IMPLEMENTATION RESEARCH

ADDRESSING ANEMIA AMONG WOMEN AND CHILDREN UNDER FIVE THROUGH PROMOTION OF LUCKY IRON FISH IN SHYNIYANGA REGION OF TANZANIA.

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TABLE OF CONTENTS

SUMMARY

Over the past two decades, significant progress has been made by Tanzania on child health and nutrition however today over half (58%) of children age 6 – 59 months suffer from anemia, (MoHCDGEC, MoH, NBS, OCGS, and ICF, 2016). Due to rapid growth, children often face the most significant consequences where anemia can result in impaired mental functioning, low motor development, differences in social-emotional behavior and increased risk of mortality, (Lozoff, Beard, Conor, Georgieff & Schallert, 2006). With iron deficiency, as one of the primary causes, efforts to address anemia among affected populations has resulted in the introduction of iron supplements, iron-based cooking ware and the biofortification of staple crops. Yet due to challenges related to cost, accessibility and cultural relativity anemia rates in the Global South remain high. Lucky Iron Fish (LIF) presents a potential alternative that is cost-efficient, durable and culturally adaptable. When placed in boiling acidified water for ten minutes, the iron ingot releases a “safe and consistent amount of iron,” ensuring that that the food or water being prepared has an increased iron content, (Lucky Iron Fish, n.d.). With regular use, LIF can support the daily iron requirements of individuals and mitigate one of the major causes of anemia. The study will involve a total of 158 children between 12-59 months of age in randomly assigned program and control groups. Hemoglobin level will be determined at baseline, and every 3 months until the end of the study. Comparison on level of reduction of anemia between the two groups will be made to determine the impact of LIF.

OBJECTIVE

Tanzania Food and Nutrition Center in collaboration of World Vision Tanzania sought to determine the effectiveness of LIF when used in daily meal preparation over a 12-month period in reducing anemia among children 12 – 59 months of age in Shinyanga region of Tanzania.

Impact objective: 5-10% reduction of anemia prevalence from the current 71.9%% (TDHS 2015/2017) in Shinyanga region among the study groups.

Specific objectives.

1. To determine extent of acceptability and adherence and use of LIF
2. To assess factors limiting or enhancing use of LIF by primary care givers.

PROJECT DURATION AND LOCATION

Two randomly selected villages (LIF program and control villages) in Shinyanga, Tanzania. The duration of the implementation research will be 12 months.

LITERATURE REVIEW

I. Lucky Iron Fish

LIF is an iron ingot that can be used to safely and effectively add iron to an individual's diet. Upon first use, the product weighs approximately 200g and is 3.5" x 2.5" x 0.5" in size, designed with maximal surface area to increase iron leaching, (Armstrong, Dewey & Summerlee, 2017; Charles, 2012). Uniquely, it is shaped as a fish which is a symbol of luck in Cambodian culture where the ingot was initially piloted, (Rappaport et al., 2017). Users are recommended to use LIF during the cooking process by placing the it in a boiling pot of acidified water for a minimum of ten minutes. Iron leaching is relative to the pH level of the cooking water, therefore depending on acidity w30 – 80mg/L Fe (ferrous and ferric iron) water can be released during cooking, (Armstrong, Dewey & Summerlee; Charles, Summerlee & Dewey, 2011; Rapport et al, 2017). Using this cooking process, the drinking water or cooked food prepared will have a greater iron content than it would otherwise. Although outcomes are dependent on the age, sex and reproductive status of the user, regular use of LIF (three days a week to daily) can result in 40% - 75% of daily iron requirements being met through its usage, (Charles, 2012; Armstrong, Dewey & Summerlee).

Prior to the development of LIF, primary approaches to addressing iron deficiency include the fortification of staple foods, iron supplements and adventitious sources of iron such as iron cooking ware. However, these approaches have been met with significant challenges including: barriers related to the legislation and distribution of biofortified crops, availability and accessibility of biofortified products and iron supplements, the costs associated with supplements and the cultural relevance of these methods to diverse populations, (Charles; Armstrong & Summerlee; Armstrong, 2016). Instead LIF presents an alternative approach that is effective, durable and culturally adaptive, retailing at USD $5.00 per unit with an average lifespan of 5 years, (Rodriguez-Vivaldi & Beerman, 2018; Armstrong & Summerlee).

