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Original Research Article

A Cluster Randomized Intervention Trial to Promote Shoe Use by Children at High Risk for Podoconiosis

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ABSTRACT

The aim was to evaluate whether an intervention including education about the role of inherited susceptibility in development of a tropical lymphedema increased shoe-wearing among high risk children without increasing community stigma. A cluster randomized intervention trial was conducted with caregivers in affected and unaffected households. Six communities in Ethiopia were randomly assigned to: (1) usual care health education (UC), (2) household-based skills training and community awareness campaign (HB), or (3) HB plus a genetics education module (GE). Recruitment for the six month intervention began in February 2012 and study activities were completed May 2013. Primary outcomes 3 and 12 months were direct observation of shoe use by an index child (age 3-6), experienced stigma among affected participants (n=585), and unaffected participants' (n=1,124) reports of enacted stigma. Among affected households, neither intervention arm increased shoe wearing or reduced stigma relative to the usual care condition at 3 or 12 months (shoe wearing 3-month difference (95% CI): HB-UC 0.15 (-0.09, 0.40); GE-UC 0.07 (-0.18, 0.32); 12- month: HB-UC -0.24 (-0.34, -0.14); GE-UC -0.18 (-0.28, -0.08); stigma 3-month: HB-UC 0.42 (-0.63, 1.47); GE-UC 0.62 (-0.43, 1.66); 12-month: HB-UC 0.49 (-0.02, 0.99) ; GE-UC 0.12 (-0.38, 0.62)). Among unaffected households, differences by intervention arms were marginally significant ($p<0.09$) with the GE and HB arms showing the largest baseline to 12 month decreases in enacted stigma: HB-UC -0.25 (-0.64, 0.15) ; GE-UC -0.45 (-0.84, -0.05). Improved understanding of disease heritability showed greatest benefit for unaffected households.

Keywords: intervention, genetics, shoe wearing, neglected tropical disease.

INTRODUCTION

Most health conditions, worldwide, are influenced jointly by genetic and environmental factors. Indeed, a number of heritable health conditions are unlikely to occur in the absence of relevant exposures. [1] Yet, most prevention interventions give little consideration to the hereditary underpinnings of disease. This is due, in part, to concerns that invoking heredity as a contributor to disease may lead the public to falsely conclude that these conditions are

unpreventable.[2] In turn, such misunderstandings are well documented and have been associated with increases in social ostracism and other stigmatizing behaviors directed to affected individuals and families. [3-5] However, even in the absence of open discussions of associations between heredity and health conditions, community members' observations that health conditions "run in the bloodline" also can result in similar misunderstandings and stigma. [2]

Experts from 58 countries have recommended the development of public engagement strategies to inform and educate the public about genomics. [6] However, the challenges of integrating genomics into health promotion interventions in low and middle income countries (LMICs) are great, particularly given the ubiquity of illiteracy and limited public health infrastructure. [7] This makes it difficult to develop effective health communication strategies and supports concerns that education efforts may inadvertently increase stigma. [8]

Prevention of podoconiosis, a debilitating lymphedema, offers an ideal context for evaluating interventions that consider these challenges. Podoconiosis is caused by the absorption of ultrafine silica particles from the soil through the skin of the feet. [9] Endemic in highland Ethiopia, [10] heightened susceptibility to soil exposure clusters in families. Siblings of a case patient are estimated to be at five-fold greater risk than the general population. [11] Older age and walking barefoot are significant predictors suggesting that the condition results from a gene-environment interaction. [11] A genome-wide comparison of the frequency of genetic variants between podoconiosis cases and unaffected controls in Ethiopia revealed that genetic variants in the HLA locus (a genomic region on chromosome 6) confer susceptibility to podoconiosis. [12]

Recent estimates indicate that as few as 9% of individuals in endemic areas routinely wear shoes. [13,14] This low rate of shoe-wearing is especially discouraging because podoconiosis is preventable if individuals consistently wear shoes and begin doing so early in life. Thus, interventions to increase shoe-wearing could have substantial public health benefit.

