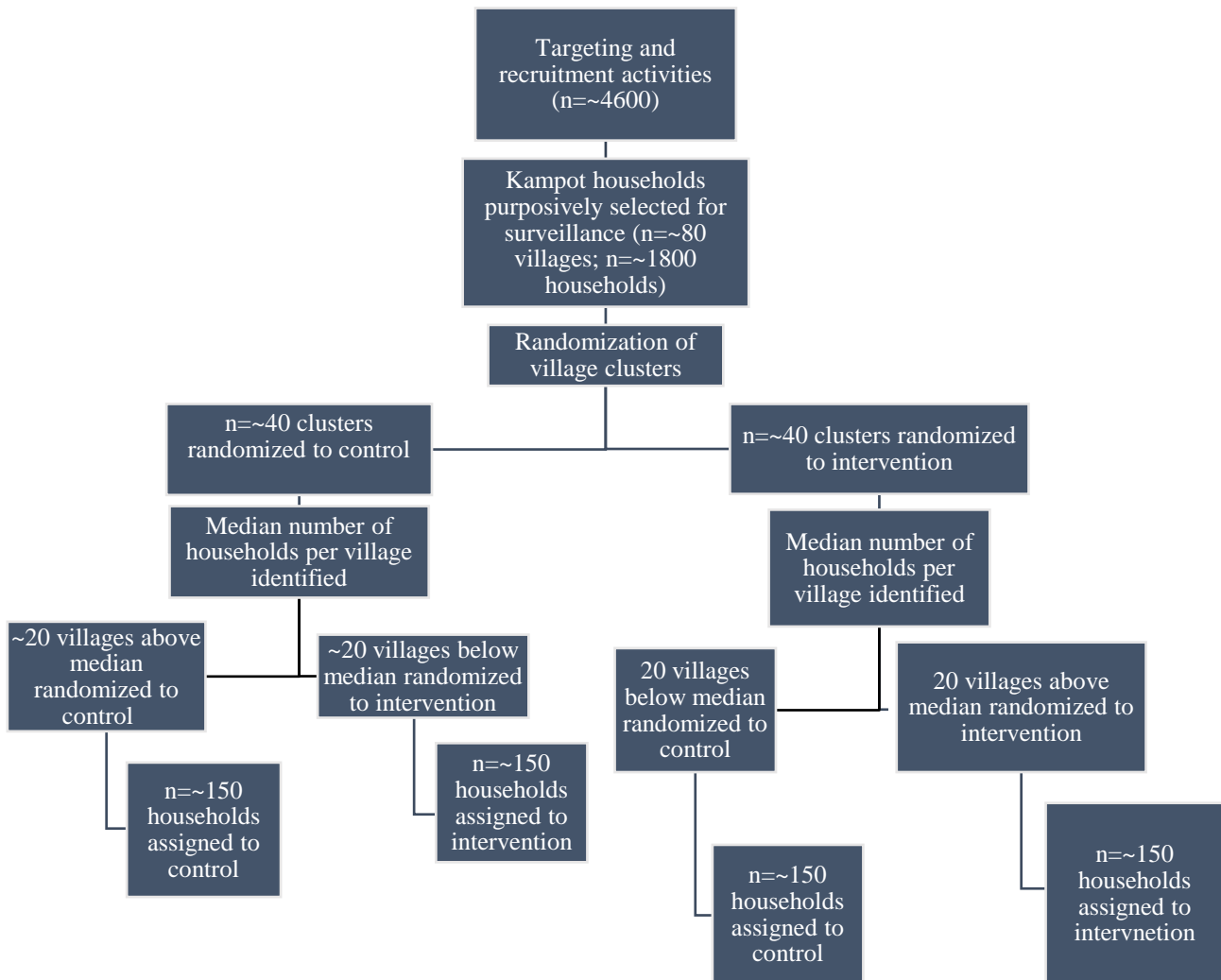


Figure 2: Surveillance trial participant flow.

The trial sample will be derived from FF4F participating households in Kampot province, where approximately 80 villages (clusters) comprising 1800 households are expected to be enrolled (see Figure 2). All 80 clusters will be included in the sampling frame and will be randomized into one of two groups, control or intervention. First, the clusters will be stratified by the median number of households per village – an even number of (n=20) clusters above and below the median will be randomized to either the intervention or control groups in order to get a proportionate number of households in each group. In the end, 300 households will be randomized to the control group (no EHFP in year one) and 300 households to the intervention group (EHFP model of their choosing for two years).