II. Safety Implications

LIF has also undergone safety testing by several scholars in the process of applying the product to the alleviation of IDA however the most significant study conducted was implemented by Armstrong, Dewey and Summerlee (2017) through the University of Guelph in rural Cambodia. In the study LIF was tested for i) the purity of iron, ii) the release of iron and potential for contaminants during boiling, iii) the impact of cooking time on acidity, and iv) the drinkability of water after an increase in the number of fish being used, (Armstrong, Dewey & Summerlee). It was found that the fish is composed of primarily ferrous iron, containing less than 12%

non-ferrous iron and when tested for potential contaminants such as: arsenic, beryllium, cadmium, chromium copper, cobalt, copper, lead, magnesium, mercury, nickel, selenium, tin, titanium and zinc, levels were either not detectable or adherent to acceptable standards set out by the World Health Organization, (Armstrong, Dewey & Summerlee).

Additionally, focus groups were formed to test the drinkability of water that had been boiled with LIF. Boiling one fish in water resulted in no evident change in colour, smell or taste to participants however when two or more fish were used participants felt the water was unpalatable, (Armstrong, Dewey & Summerlee). The study concluded that "…Lucky Iron Fish may be a safe treatment for iron deficiency" as there were no evident negative side effects or consequences in the use of the product, (Armstrong, Dewey & Summerlee). The authors did however note that using LIF outside of instructed parameters (i.e. using more than one fish during cooking) could result in the release of iron over what is recommended as a daily requirement, (Armstrong, Dewey & Summerlee)

III. Lucky Iron Fish in Alleviating IDA

A. Previous Trials

Overall, four trials have been conducted by researchers between 2008 to 2016 on the efficacy of LIF and although many share similar locations, contexts and participant instructions they greatly differ in study design, inclusion and exclusion criteria and results. For the ease of comparison, they will be referred to as Trial "A", B", "C" and "D".

The first trial of LIF as a tool in addressing IDA took place in Preak Ruesi, Cambodia beginning in September of 2008. The study was spearheaded by Christopher Charles at the University of Guelph, with the objective of investigating the impact of LIF on IDA in addition to exploring issues related to compliance, (Charles). Rural women (n = 189) who met inclusion criteria (mild to moderate anemia) were enrolled in the trial and randomly assigned to one of three trial arms including: i) a control group, ii) an intervention group that received LIF introductory session and iii) a second intervention group that received LIF, an introductory session and follow-up visits to enhance compliance, (Charles). Participants were instructed to use LIF daily in a traditional Cambodia soup (containing ascorbic acid) or by boiling drinking water with a small amount of acidity over a six-month period where hemoglobin and serum ferritin levels would be tested against the baseline, (Charles).

Although this study was partially successful (see Results), unexpected environmental complications related to the cooking water were thought to have negatively interfered with the outcomes. To address this, a second 12-month trial (Trial B) was conducted by the same research team in Lvea Aem District, Cambodia to test the impact of LIF on increasing hemoglobin and serum ferritin levels amongst anemic participants, (Charles et al., 2015). Inclusion criteria included that the participant be female, 16 years of age or greater, that she reside in the study area with no intention of relocation throughout the course of the trial and be experiencing mild to

moderate anemia, (Charles et al.,). Exclusion criteria included use of iron supplements within three months of the trial, pregnancy and severe anemia (<70 g/L) where the individual would instead be referred to a healthy facility, (Charles et al.,). A total of 304 women met this criterion and were randomly assigned to a group: i) an intervention group receiving an iron ingot, ii) a second intervention group receiving an iron ingot plus six follow-up sessions with nutritional education and iii) a control group, (Charles et al.,). Participants in the intervention arms were instructed to use LIF each day whether in the meal preparation process or by drinking LIF boiled water with the addition of citrus juice, (Charles et al.,). The control group was also instructed to boil their drinking water with citrus juice for comparison. Participants were visited by field staff at baseline and at each three-month mark for the remainder of the year where blood samples and a questionnaire were collected, (Charles et al.,).

A third study (Trial C) was carried out in Rovieng District, Cambodia between April 2015 and 2016, with 327 female participants between the ages of 18 – 49 years, (Rappaport et al.,). Inclusion criteria was similar to other trials as women were required to reside in the area for the entirety of the study, not be pregnant and be identified as having mild to moderate anemia (80 – 119 g/L) however they were also to be considered the female head of the household, (Rappaport et al.,). Exclusion criteria included women with severe anemia (<80 g/L), pregnancy and those active with other non-governmental nutrition interventions, (Rappaport et al.,). The three-arms of the trial included i) LIF intervention group with training, ii) iron-supplement group and iii) a control group with no placebo, (Rappaport et al.,). All groups also received nutrition education specific to iron deficiency and anemia. Monitoring took place monthly to encourage compliance alongside data and blood collection at the baseline, six-month point and twelve-month point of the study, (Rappaport et al,).