Prior work among residents of endemic areas suggests that misconceptions about podoconiosis being contagious and inherited are common [2,14] and associated with increased social stigma, [15] and lessened motivation to wear shoes consistently. [2] While there is no national prevention and treatment program for podoconiosis, Mossy Foot International (MFI), an international Non-Government Organization (NGO), offers prevention and care to approximately 30,000 patients per year in southern Ethiopia. [16]

In consideration of the heritability of podoconiosis, the MFI regularly distributes shoes to children and adolescents under the age of 18 who have at least one first degree relative with podoconiosis -- henceforth referred to as high-risk children. While this approach could have considerable public health benefit, distributing shoes solely to those at genetically high risk could exacerbate existing interpersonal stigma created by misconceptions about the controllability of podoconiosis.

A plethora of research confirms that ensuring access to preventive services, though necessary, is not sufficient to induce behaviors essential to adherence. [17,18] Numerous barriers to footwear have been documented, including beliefs that regular shoe wearing runs counter to a common desire to preserve shoes. [2,14] No research has been conducted to date to address these and other barriers among high-risk children and their caregivers, the target groups most

important for primary prevention of podoconiosis.

Most interventions in LMICs have relied on the involvement of individuals from the community (e.g., lay health educators) to provide ongoing support and to model desired behaviors. This strategy has the advantage that it fosters community ownership of the intervention and increases the long-term sustainability of the intervention [19] and been shown to be effective in a variety of health programs. [20] Accordingly, MFI relies on recovered patients to serve in the role of lay health educators (LHEs) are volunteers who have been treated themselves for podoconiosis.

This report describes a cluster randomized community-based intervention trial aligned with MFI shoe distributions to high risk children in six rural Ethiopian communities.

MATERIALS AND METHODS

Trial recruitment began in February 2012 with data collection completed in May 2013. Study protocols were reviewed and approved by the University of Addis Ababa and National Human Genome Research Institute ethical review panels.

Setting: The study was conducted in the Wolaita zone of southern Ethiopia. This zone is the location of an NGO (Mossy Foot International, MFI) that for the past 16 years has provided treatment to podoconiosis patients through a structured system of 13 'outreach clinics'. Six communities participating in MFI-sponsored shoe distribution were identified. Communities selected were those with clinics that served the largest number of affected families to enable rapid recruitment and intervention delivery before the onset of the rainy season.

***Randomization*:** Communities were stratified by distance from the MFI headquarters in the zonal capital (Wolaita Sodo), and then matched pairs (one distant and one closer site) were randomized using a lottery draw method to one of the three intervention arms: standardized health education (UC), household-based skills training plus community awareness campaign (HB), HB plus education about inherited soil sensitivity (GE). The procedures used to identify and select affected and unaffected households are described in detail in the attached appendices.

Selection of Households: MFI ledgers were used as the sampling frame to identify children ages 3 to 6 scheduled to participate in shoe distributions in the six participating sites. A random sample of 100 children was selected from those scheduled to receive shoes at each of the distribution sites, and data collectors visited their households. Neighboring households were eligible based on the following criteria: (1) no one in the household was a blood relative of anyone living in the matched affected household; (2) the care-giver in the household was not a first degree relative of an individual with podoconiosis; (3) the household included at least one child in the target age group; (4) the household was within 500 meters of the participating affected household; (5) an adult household representative agreed to participate in the study.

Data collection: Interviews were conducted in all six communities at baseline, 3- and 12 months after completion of intervention components. A total of 12 data collectors (2 per community) participated in a three-day training to conduct household enumerations and interviews. The primary outcome for the trial was directly observed shoe wearing at 3- and 12-month follow-up and reported levels of interpersonal stigma. Secondary outcomes included understanding of podoconiosis, situation-specific confidence to prevent and explain causes of podoconiosis and internalized stigma.

Interventions

Standardized Health Education (UC): Affected households in all six communities received standardized health education about proper foot hygiene on the day of the shoe distribution. MFI volunteers provided instruction to parents of the children using laminated pictorial education materials. Unaffected participants in the UC group received no household-based instruction.