Selection criteria

To be eligible for participation for the trial, households are required to meet the following criteria:

- Have a woman of reproductive age between 15-49 years of age living in the household;
- Have a child 6-59 months of age living in the household;
- Fall within the two lowest wealth quintiles determined by village wealth rankings based on income and assets;
- Demonstrate a willingness to cost-share on agricultural inputs;
- Have suitable land for EHFP activities; and
- Give informed consent to participate in the program.

Data collection procedure

To account for seasonal variation in diets and obtain detailed information on dietary habits, an adapted version of the 24-hour dietary recall interview method, the multi-pass method, will be used.¹⁴ Trained enumerators will visit households two days prior to the interview and provide respondents with eating utensils (2 bowls, 2 cups, 2 plates, and 2 spoons) and a picture chart of commonly consumed food items and beverages. Respondents will be asked to use the provided utensils the day before the interview and to mark everything they consume from the time they wake up to the time they sleep for both themselves and their child. At the time of the interview, respondents will be asked to produce the marked-up picture chart and all food packaging from the previous day. The open-ended interview will be conducted in four distinct steps or “passes”. Information will be systematically recorded with picture aids and probes to aid recall and obtain full description of items. Specifically, the respondents will be asked to estimate portion sizes using modelling clay and rice on the provided utensils in order to increase visualization and improve estimation of portion sizes. Repeat recalls on a non-consecutive day within a 20% sub-sample of the same group will also be conducted to account for day-to-day variation in food consumption. Seasonal variation in

dietary patterns will also be captured by conducting interviews at two points in the agricultural cycle (see Table 2).

To objectively measure production of fruit, vegetable, fish and poultry outputs, participating households will be given scales and simple, picture-based ledgers to record production and record in kilograms the types and amounts of EHFP outputs harvested, consumed, gifted and sold daily, as well as any income earned from the sale of goods. Once a month, HKI staff will visit households and record production and income data on an electronic surveillance form. Market values for all varieties of vegetables, fruits, fish and poultry outputs will also be collected from the nearest retailer (e.g. district, local, or village markets and, mobile seller) for each cluster monthly. Together, these two surveys will be used to account for market fluctuations and allow us to monetize EHFP outputs throughout the whole agricultural cycle.

Outcomes

The two primary outcomes for this trial are differences between control and intervention groups in:

- Change in mean intake of zinc and vitamin A [measured by 24-hour dietary recall surveys with women of reproductive age (15-49 years) and children (6-59 months) at time 1 and time 2 with repeat recalls on a subset of the sample].

The secondary outcome measures of interest are differences between control and intervention groups in:

- Change in mean energy, protein, fat, riboflavin, thiamine, iron, and calcium intake [measured by 24-hour dietary recall surveys with women of reproductive age (15-49 years) and children (6-59 months) at time 1 and time 2 with repeat recalls on a subset of the sample].
- Change in Household food security [measured by scores on household food insecurity access scale (HFIAS) at baseline and end-line].¹⁷
- Change in Women's empowerment / gender equity [measured by modules from the Women's Empowerment in Agriculture (WEIA) questionnaire pertaining to household decision-making on production and use of money at baseline and end-line].¹⁸
- Change in incremental net monetary benefit [measured by cost-benefit analysis from the perspective of the project. Costs will be determined from HKI's budget expenses and participants' reported expenditures on inputs from monthly production and market surveys. Benefits will be measured by converting the total kilograms of each EHFP output produced over one year to a dollar value using local market prices from monthly production and market surveys].

- Change in WASH practices [measured by questionnaire on knowledge, attitudes and practices and percentage of uptake at baseline and end-line].

Data analysis

1. Dietary intake

Statistical analysis will be conducted by UBC's Collaboration for Outcomes Research and Evaluation using SAS version 9.4 (SAS Institute Inc. Cary, NC). Descriptive statistics will be summarized for all trial participants at project baseline and compared for any difference between groups. To identify the seasonal variation in dietary intake, we will compute the mean (95% CI) protein, energy, fat, thiamine, riboflavin, iron, calcium, vitamin A and zinc at both the lean and peak agricultural seasons. Prevalence of inadequate intake (POII) at both time points will also be assessed and compared across groups. Secondary outcomes pertaining to livelihood, food security, WASH, and women's empowerment will be compared across treatment groups using the larger program's baseline and end-line surveys.