Most recently, a twelve-month randomized control trial was conducted in rural Guatemala (Trial D) in 2016 with a final sample size of 145 participants, (Rodriguez-Vivaldi & Beerman, 2018). Inclusion and exclusion criteria were minimal, accepting both male and female participants over the age of five if identified as having an iron impaired status according to WHO standards, (Rodriguez-Vivaldi & Beerman). The study contained a single intervention group as a control group was not utilized due to “ethical considerations associated with withholding treatment,” (Rodriguez-Vivaldi & Beerman). Being the head of the household was not required to participate however, those responsible for meal preparation in the household were identified and instructed to prepare at least one meal daily with LIF and a Vitamin C tablet (250mg) for acidification, (Rodriguez-Vivaldi & Beerman). Follow-up with participants throughout the study did not take place, with personnel returning to assess iron statuses post-intervention (week 52), (Rodriguez-Vivaldi & Beerman).

B. Compliance

Compliance amongst participants differed with higher rates (83% - 94%) in the studies that took place in Cambodia (Trials A, B and C)

compared to Guatemala (Trial D). Charles (et al) (2015) proposed several explanations of compliance success in Cambodia, the first being that LIF's physical design was culturally relevant as fish are considered lucky and are frequently consumed in Cambodian culture making the product itself favorable to participants, (Charles et al.,). The fish was also designed as "easy-to-clean" to avoid buildup of rust or other contaminants that could modify the taste or discolor the item being prepared, (Charles et al.,). In terms of elemental design, iron is released at a gradual and consistent rate which mitigates the likelihood of side effects that are commonly associated with the use of iron pill supplements, (Charles et al.,). Although there was the possibility of sharing the iron fish among households and complicating daily use, it is not custom to share items outside of immediate family in Cambodian culture and thus this issue did not occur, (Charles et al.,). Finally, Trials A, B and C all included frequent monitoring of participants that encouraged compliance through follow-up visits, education sessions, field visits, data collection using questionnaires and blood sampling.

In comparison, Trial D in Guatemala had a culturally different sample population and study design. Rodriguez-Vivaldi and Beerman (2018) assert that low rates of compliance may have been for several reasons, including that the design of LIF as a fish may have been culturally inappropriate to Guatemalan culture where due to superstitious beliefs "… unfamiliar objects could be perceived as having bad spirits, (Rodriguez-Vivaldi and Beerman). Ultimately 38% of participants returned to have their iron levels retested of which 75% reporting using LIF at least twice a week, (Rodriguez-Vivaldi and Beerman). The low return rate was also equated with the possible death or illness of participants or commitments regarding work and school, (Rodriguez-Vivaldi and Beerman). Although, the trial took place over a twelve-month period there was no follow up during the study itself. Retesting at the end of the trial period required participants to travel to a central location and communication about this information was solely dispersed through word-of-mouth as telephone, mail and internet in the area where not available, (Rodriguez-Vivaldi and Beerman). This could have greatly hindered compliance as participants were not engaged with over the twelve months of the study.

C. Results

Trial A showed mixed results, with promising data at the mid-line of the study with elevated hemoglobin and serum ferritin levels amongst participants that had regularly used LIF in meal preparation or while boiling drinking water. However, the positive effects of usage did not continue and by the end of the trial the same improved levels had fallen with the proportion of anemic women also having increased. Researchers equated the mixed results with water contamination that occurred mid-study as participants entered dry season and switched to the use of harvested rain water that had high levels of manganese and arsenic which are known to complex iron, (Charles). Determinations at the end of the trial were inconclusive, stating that due to the promising results at the beginning of the trial that LIF "may be a useful iron supplement" and that

a more thorough study should be conducted where able to avoid water contamination, (Charles). Thus, although the initial trial of LIF in Cambodia held positive results in the first three months of the trial, concrete inferences on the validity of LIF in addressing anemia cannot be ascertained due to the inconclusive nature of the study.