***Community Awareness Campaign*:** Communities assigned to HB and GE were exposed to a public education campaign aimed to raise general awareness of the importance of children wearing shoes. A series of posters, stickers and buttons with the study logo and messages addressing barriers to shoe wearing, and a song about the importance of shoe wearing sung by children in a locally popular music style were used in the campaign. The kick-off of the campaign coincided with the scheduled shoe distribution. On the market day that coincided with shoe distribution, posters were placed in the public market areas. The children's song was played on boom boxes with loudspeakers. Buttons and stickers were distributed. This special event occurred twice during the intervention window. The second event coincided with the scheduled booster household sessions described below. Table 1.

Table 1: Overview of Intervention Activities by Arm

	Initial Activities (within 2 weeks of shoe distribution)		Booster Activities (approximately 6 months later)	
Intervention Arm	Affected	Unaffected	Affected	Unaffected
Standardized Health Education (UC)	Standardized health education during shoe distribution	None	Repeat standardized education	None
Community Public Awareness Campaign + Household–based Skills Training (HB)	Public awareness campaign on market day supported by posters, stickers, buttons and children's song		Repeat of community campaign	
	90-minute household-based training conducted by lay health advisors to overcome barriers to shoe-wearing		Repeat of household training to overcome new barriers	
Community Public Awareness Campaign + Household–based Skills Training + Inherited Soil Sensitivity Education (GE)	Public awareness campaign on market day supported by posters, stickers, buttons and children's song		Repeat of community campaign	
	90-minute household-based training by lay health advisors includes extra module on the role of heredity in susceptibility to soil sensitivity as a cause of podoconiosis		Repeat of household training to address barriers, and correct misperceptions about genetic susceptibility	

***Household Skills-Building Sessions (HB and GE)*:** LHEs visited all participating (both affected and unaffected) households to conduct a 90-minute discussion of educational modules. The education modules: (a) provided didactic information about protecting the child's foot from exposure to the soil and how best to wear shoes, and maintain foot hygiene; (b) facilitated discussion of barriers that might interfere with the index child wearing shoes, and (c) encouraged care-givers to problem solve along with other family members about how to overcome these barriers.

Educational module on Inherited Soil Sensitivity (GE): GE participants (both affected and unaffected) received HB modules and one additional module on "Inherited susceptibility to soil sensitivity" guided discussion of the particular importance for children at high risk to wear shoes due to their possible inherited sensitivity to soil exposure.

Booster household sessions: Booster sessions of approximately 90-minutes were conducted with all households in HB and GE approximately six months after the initial intervention session. The objectives for the booster visit were to: (a) refresh didactic information; (b) go over experiences dealing with barriers to shoe wearing and reinvigorate efforts to overcome barriers, and (c) address barriers specific to the rainy season that made it

harder to consistently wear shoes. Additionally for GE, the LHE reviewed issues related to inherited soil sensitivity and discussed any recurring misconceptions.

Primary Outcomes

Observed shoe-wearing (Affected index child): As part of baseline and each follow-up interview, data collectors directly observed and noted whether the index child was present and wearing shoes. Consistent with an intent-to-treat approach to analysis of the full randomized sample, a binary indicator of shoe wearing was coded as "1" (success) if the child was observed at the interview to be wearing shoes, and "0" (failure) if the child was not wearing shoes or was not observed. Results are also presented of a sensitivity analysis using an alternative measure ("*present and wearing shoes*") which was coded similarly, except that the records of children who were not present at the interview were excluded from the analysis

Experienced stigma* (*Affected households): Participants were asked to rate the frequency of ten negative interpersonal experiences (e.g., "people cut down visiting you") that had occurred in the prior three months. Responses to the ten items were averaged (range 1-4) where higher scores were indicative of more experienced stigma (Internal reliability = 0.94).

Enacted stigma* (*Unaffected Households): A measure of preferred social distance was adapted for the context of podoconiosis. Participants were presented with a hypothetical situation and asked their willingness to be in six levels of proximity the hypothetical affected person Mean scores (range 1-3) were calculated from responses to six items, where higher scores indicate higher enacted stigma (Cronbach's alpha = 0.91).

Secondary Outcomes

Consistent with our conceptual framework described elsewhere [2] we identified several secondary outcomes that might be influenced by the interventions.

