
Title: A Family-Centred approach to enhance lifestyle change and behavioural modification for prevention of cardiovascular Diseases among adolescents and their families in Uganda

Acronym: FaCe-D study

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By my signature below, I hereby confirm that the study will be conducted in accordance with this protocol and compliance with the tripartite harmonized ICH Guideline for Good Clinical Practice 1996 and the version of such protocol agreed to by the applicable regulatory authorities and approved by all Institutional Review Board and Ethical Committees.

Principal Investigator:

Name: Josephine Birungi Signature: Date 13 March 2025

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1.0 Introduction

Uganda suffers a dual burden of non-communicable diseases (NCDs) and HIV/AIDS with an overall prevalence of pre-hypertension of 38.8% among its 42 million population (adolescents account for 23.6% of this) and 5.8% for HIV/AIDS. A nationwide study among persons ≥ 12 years in the country found the prevalence of hypertension (blood pressure $\geq 140/90$) as high as 34.3% in urban areas, and 22% in rural areas³ (Lunyera et al 2018). While another nationwide study found that only 7.7% of the adult population were aware of their high blood pressure (Guwatude et al, 2014). Furthermore, 24.3% of 15,000 adults living with HIV (PLHIV) screened at an urban clinic were found to be hypertensive (Muddu et al, 2021). The 2021 global nutrition report indicates Uganda has shown little progress towards achieving diet related NCD targets that include halting the rise in obesity and diabetes, 30% mean reduction in population intake of salt (<5 mg per day) and 25% relative reduction in raised blood pressure. According to this same report, 10.4% of the adult women (>18 years) and 2.3% of the adult men are obese (Global Nutrion report, 2021).

In a study conducted in Uganda and Tanzania in 2015 by Nsanya and others, the prevalence of high (elevated) blood pressure defined as mean systolic and/or diastolic BP at ≥ 90 th percentile among adolescents aged 12 to 19 years was 36% (Nsanya et al 2019). Another study report showed that over 50% of adolescents in western Uganda had some knowledge of the risk factors for CVD (health diet and physical activity), but many engage in behaviours that put them at risk for CVD (Agaba and Muhumuza, 2021). In 2020, only 36.3% of the school going children (10-12 years) in Kampala met the WHO recommended amount of physical activity defined as at least 60 minutes of moderate-to-vigorous physical activity per day. According to Akseer and others who conducted a systematic review on NCDs among adolescents in 194 countries (Uganda Inclusive), physical activity was inadequate in over 80% of the adolescents aged 11 to 17 years across all regions and both sexes (Akseer et al, 2020).

In Kampala, Uganda, a concerning 63.7% of school-going children aged 10-12 years fail to meet World Health Organization (WHO) physical activity guidelines, with notable disparities: boys, children of normal weight, and those attending public schools exhibit higher activity levels (Nakabazzi et al., 2020). Encouragingly, school-based initiatives have shown considerable promise in mitigating NCD risk factors, with 80% of studies demonstrating positive outcomes, especially when incorporating family and community engagement (Saraf et al., 2012). Regular physical activity and aerobic exercise have proven beneficial in reducing cardiovascular issues and enhancing quality of life among adolescents living with HIV (Ndirangu-Mugo et al., n.d.). These findings underscore the critical need for tailored interventions promoting physical activity and NCD prevention among adolescents, particularly vulnerable populations.

1.1 CVD and Mental health disorders among adolescents

Furthermore, recent studies indicate a high prevalence of anxiety and depression among adolescents globally. In Jordan, 78.2% of adolescents reported severe anxiety symptoms, while 49.1% experienced severe depressive symptoms (Entisar Dwekat et al., 2021). A study in India found moderate to severe anxiety in 9.9% and depression in 18.5% of adolescents, with depression more common in boys and increasing with age (D. Patel & D. Patel, 2020). Research in Colombia revealed anxiety symptoms in 37% of adolescents and depression symptoms in 12.3% (Ospina-Ospina et al., 2011). A study in Bangalore, India, during the COVID-19 pandemic found even higher rates, with 62.74% of adolescents experiencing anxiety and 50.32% experiencing depression (Neha et al., 2022). Factors associated with these conditions include gender, age, socioeconomic status, and parental education levels.