However, the postulation that water contamination negatively impacted the study was countered by Rappaport (2017) in Trial C as it was also implemented through both wet and dry seasons in Cambodia without similar results. In fact, researchers found no significant changes in hemoglobin or serum ferritin levels over the twelve-month period between all three study groups including those who had ingested iron supplements, utilized LIF in meal preparation and the control group. It was determined that although high rates of anemia were present in the population, low levels of iron deficiency based on serum ferritin concentrations influenced the effect of the iron ingot on the participants, (Rappaport et al.,). Further, Rappaport concluded that in areas where the prevalence of iron deficiency in non-pregnant women is low, but the prevalence of genetic hemoglobin disorders is high, LIF should not be utilized, (Rappaport et al.,). These findings counter the results of LIF's success in both Trial A and B however, it is not necessarily evident if this is due to the sample population or study design.

Trial B resulted in much different developments. At the end of the trial, participants in the control group were 4.1 times more likely to be anemic and 2.8 times more likely to be iron deficient than either LIF intervention group, (Charles et al.,). Hemoglobin levels differed by 11.8g/L between intervention and control groups with significant differences in serum ferritin values also, (Charles et al.,). Similar to trial C, low levels of iron deficiency were recorded in the population at the baseline however anemia amongst LIF users was reduced by 46% by the end of the trial, (Charles et al.,). This counters greatly to outcomes of Trial C and Charles (et al) concluded that LIF is "a very effective, innovative form of homestead food fortification intake, (Charles et al.,). It should be noted that one of the limitations of the study was that it did not exclude post-menopausal women due to numerical requirements as per the sampling frame. However, the Charles does explain that 3/4 of participants were pre-menopausal and that "no association between outcomes and menstrual status was found," (Charles et al.,).

In the most recent study (Trial D), although only 38% (n = 56) of participants returned for iron status retesting, 80.3% of those measured at baseline were no longer anemic with increases in both hemoglobin and hematocrit levels, (Rodriguez-Vivaldi & Beerman). Of the participants that remained anemic, two individuals reported using LIF less than once a month compared to other subjects that were no longer anemic who reported using LIF a minimum of twice a week (74%), (Rodriguez-Vivaldi & Beerman). Researchers also concluded that although there were issues due to loss of follow-up and a singular group of study, "the results strongly suggest that the LIF is efficacious in improving iron status in regions where IDA prevalence is high," (Rodriguez-Vivaldi & Beerman). Although results

from Trial D are promising in LIF's application in alleviating anemia, the lack of control group and loss of participants in follow-up must also be considered. Additionally, it should be noted that this trial included male participants that both lose less iron daily and require less iron daily and children over the age of five who require proportionately more iron daily.

To conclude, results in the use of LIF as a tool in elevating iron levels and addressing anemia have been mixed. Previous trials have typically included the use a LIF intervention arm and a control arm (besides Trial D) that have allowed for a thorough comparison of hemoglobin and often also serum ferritin levels. Trials A, B, C were centered on anemia levels of women (over 16 – 18 years of age) however, Trial D did include both male and female participants over the age of 5. Additionally, trials B, C and D all occurred over a time span of one year with trial A being conducted for a period of 6 months. Typically, LIF intervention arms were supposed with an introductory session and follow-up monitoring which seemed to result in an encouragement of compliance.

"Addressing Anemia in Children Aged 12 – 59 Months Through the Promotion of Lucky Iron Fish in Shinyanga, Tanzania" presented the opportunity to study for the first time, the application of LIF in Africa where anemia rates are amongst the highest in the world, (World Health Organization, 2008). The study was necessary to address gaps in existing literature where the promotion of LIF in alleviating anemia among children was yet to have been investigated due to exclusion criteria. Thus, the promotion of LIF in Shinyanga will be the first formal study of LIF in an African context with a specific focus on children age 12 – 59 months. The results of study are presented below.

STUDY AREA

Shinyanga Region is one of Tanzania's 31 administrative regions. The regional capital is the municipality of Shinyanga. According to the 2012 national census, the region had a population of 1,534,808. The region is bordered to the north by the Mwanza, Mara, and Kagera Regions and to the south by the Tabora Region. Kigoma Region borders to the west, and the Simiyu Region to the east. With the overarching objective of IDA rate reduction, the area was identified as a target region due to the high rate of anemia (71%) of children aged 6 – 59 months of age, (MoHCDGEC, MoH, NBS, OCGS, and ICF). ENRICH is implemented in Kishapu, Kahama and Shinyanga districts.