Accuracy of Understanding (Affected and Unaffected): Participants were asked to rate their level of agreement with each of five statements (e.g., "if there is podo in the family there is nothing that can be done to prevent the disease"). Responses to the five items were dichotomized as correct or incorrect, summed and averaged to compute mean accuracy scores ranging from zero to five(Cronbach's alpha=0.53).

Confidence to prevent podoconiosis (Affected and Unaffected): Responses to three items concerning participants' confidence to prevent podo (e.g., "I have a clear understanding of why some individuals develop podo and others do not") were summed to create a scale. Higher scores (range 0-3) indicate greater confidence (Cronbach's alpha=0.57)

Situation-specific confidence to influence index child to wear shoes (Affected only): For each of six situations (e.g. doing chores, going to school) participants were asked to rate their confidence in "I am able to make sure that the [index child] wears shoes". Mean scores (range 1-5) were calculated from responses to six items, where higher scores indicate higher confidence Cronbach's alpha=0.85).

Confidence to explain causes of podo (Affected and Unaffected): This measure was based on agreement with the statement "I would find it easy to explain to someone else how wearing shoes can protect a person from developing podo". Higher values (range 1-5) indicate greater confidence.

Internalized stigma: To assess internalized stigma, participants were asked to rate the frequency of five different thoughts, feelings or events that had occurred in the prior three months (e.g., "You felt ashamed that members of your family had podo"; Internal reliability = 0.93). Higher scores (range 1-4) were indicative of more internalized stigma

Observed shoe wearing (unaffected index child): This variable was constructed as described above for the affected index child.

Analysis

To account for the cluster randomized design, outcomes were analyzed in Hierarchical Linear Models (HLMs) with 2 levels (level 1: participant, level 2: site). Intraclass correlations from unconditional models ranged from 0.02 to 0.70. The analysis models controlled for a baseline (pre-test) value of the outcome measure and other covariates (participants' age, sex, family size, and child age and sex). For shoe wearing outcomes among affected children, we tested both logistic and linear models. As results did not differ for these approaches, we present results of linear models with adjusted change in outcome from baseline to follow-up. When differences among the treatment arms were detected using a liberal criterion ($p<.10$), results of pairwise tests of differences between each arm are presented.