Research has also indicated a significant relationship between cardiovascular disease (CVD) risk factors and mental health issues among youth. A study of children and adolescents with major depressive disorder found

that 52% had at least two CVD risk factors, including hypertension and elevated cholesterol levels (Korczak et al., 2021). Another study revealed that depressed adolescents exhibited poorer vascular functioning and increased CVD risk compared to controls (Waloszek et al., 2015). Not meeting physical activity recommendations and having a depression diagnosis were significant predictors of obesity risk in adolescents (Kaar et al., 2022). The interconnection between cardiovascular and mental health underscores the need for a holistic approach to healthcare that integrates treatment of physical symptoms with interventions addressing mental health issues (Borkowski & Borkowska, 2024). These findings highlight the importance of considering mental health in CVD risk assessment and prevention strategies for youth, potentially warranting routine CVD risk factor screening among depressed youth regardless of BMI.

Additionally, there is strong evidence showing that poor sleep quality, such as short sleep duration, insomnia, or sleep apnea, is associated with an increased risk of CVD such as hypertension, atherosclerosis, and myocardial infarction (Covassin & Singh, 2016). Sleep disturbances are thought to contribute to elevated stress hormones, systemic inflammation, and impaired vascular function, all of which play a crucial role in the pathogenesis of CVD (Raggi et al., 2021)

1.2 Economic Burden of CVDs:

The economic burden of cardiovascular diseases (CVDs) and mental health disorders in low- and middle-income countries (LMICs) is substantial, affecting individuals, households, and communities. Households affected by these conditions face severe financial strain, including higher healthcare expenditures, reduced income, and increased use of detrimental financial coping strategies (Kazibwe et al., 2021; Lund et al., 2019). In Africa, CVDs alone result in billions of dollars in lost productivity and healthcare costs annually (Gaziano, 2008). Comorbid depression in CVD patients further increases healthcare utilization and costs while reducing employment productivity (Rodwin et al., 2013). The chronic nature of these conditions can result in catastrophic health expenditure, pushing households deeper into poverty and entrenching inequality (Kazibwe et al., 2021). However, innovative care delivery models targeting depression in CVD patients have shown potential to reduce costs or be cost-neutral while improving quality of life (Rodwin et al., 2013).

1.3. Definition of cardiovascular Disease (CVD) and the risk factors

CVDs is a broad term that encompasses a range of conditions affecting the heart and blood vessels, including myocardial infarction, angina, coronary heart disease, stroke, transient ischemic attack, peripheral vascular disease, and congestive heart failure. The key risk factors for CVD include high blood pressure, high cholesterol, diabetes, smoking, obesity, physical inactivity, and family history. Identifying and addressing these modifiable risk factors is crucial for preventing the development and progression of cardiovascular disease. Lifestyle changes, such as a healthy diet, regular exercise, and smoking cessation, can significantly reduce an individual's risk of developing CVD, while medical interventions like medication and surgical procedures may be necessary in some cases to manage the condition.

The "Life Simple 7" framework outlines seven essential components for achieving ideal cardiovascular health: (1) no smoking, (2) a BMI of less than 25 kg/m²(< 85th percentile those below 20 years, (3) at least 150 minutes of moderate-intensity physical activity per week in adults and at least 60 minutes daily for children, (4) a heart-healthy diet rich in fruits, vegetables, and whole grains with at least 4-5 servings daily, (5) blood pressure below 120/80 mmHg or less than 90th percentile in children below 20 years, (6) total cholesterol levels under 200 mg/dL in adults and less than 170mg/dl in children , and (7) fasting blood glucose below 100 mg/dL. This matrix serves as a practical guide for individuals and communities to enhance cardiovascular health and reduce disease risk (American Heart Association, 2010).

1.4 Evidence- based intervention

The iHealth-T2D study, a cluster randomized controlled trial (Kasturiratne et al., 2020, Muilwijk et al 2021), demonstrated the effectiveness of the Family Centred Approach (FCA) in preventing type 2 diabetes among high-risk South Asians. The intervention group showed significant reductions in weight and waist circumference compared to the control group (Muilwijk et al., 2021). The education sessions were delivered through 22 contact sessions over 12 months (Muilwijk et al., 2021). The FaCe-D study, will adapt and evaluate the iHealth-T2D intervention in Uganda, targeting improvement of cardiovascular health and reduction of cardiovascular disease risk among adolescents.