SAMPLING

Methodology

A list of villages across the three districts will be assembled and through a cluster randomized control, two villages will randomly be selected for the trial. Villages receiving nutrition or health interventions from World Vision Canada at the time will be excluded from eligibility in the study. Of the two villages selected, the first (LIF Arm) i) will receive LIF intervention and health and nutrition education, the second (Control Arm)

will receive nutrition and health education only. Each arm will have a sample size of 79 participants per village, totaling a sample size of 158.

Census information will be utilized to identify children age 12 – 59 months and screening will be done based on inclusion and exclusion criteria. Inclusion criteria will include that the child should be between 12 – 59 months of age, resided in the village for a minimum of six months and that the family intended on remaining in the village for one-year post-study enrollment, that a mother or direct caregiver has given consent for the child's participation and that the child's hemoglobin level be ≥7gm/dl ≤11gm/dl. Participants will be excluded if acute illness or fever is present and/or if the child is suffering from severe anemia (<7gm/dl) where the individual will be immediately referred to a health facility. Additionally, dependent variables include anemia (Hgb <11gm/dl) and independent variables include LIF use, age, educational status of primary caretaker, economic status of family, occupation of head of the household, availability of health services and marital status of the primary care taker

P= prevalence of anemia in Shinyanga region (TDHS 2015/16) = 71%

$$n=\frac{p(1-p)^2}{e/1.96} \quad ¿\frac{0.71(1-0.71)}{(0.1/1.96)^2} = 79$$

$$n=¿ \ 79.09854$$

$$n=79$$

$$LIF\ ARM=79$$

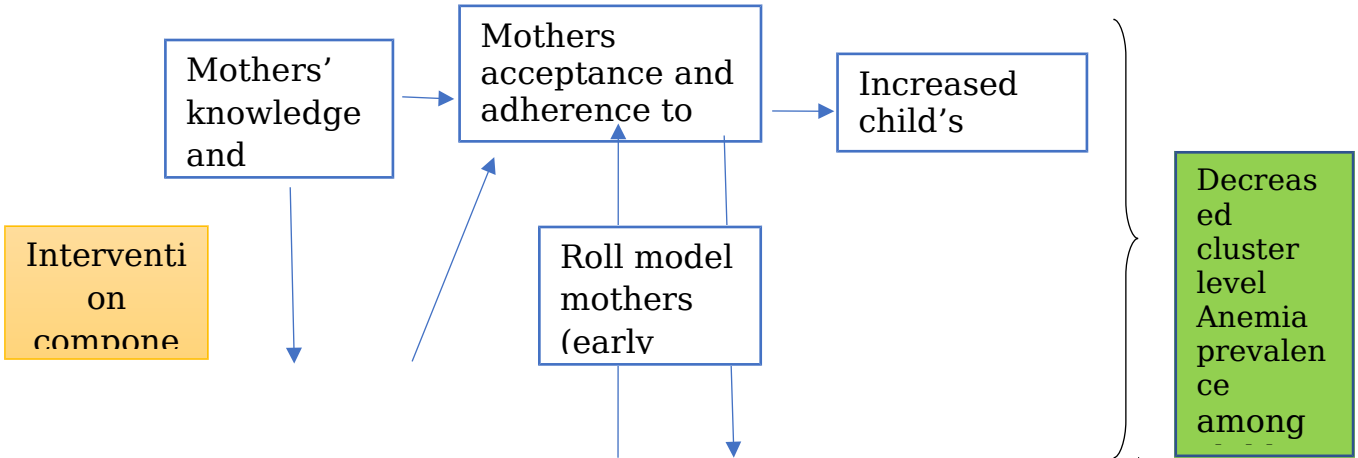
$$CONTROL\ ARM=79$$

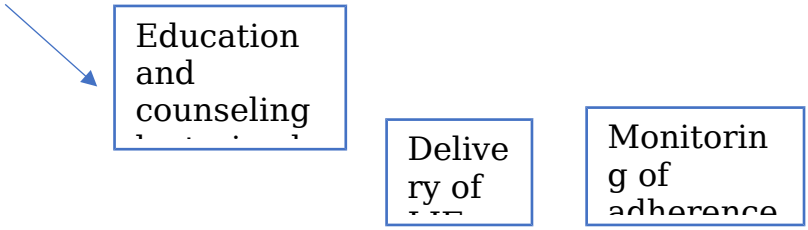
TOTAL SAMPLE SIZE = 158.