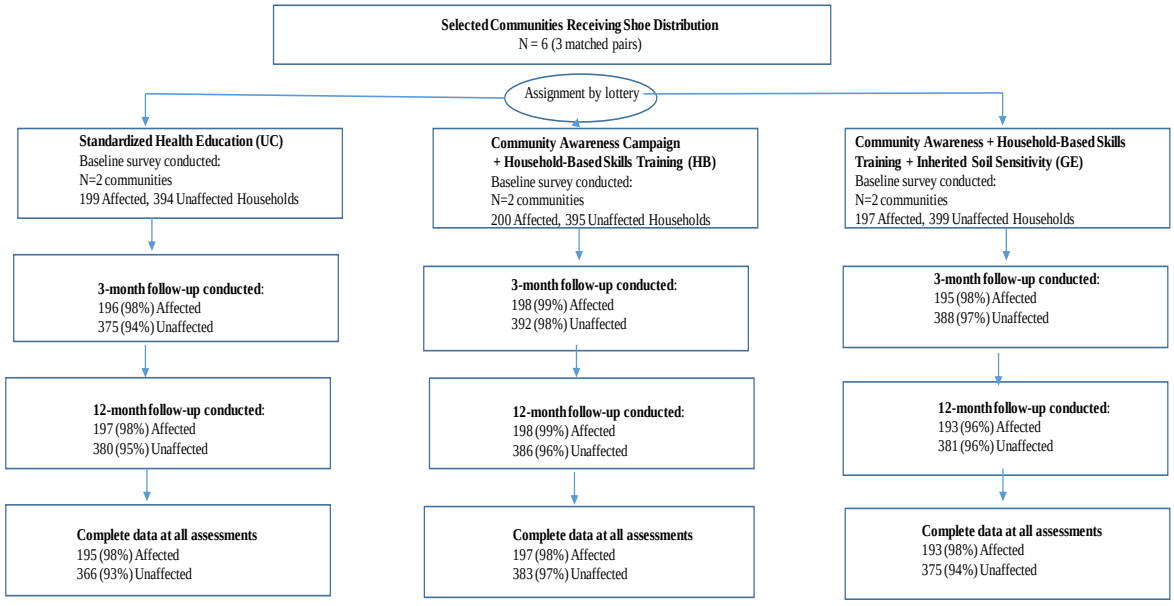
RESULTS

Sample Accrual and Retention

Virtually all of the identified households (N=600 affected; N=1200 unaffected) approached agreed to participate in the trial. Over 90% of study participants completed each follow-up across communities in both affected and unaffected households. Thus, trial results are based on the sample of affected and unaffected households that have complete data at baseline, 3- and 12-month follow-ups (N=585 (98%) and N= 1124 (94%), respectively)

Figure 1: Flow Diagram and retention

Figure 1: Trial Profile



Baseline characteristics of participants by intervention arm

Among affected household, only the proportion of caregivers who reported being married differed significantly by arm with fewer reporting being married in the GE arm. Among unaffected households, there were no significant differences by arm in

demographic characteristics. The majority of caregivers was female and reported not being able to read or write. About half of the index children in both affected and unaffected households were reported to have shoes at baseline.

Table 2: Baseline Characteristics by Intervention Arm

Baseline Characteristic	UC		HB [a]		GE [b]	
	Affected (n=195)	Unaffected (n=366)	Affected (n=197)	Unaffected (n=383)	Affected (n=193)	Unaffected (n=375)
% Female	87	85	78	87	91	92
Household size (mean (sd))	6.68 (1.93)	5.94 (1.72)	5.85 (1.76)	5.91 (1.79)	6.62 (1.99)	5.70 (1.63)
% Unable to read or write	48	72	60	64	34	46
% Married	97	91	92	94	82[c]	91
% Index child had shoes	57	45	44	54	57	57

Primary Outcomes among Affected Households

Results from both the primary outcome measure (all index children included) and alternative measure (children excluded if not present) indicated no significant differences among intervention arms in changes in shoe wearing from baseline to 3-month. However, given the sizable differences in baseline levels of shoe wearing among the arms, we conducted additional sensitivity analyses using two-level HLMs with a change score as the dependent variable, and with no pre-test covariate, to determine if results were sensitive to the analytic approach. Results were sensitive to the use of the analytic approach using a gain score as the dependent variable, and therefore the sensitivity results are reported.

However, from baseline to 12-months, the intent-to-treat and the alternative measure of shoe-wearing varied significantly among intervention arms with the UC group having the largest increases in shoe wearing (Table 3). Results from the gain score analytic approach indicated significantly greater gains in shoe wearing at 3-months for HB and GE groups relative to UC, but no significant differences among intervention arms at 12 months.

While all three groups reported considerable decreases in experienced stigma at 12 months, there were no significant differences among the intervention arms at either follow-up.

Primary Outcomes among Unaffected Households

Unaffected household in all three intervention arms reported decreased enacted stigma at both follow-ups. There were marginally significant differences among the three arms at12-months favoring the GE intervention.

Secondary Outcomes among Affected Households

There were no differences among the three intervention arms in accuracy of understanding, situational confidence levels, or internalized stigma at 3- or 12-month follow-ups for respondents in affected households (see Table 4).

Table 4: Secondary Outcomes for Affected Households

Secondary Outcomes among Unaffected Households

By contrast, unaffected households in the HB and GE intervention arms had greater gains at both follow-ups than those in the UC group in accuracy of understanding, and confidence to prevent podoconiosis. Changes in confidence to explain the causes of podoconiosis favored the GE intervention (Table 5). Changes in shoe wearing of unaffected index children favored the GE and UB arms at 3-months, but were not significant at 12-months.

