Improving dietary quality and livelihoods using farm and wild biodiversity through an integrated community-based approach in Kenya and Ethiopia

Submission date 29/04/2020	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 05/06/2020	Overall study status Completed	 Statistical analysis plan Results
Last Edited 08/06/2020	Condition category Other	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

Despite the progress towards ending hunger and malnutrition, more than 800 million people are still affected by undernutrition and another 2 billion by micronutrient malnutrition. Underutilized food including wild plants have now received recognition globally due to their nutritional potential and their ability to survive in harsh climatic conditions like Turkana county in Kenya and Tigray Region in Ethiopia. Although information on their nutrient composition, use and income potential is scanty and fragment, few studies available have shown that they have comparable and sometimes superior nutrient compositions. However, their utilization has been hampered by inadequate knowledge on their nutrition composition and better ways to prepare them appetizingly and a lack of knowledge on how to promote their utilization while still ensuring sustainability. A project is proposed that will use integrated participatory communitybased approach to empower the community to develop action plans for their utilization for incomes, food security and resilience. Participatory methods that incorporate social and behavior change communication in the interventions have been shown to yield positive outcomes and are key to program sustainability. Few projects however exist where the community in involved right from the design stage and most have involved the communities in the intervention only sometimes with very minimal participation. The project will be implemented by Bioversity International and its partners – Save the children, regional governments, Concern International, Mekelle University, and other partners over a period of three years.

Who can participate?

Households in the Tigray region of Ethiopia and Turkana County in Kenya, with at least one woman aged 15 – 49 years and a child aged 6 - 59 months.

What does the study involve?

Communities that have been selected to receive this intervention will undergo empowerment through six training workshops that lead to development of a community plan of action and its

subsequent implementations for a period of one year. The plans of actions developed will vary from one community to the other depending on their own choices and resources available to them. At the start of the project, seed money will be given to the community to fund some of the activities in the action plans. During the implementation, the communities will from time to time receive nutrition education including cooking demonstrations of some local recipes and technical training in line with the action plans being implemented. Communities that do not immediately fall within the intervention communities on the other will wait for at last one year after which they will also be guided through a similar exercise as the first group.

What are the possible benefits and risks of participating? Communities will benefit from nutrition education sessions and training offered during the project implementation. This will help the beneficiary communities to improve nutrition and diets. The study has no risks to the participants.

Where is the study run from? Alliance of Bioversity International and the International Center for Tropical Agriculture (CIAT)

When is the study starting and how long is it expected to run for? June 2020 to August 2022

Who is funding the study? BMZ: Federal Ministry for Economic Cooperation and Development (Kenya)

Who is the main contact? Francis Oduor, f.oduor@cgiar.org

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers BIOVERSITY-01/2020

Study information

Scientific Title

Cluster-randomized control trial to improve dietary and livelihood of communities in Turkana County (Kenya) and Tigray Region (Ethiopia) using integrated community-based approach

Study objectives

A community-based participatory approach that empowers the community through nutrition education is effective in promoting the use of wild and underutilized plant species and can improve diet quality of women and children.

This study will be based on the successful concept of community based participatory approach used in a proof of concept study in Vihiga county (Boedecker et al., 2019) and will test the use of the approach in a different context in Turkana county and Tigray region.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/01/2020, Amref Ethics and Scientific Review Committee(ESRC) (PO Box 30125-00100, Nairobi, Kenya; +254 (0)20 699 4000; esrc.kenya@amref.org), ref: ESRC P688/2019

Study design

Randomized controlled cluster trial

Primary study design

Interventional

Secondary study design Cluster randomised trial

Study setting(s) Community

Study type(s) Quality of life

Participant information sheet

See additional file ISRCTN11778499_PIS_26May2020 (added 08/06/2020)

Health condition(s) or problem(s) studied

Dietary quality of women and children

Interventions

Study Design: Cluster – randomized controlled trial with an intervention arm and a control arm. The study period is three years and will be implemented in two phases comprising the preparatory phase or diagnostic phase and the intervention phase. The intervention phase will further be divided into two phases due to the participatory nature of the study – the intervention identification phase and the intervention implementation phase.

Sampling: Multi-stage sampling strategy will be used for sampling. In the first stage criterion sampling was used sample two sub-counties in Turkana county and two Kabeles in Tigray with rich diversity of wild edible plant species, accessible, good security levels, high food insecurity and no similar intervention programs currently. The second stage is the random sampling of twenty (20) clusters from each site. In Turkana County the clusters are the community units (CU) while in Tigray the clusters are the cushets.