1.5. Why adolescents are the target population:

Adolescence is critical development stage characterised by significant physical, cognitive, emotional and social changes. Adolescence is often marked by the onset of puberty and development of sexual and reproductive maturity, and the pursuit of increasing independence and identity formation. During this period, individuals undergo profound psychological and behavioural transformations as they navigate their way from childhood to adulthood. It is a stage when one establishes health behaviour that may affect one's health and wellbeing later in life and it is also a time when we observe increase in risky behaviour which can lead to harmful outcomes. Furthermore, the clinical signs and symptoms of cardiovascular disease (CVD) may present in adulthood, but the atherosclerotic process often begins in adolescence ¹²⁻¹⁴. The progression of this atherosclerotic process in the young people is often influenced by modifiable CVD risk factors such as unhealthy diet, physical inactivity, overweight and obesity. For instance, it has been shown that 8 in 10 obese teenagers have gone on to become obese in adulthood ¹⁵.

In Uganda, almost a quarter of the population are adolescents. As a country that has suffered the effects of HIV epidemic for over three decades, some of the adolescents have been living with HIV since birth. Yet research among adult HIV positive persons in Uganda showed a prevalence of 18% subclinical atherosclerosis¹⁶. Additionally, some modifiable risk factors such as obesity and dyslipidaemia are more prevalent among HIV positive than negative individuals¹⁷. This puts People Living with HIV at increased risk of cardiovascular diseases. Therefore, by intervening during adolescence, the adulthood phase is likely to have a lesser burden of morbidity and mortality due to CVD and the related complications.

For example, a cluster-randomised controlled trial in United Kingdom and South Asia, known as iHealth-T2D study showed that an intensive family-based lifestyle intervention, referred to in this protocol as Family Centred Approach (FCA) leads to effective reduction in weight, waist circumference and blood pressure among adult persons at risk of type 2 diabetes ¹⁸. The iHealth-T2D intervention comprised of 22 contact session in 12 months; nine (9) being one to one visit and 13 telephone calls delivered by community health workers. The education sessions focused on health diet and increasing the physical activity among health persons at risk of type 2 diabetes. We propose to adapt, implement and evaluate this family- based intervention to determine its effectiveness in improving cardiovascular health of adolescents in Uganda, measured by the life's simple 7 metrics¹⁹.

2.0. Overall Study aims

Our primary aim is to adapt and implement a modified version of FCA that was implemented in the iHealth-T2D study¹⁸, and evaluate its effectiveness in reducing cardiovascular disease risk among adolescents and their families in Uganda using the Life's Simple 7 metrics. Furthermore, we wish to determine its effect on anxiety, depression, sleep quality and the uptake, implementation costs, barriers and facilitators.

2.1. Hypothesis

We hypothesize that implementing the FCA will significantly improve cardiovascular health and reduce CVD risks among adolescents in Uganda and that the intervention will demonstrate favourable implementation science outcomes, supporting its scalability and sustainability.

2.2 Study Objectives:

2.2.1 Primary Objective:

To evaluate the effectiveness of the FaCe-D intervention in enhancing cardiovascular health among adolescents.

This will be measured by assessing the intervention's effect on the proportion of adolescents achieving Ideal Cardiovascular Health (ICH) score based on the Life simple 7 metrics after 12 months of follow -up.

2.2.2 Co-primary Objective:

To assess the acceptability, adoption, and fidelity of the FCA in the Ugandan context.