Table 3: Changes in primary outcomes by intervention arm at baseline, 3- and 12-month

Outcome	Baseline Mean (Pooled SD)			Δ 3 months			Δ 12 months			Differences Among Treatment Arms (95% Confidence Interval)			
	UC[a] n=195	HB[b] n=197	GE[c] n=193	UC n=195	HB n=197	GE n=193	UC n=195	HB n=197	GE n=193	Overall p-value	HB vs. UC	GE vs. UC	GE vs. HB
Affected households	0.49	0.29	0.26	-0.02	0.13	0.05				0.48			
Observed shoe wearing (Range = 0-1)		(0.47)					0.17	-0.07	-0.01	0.00	-0.24 (-0.34,-0.14)	-0.18 (-0.28,-0.08)	0.06 (-.04, 0.16)
Sensitivity Analysis (Change Score Outcome)	0.49	0.29	0.26	-0.15	0.20	0.12				0.02	0.34 (0.07,0.61)	0.26 (-0.01,0.53)	-0.08 (-0.35,0.19)
Observed shoe wearing (Range = 0-1)		(0.47)					0.04	0.00	0.06	0.96			
Observed shoe wearing – index child present at interview[d] (Range = 0-1)	0.51	0.31	0.32	0.03	0.18	0.15				0.43			
		(0.48)					0.27	-0.02	0.14	0.01	-0.29 (-0.46,-.11)	-0.13 (-0.31,0.05)	0.15 (-0.03,0.34)
Sensitivity Analysis (Change Score Outcome)	0.51	0.31	0.32	-0.07	0.27	0.22				0.09	0.34 (0.01,0.67)	0.29 (0.04,0.63)	-0.05 (-0.38,0.29)
Observed shoe wearing – index child present at interview[d] (Range = 0-1)		(0.48)					0.16	0.14	0.19	0.98			
Experienced Stigma (Range = 1-4)	1.78	2.69	2.25	-0.50	-0.08	0.12				0.50			
		(1.02)					-0.83	-0.35	-0.71	0.14			
Unaffected households	n=366	n=383	n=375	n=366	n=383	n=375	n=366	n=383	n=375				
Enacted stigma (Range = 1-3)	2.19	2.10	1.80	-0.11	-0.29	-0.38				0.71			
		(0.71)					-0.02	-0.26	-0.47	0.09	-0.25 (-0.64,0.15)	-0.45 (-0.85,-0.05)	-0.20 (-0.60,0.20)

[a] Usual Care, [b] Community-wide Public Awareness Campaign + Household–based Skills Training; [c] Community-wide Public Awareness Campaign + Household–based Skills Training + Inherited Soil Sensitivity Education, [d] N's by arm b-line, 3, 12 month follow-ups: (UC: 188, 155,150; HB: 185, 162, 142; GE: 157, 131, 114)

Table 4: Changes in secondary outcomes by intervention arm at baseline, 3- and 12-month follow-up *among affected households*

Outcome	Baseline Mean (Pooled SD)			Δ 3 months			Δ 12 months			Differences Among Treatment Arms (95% Confidence Interval)			
	UC[a] n=195	HB[b] n=197	GE[c] n=193	UC n=195	HB n=197	GE n=193	UC n=195	HB n=197	GE n=193	Overall p-value	HB vs. UC	GE vs. UC	GE vs. HB
Affected households	2.36	2.93	2.00	0.14	0.37	0.34				0.57			
Accuracy of Understanding (Range 0-5)		(1.35)					0.77	0.59	1.25	0.17			
Confidence to prevent podoconiosis	2.38	2.74	2.15	-0.41	0.10	-0.02				0.39			
(Range = 0-3)		(0.63)					0.02	-0.05	0.18	0.90			
Confidence to explain causes of podoconiosis	4.94	4.87	4.78	-0.62	-0.08	-0.28				0.27			
(Range = 1-5)		(0.60)					-0.53	-0.22	-0.18	0.54			
Situation specific confidence to have children wear shoes	4.94	4.67	3.80	-0.22	0.04	-0.50				0.44			
(Range = 1-5)		(0.87)					0.02	0.24	0.09	0.90			
Internalized Stigma	1.83	2.61	2.31	-0.33	-0.04	0.19				0.78			
(Range 1-4)		(0.96)					-0.76	-0.33	-0.64	0.32			

[a] Usual Care, [b] Community-wide Public Awareness Campaign + Household–based Skills Training; [c] Community-wide Public Awareness Campaign + Household–based Skills Training + Inherited Soil Sensitivity Education.