Randomization: Prior to the randomization, a diagnostic study (Phase I) will be conducted in all the clusters to study the dietary patterns and the existing local agrobiodiversity. Results from the diagnostic survey will be used for pair-matching clusters in each of the countries. For each pair, one cluster will be randomized to control or intervention arm.

Treatment of the intervention clusters: The treatment in the study is the implementation of the Integrated Community based approach for farm, market and diet diversity developed by Bioversity International from the Vihiga proof of concept study. The intervention will be implemented in two phases: the participatory development of the Community Action Plans (CAP) and the implementation of the CAPs.

Phase II: The identification of intervention phase or participatory development of Community Action Plans: First, the community will be guided through a series of six workshops delivered leading to the development of a community action plan (CAP). In workshops I and II the results of the diagnostic study will be discussed in order to raise awareness on the nutrition situation in the community and to mediate basic nutrition knowledge as well as the importance of dietary diversity, with a focus on the diets of women and small children. Workshops III and IV will aim at identifying the factors influencing dietary intake in the community and to raise awareness on the nutrition potential of the local food environment with special attention to the neglected and underutilized foods. In addition, possible interventions to improve nutrition will be identified. In the last two workshops V and VI, the communities will be guided to develop CAPs including the timelines and budgets for the implementation of the identified interventions. Communities will also discuss how they intend to gather the necessary funds to implement their CAPs.

Phase III: The implementation of Community Action Plans or proper intervention phase: In this final phase the CAPs will be implemented in the community. A kick-off event marking the official launch of the interventional activities will be organized where partners and all other community members will be invited. A small financial incentive as an injection to the implementation of the CAPs will be given to each community by the project. During the kick-off event, the community will be requested to bring with them different food stuffs including the wild foods for learning and cooking demonstrations.

The CAPs will be implemented for about one year during which technical trainings in line with the activities specified in the CAPs, nutrition education activities and cooking demonstrations, trainings on community dynamics, leadership and entrepreneurial skills (farmer business schools), will be provided. Links with other groups such as women groups, mother clubs or farmer groups within the intervention communities will be actively sought to foster information and experience sharing.

Treatment of the control clusters: treatment in the control clusters will be delayed for one year after which the same treatment as the intervention clusters will be implemented.

Intervention Type

Behavioural

Primary outcome measure

Diets of the children and women as measured from baseline to endline as measured by multipass quantitative 24 hour recall on two non-consecutive days per subject per survey round by: 1. Dietary diversity scores (percentage of women/children meeting minimum dietary diversity) 2. Nutrient adequacy ratios of the women's and children's diets

Secondary outcome measures

At endline:

1. Income opportunities from marketing of wild foods and other locally available agrobiodiversity measured using household interviews

2. Caregiver knowledge and attitudes and practices related to diet quality and nutrition measured measured through a knowledge, attitudes and practices assessment using individual interviews

3. Household food security measured by Household Dietary Diversity Score (HDDS), Months of Adequate Household Food Provisioning (MAHFP); Household Food Insecurity Access Scale (HFIAS), Household Hunger Scale (HHS)

4. Women empowerment measured using reach and process Indicators, economic advancement indicators and agency or power indicators within the Woman's Economic Empowerment Framework

Overall study start date

01/07/2019

Completion date

31/08/2022

Eligibility

Key inclusion criteria

Households with at least one woman aged 15 – 49 years and a child aged 6 - 59 months will be the main target for the study

Participant type(s) Healthy volunteer

Age group Mixed

Sex Both

Target number of participants 40 Clusters in two countries **Key exclusion criteria** Does not meet inclusion criteria

Date of first enrolment 01/06/2020

Date of final enrolment 31/07/2021

Locations

Countries of recruitment Ethiopia

Kenya

Study participating centre Tigray region Ethiopia NA

Study participating centre Turkana County Kenya NA

Sponsor information

Organisation Bioversity International

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Sponsor type Research organisation Website http://www.bioversityinternational.org/

ROR https://ror.org/04xsxqp89

Funder(s)

Funder type Government

Funder Name BMZ: Federal Ministry for Economic Cooperation and Development

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal.

Intention to publish date 31/08/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://dataverse.org)

IPD sharing plan summary Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		26/05/2020	08/06/2020	No	Yes