The independent variable will be categorical; that is, EHFP intervention (regardless of model) or control. Continuous dependent variables used to assess usual nutrient intake will be zinc, vitamin A, energy, protein, fat, thiamine, riboflavin, iron, and calcium. To calculate POII, the estimated average requirement (EAR) cut-point method or probability approach will be used.¹⁵ Since there are no established EARs for fat and energy, POII in the population will only be assessed for protein, zinc, vitamin A, calcium, thiamine, riboflavin, and iron. For iron requirement, non-normal distribution patterns for menstruating women and young children are incongruous with the EAR cut-point method, therefore, the probability approach will be used to estimate prevalence of inadequacy.¹⁶ Usual iron distribution in the sample will be compared to iron requirement distribution percentiles at (15%, 10% and 5% bioavailability) to estimate the probability of inadequacy.¹⁴

To detect the difference in mean intake of zinc and vitamin A across the study arms at end-line, generalized linear mixed models will be performed to include the clustering (village) effect and adjusted for baseline covariates. Secondary outcomes pertaining to livelihood, food security, WASH, and women's empowerment will be analyzed similarly.

2. Production

To ascertain the impact of EHFP on production and the net monetary benefits (NMB), a cost-benefit analysis will be conducted. To estimate the NMB of EHFP, the total average costs of inputs will be subtracted from the monetized benefits (total dollar value of production) for both treatment groups. Because this is a pragmatic study intended to depict real world conditions, a per-protocol analysis will be employed in addition to the intent-to-treat

analysis. Average production value of fish, poultry, fruit and vegetable outputs will be determined according to randomization in to the control or intervention group. Per-protocol analysis however, will only include households that maintained their selected EHFP models. A generalized linear mixed model will be used to adjust for the clustering and determine differences in production between treatment groups.

DISCUSSION

Combating food insecurity and under nutrition requires a multi-pronged approach that addresses factors that constrain women's agency in Cambodia, namely, poverty, lack of resources and gender inequity, as well as environmental conditions that impede household food production.^{4,19} Furthermore, suboptimal IYCF practices coupled with poor sanitation and hygiene practices have been shown to negatively impact maternal and child nutrition.²⁰ The effectiveness of EHFP in improving food security and nutrition outcomes has been assessed in the FOF RCT however, methodological limitations with respect to dietary assessments, agricultural production data, and high attrition rates, call for more rigorous research to be conducted.⁶⁻⁸ Indeed, a systematic review conducted by Pandey et al, revealed that although numerous nutrition-sensitive agriculture studies have been commissioned in recent years, there is a lack of conclusive evidence of the impact of agriculture on nutrition outcomes.²¹ FF4F seeks to build on the lessons learned in FOF and through a PDCRCT design capture the seasonal variation in dietary intake of women and children with or without the intervention.

A key limitation that may impact our data will be the temporal change in the children. Because of the delayed intervention design, children in the intervention group will be on average one year older than their control counterparts. Despite this, this trial will determine the impact of EHFP on household food production as well as the monetized net benefits of EHFP outputs across the agriculture cycle.

ACKNOWLEDGEMENTS

The University of British Columbia and Helen Keller International, Cambodia extend their gratitude to Global Affairs Canada and the International Development Research Centre for lending financial support to this study. Additional thanks are also given to project and field staff and participating households without whom this project would not have been possible.

Funding: This study was funded by grant 107982-002 from Global Affairs Canada and the International Development Research Centre Food Security Research Fund (CIFSRF)

Conflict of interest: None declared

Ethical approval: The study was approved by National Ethics Committee for Health Research (Approval Number: 471NECHR) from the Kingdom of Cambodia and University of British Columbia Behavioral Research Ethics Board (Approval Number: H1500720)

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Cite this article as: Moumin NA, Hou K, Michaux KD, Stormer A, Mundy G, Porter K, et al. Impact of an enhanced homestead food production program on household food production and dietary intake of women aged 15-49 years and children aged 6-59 months: a pragmatic delayed cluster randomized control trial protocol. *Int J Clin Trials* 2017;4(4):157-65.