Established hypothesis:

- H_0 : LIF does not improve the hemoglobin status among children 12-59 months.
- H_1 : LIF does improve the hemoglobin status among children 12-59 months
- **Dependent**

Hypothesized Casual Pathway:





Materials and Procedure

Community Health Workers (CHW) associated with World Vision will be trained on the use of LIF and necessary follow-up procedures. CHW's will distribute LIF to participating households in LIF Arm. Individuals in the household responsible for daily meal preparation will be identified and receive an instructional session on LIF use by CHW in addition to general health and nutrition education. Although the Control Arm will not receive LIF, participants will receive the same general health and nutrition education. A placebo was not necessary as the arms were in two separate villages. CHW's will visit the homes of participants in both arms on monthly bases to ensure adherence and provide additional information.

Data Collection

Semi-structured questionnaires (see Appendices A) will be used and will be administered by CHW's to all 158 participants in both arms at both baseline and completion of the study. The questionnaire will have questions regarding knowledge on appropriate child feeding practices, Additionally, hemoglobin levels of all participants will also be measured both through an invasive (Hemocue) and non-invasive (Masimo) meter. The data will be collected by a Ministry of Health laboratory technician at baseline, each 3-month mark and at the completion of the trial (12 months). To validate collection methods, tools will be tested prior to the study in similar areas to address any limitations before carrying out the formal phase of research. Data analysis will include the use of mean, median, standard deviation, ci square and difference in difference analysis between both study arms. Data will initially be collected by hand and later entered into an Excel database.

Inclusion criteria

- children between 12-59 months of age,
- Resident for at least 6 months in the selected villages and intend to reside in the village for 1 year after enrolment
- Mother/care giver consent to participate
- Hemoglobin > 7gm/dl <11gm/dl

Exclusion criteria

- Acute illnesses or fever (will be referred to health facility)

- Severe anemia Hgb <7gm/dl - (will be referred to health facility)

ETHICAL IMPLICATIONS

As the study is relative to child health, If a child is identified suffering from severe anemia anytime throughout the project, the child will be immediately referred to a healthcare facility. Written consent for participation in the project will be obtained in addition to the completion of a Patient Information Form *(see Appendices B),* Adult Consent *Form (See Appendices C)*, Under 18 Consent Form *(See Appendices D)* and Data Transfer Agreement Form *(See Appendices E)*.

In terms of confidentially, access to data collected throughout the trial will be limited to only relevant researchers and authorities.

BUDGET

BUDGET ITEM	**BUDGET IN CAD CAD$**	**NOTES**	**LIF contribution**	**Remarks**
PRODUCT				
Lucky Iron Fish - 3592 units	$19,760.00	$5.50/unit		
Donated Iron Fish units (1,000)	$0.00		$5500	
Shipping (4,592 units SEA PORT)	$3,940.00	sea shipment to port and delivery to final destination		
Delivery of units to destination	$0.00	W/V covering		
Customs (tax and duty 18%)	$3,240.00	May be exempt because of WVC non-profit status and goods having direct benefit to society		
Total Product	**$26,940.00**			
TRAINING				
World Vision Staff/Volunteer Training (2.5 days) by LIF staff (2 people) Community workshop with End Users (2 days)	In kind	Training on ID/IDA, regional specific opportunities and barriers, product use and safety, distribution (in		

Initial Distribution		home and community workshops, impact assessment) Home visits and community workshops		
Printed materials (training & assessment)	$500.00			
Supplies for community workshops (sourced in country)	$300.00	Cook stoves, soup/traditional foods, sample cups/spoons		
Develop custom training material in Swahili	$2,950.00	site seller, leaflets, manual, impact assessment tools		
Training Video (Swahili)	$500.00	Animated Video Subtitles Voice Over W/V owns copy after training		
Total Training	**$4,250.00**			
TRAVEL (2 people) LIF Trainers				
Air Travel	$5,000.00	Return Economy YYZ to Kilimanjaro or Dar El Salaam (2people)		
Accommodation & per diem (6 nights - 2 trainers)	$2,060.00	Accommodation and per diem $70 per day per person		
Ground Transportation	**$0.00**	WV Tanzania to take care of		
Total Travel	**$7,060.00**			
Sub Total	**$38,250.00**			
Overhead	$6,750.00			
Total	**$45,000.00**			

RESOURCES

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