2.2.3 Secondary Objectives:

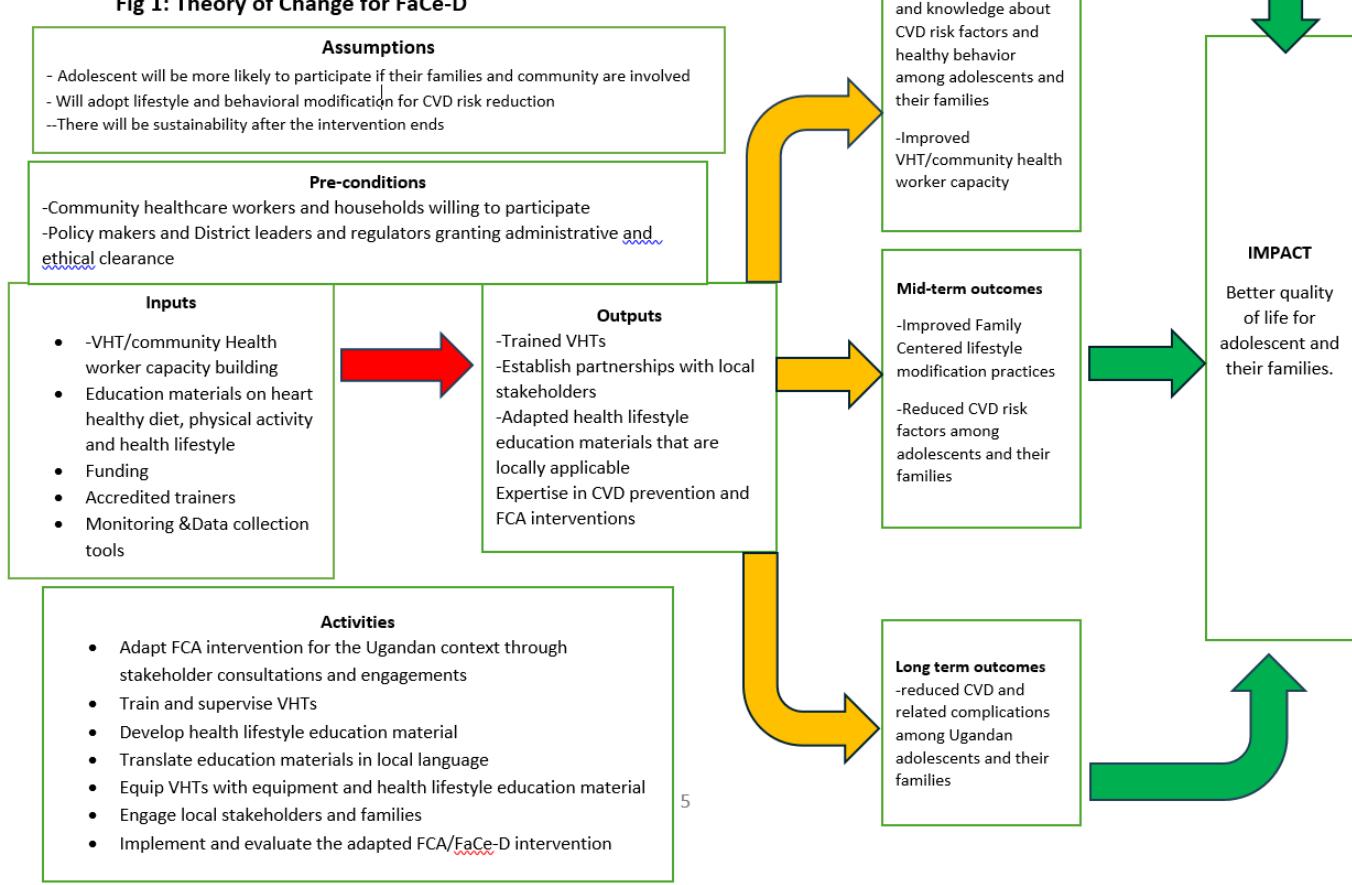
1. To establish the contextual factors, barriers, and facilitators that influence uptake, implementation and outcomes of the FCA in Uganda.
2. To explore and evaluate the effects of the FaCe-D intervention on anxiety, depression and sleep quality among adolescents.
4. To determine the costs and cost-effectiveness of implementing the adapted FaCe-D study, including estimation of incremental cost-effectiveness ratio.

2.3 Proposed intervention by study team before seeking views of stakeholders

The FaCe-D study team proposed to implement an intervention similar to that of iHealth T2D study (Muilwijk et al, 2021) in Uganda where Village Health Team members would visit families residing in the study villages and educate them about health diet as well as physical activity. As part of first step in the adaption process, the study team proposed some changes to the iHealth T2D study intervention to make it easier for the participants and the stakeholders to understand and make meaningful input into the design. The adaptation of iHealth T2D intervention focused majorly on the context; changes in setting in which the intervention would be implemented, cadre of personnel to implement the intervention, and study population. In addition, the adaptation was to involve revisions to the content of education materials, frequency and length of some components of the intervention to suit the Ugandan setting. It is this modified design of the intervention that was presented to the stakeholders and study participants for their suggestions and perspectives.