Table 5: Secondary Outcomes for Unaffected Households

Table 5: Changes in secondary outcomes by intervention arm at baseline, 3- and 12-month follow-up *among unaffected households*

Outcome	Baseline Mean (Pooled SD)			Δ 3 months			Δ 12 months			Differences Among Treatment Arms (95% Confidence Interval)			
	UC[a] n=366	HB[b] n=383	GE[c] n=375	UC n=366	HB n=383	GE n=375	UC n=366	HB n=383	GE n=375	Overall p-value	HB vs. UC	GE vs. UC	GE vs. HB
Unaffected households Accuracy of Understanding (Range 0-5)	1.28	1.49	1.63	0.05	1.91	1.27				0.00	1.86 (1.26,2.46)	1.22 (0.62,1.82)	-0.63 (-1.23,-0.04)
		(1.18)					0.25	1.87	1.24	0.00	1.61 (1.21,2.02)	0.99 (0.58,1.39)	-0.63 (-1.03,-0.22)
Confidence to prevent podoconiosis (Range = 0-3)	2.47	1.79	2.41	0.31	0.48	0.47				0.01	0.17 (0.0,0.28)	0.16 (0.05,0.27)	-0.01 (-0.12,0.10)
		(0.88)					-0.16	0.38	0.42	0.07	0.54 (-0.01,1.09)	0.58 (0.03,1.13)	0.04 (-0.51,0.59)
Confidence to explain causes of podoconiosis (Range = 1-5)	4.74	4.03	4.70	0.05	0.00	0.36				0.00	-0.05 (-0.17,0.06)	0.31 (0.20,0.43)	0.37 (0.25,0.48)
		(1.13)					-0.45	-0.07	0.23	0.10	0.38 (-0.24,0.99)	0.68 (0.06,1.30)	0.30 (-0.32,0.92)
Observed shoe wearing (Range = 0 -1)	0.18	0.25	0.38	-0.15	-0.03	0.03							
		(0.44)					-0.03	0.10	0.01	0.45			
Observed shoe wearing – index child present at interview[d] (Range =0-1)	0.20	0.28	0.40	-0.15	-0.02	0.03				0.00	0.13 (0.06,0.21)	0.18 (0.10,0.26)	0.05 (-0.03,0.12)
		(0.45)					-0.06	0.10	0.08	0.21			

[a] Usual Care

[b] Community-wide Public Awareness Campaign + Household–based Skills Training;

[c] Community-wide Public Awareness Campaign + Household–based Skills Training + Inherited Soil Sensitivity Education

DISCUSSION

Taken together, results among affected households showed no benefit of the household-based interventions for sustained shoe-wearing. This may be attributed in part to the effectiveness of usual care intervention that had been conducted by a local NGO for 10 years among families affected by podoconiosis. Accordingly, affected households showed high baseline levels of knowledge and confidence.

However, provision of genetics education also showed no negative influences on levels of experienced or enacted stigma decreased across all intervention arms. Indeed, among unaffected households, reports of enacted stigma showed improvements with a trend that favored the genetics education arm. Studies of other conditions in LMICs have shown that improved understanding of disease etiology was associated with lessened stigma. [21]

For the secondary outcomes, unaffected households appeared to benefit more from interventions than affected households. Participation in the HB intervention was associated with sizable improvements in knowledge, and confidence among unaffected households. The inclusion of information about inherited soil sensitivity (GE arm) also was associated with unaffected care-givers' reporting increased confidence to explain the causes of podoconiosis and short-term improvements in shoe-wearing relative to usual care.

Like any study, there are several limitations that must be considered. The randomization of a small number of communities to intervention arms resulted in limited statistical power and some large baseline differences in our primary outcomes, and consequently, sensitivity of results to model specifications. Survey measures presented challenges for this low literacy population and restricted the variability of responses. However, taken together, results support continued exploration of integrating new knowledge about genomics with public health interventions in LMIC settings.

CONCLUSION

Efforts in LMICs to improve awareness of inherited susceptibility regarding health conditions while linking this awareness to preventive behaviors could have benefit for the broad community without necessarily increasing interpersonal stigma.

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