3.0 Theory of change:

The adolescents are often guided and depend on their families for support in Uganda. We therefore assume that once the families are willing to participate, the adolescents will also be willing to participate. We will design adolescent friendly education materials, and work with both the VHTs and their peers to implement this intervention. By doing this, they will be motivated to change diet and engage in the recommended level of physical activity per day. The life style modification and behaviour change will result in increased knowledge and awareness about CVD in the short term, reduced CVD risk in the medium term, and delayed progression tot disease and complications.



4.0 Methodology

4.1. Study phases

The study will be conducted in three (3) phases listed below.

- Formative phase (data collection and analysis of this phase is completed)
- Implementation phase
- Evaluation (effectiveness and process evaluation) phase

Following the completion of the formative phase (UVRI REC approval number GC/127/991), we present the additional two phases of the study as explained in detail to indicate the data collection and the frameworks to be used.

- The Implementation phase during which we will roll out the intervention to the participating households and
- The Evaluation phase (checking the effect of the intervention on the clinical outcomes, including mental health outcomes, implementation science outcomes). We will also conduct the process and health economic evaluation.

5.0 Formative Research phase

This first phase of the project was completed successfully, and the findings were used to design the FCA study intervention. In this phase we focused on adapting the intervention, guided by the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al 2009, Damschroder et al 2015). This framework guided the research team to adapt the intervention based on the identified barriers and

facilitators to delivering the FCA. We established the process of negotiating access to and mobilizing adolescents, families and communities. We also learnt how best to approach and engage stakeholders at village, parish, division and district levels, identification and recruitment of the community health workers (in this case the Village Health Teams also known as VHTs) to implement the intervention.

5.1 Aim and Objectives for the formative phase

The aim was to explore the knowledge on cardiovascular health including CVD risk, perceptions and attitudes of participants, providers and other stakeholders towards the ihealth-T2D FCA intervention, obtain their input in the modification and design of the intervention to make it appropriate for Ugandan context.

Specifically, we hoped to achieve the following objectives in this phase.

- 1) To explore the knowledge on cardiovascular health, perceptions, preferences and recommendations of potential participants on the FCA as an intervention for reducing and controlling common CVD risk factors among adolescents and their families. We set out to identify the preferences for the frequency and duration of visits, and phone calls, attitudes towards healthy eating, physical activity, and taking records of the food consumed and time spent on physical activities and any anticipated challenges to adopting healthy behaviours.
- 2) To identify potential facilitators and barriers to adapting and implementing the FCA intervention in Uganda. We sought to understand the likely feasibility of engaging adolescents and their families in a longitudinal intervention and the optimal timing during the day and week for home visits by the village health teams.
- 3) To use the data generated to design implementation strategies to promote the delivery, and uptake of the adapted FCA.

5.2. Methods for formative phase

5.2.1 Study design

The formative phase employed a cross sectional study design to collect qualitative data. We conducted focus group discussion (FGDs) to collect data from adolescents, household heads and members in charge of preparing food and VHTs. The key informant Interviews (KII) were conducted to collect data from the policy makers and other experts in this field.

5.2.2 Study population of the formative phase

The primary target population for this phase of the study included adolescents and their families residing either in Jinja or Kampala. Among household members, we targeted the household head and the member in charge of food preparation. The participants were selected using the purposive sampling technique²² in consultation with the VHT and LCs (local leaders).

Inclusion and exclusion criteria for adolescents:

Adolescents aged 10-19 years and able to provide consent /ascent, emancipated minors were included and exclude adolescents in boarding school and those without parental consent.

5.2.3 Setting

The formative study was conducted in Nakawa division of Kampala district (urban) and Mafubira- Namulesa divisions of Jinja district (rural) – refer to figure 2.

5.2.4 Recruitment Approach

Working with the local council (LCs) leaders and village health team members (VHTs), we identified potential participants in the formative phase. The VHTs in each of the two participating districts then identified a minimum of 20 families with at least one adolescent aged 10-19 (in or out-of-school). The VHT member also visited the identified family to provide some information regarding the study, seek consent and provide an invitation letter to the venue where the FGD was to be held. The FGD comprised of 8-12 members from different household.

5.3 Data collection

Data collection was stratified by rural and urban residence, as we anticipated that preferences and potential barriers and facilitators may differ between these settings.

We set out to conduct four to six (4-6) focus group discussions (FGDs) that involved adolescents, two -four (2-4) FGDs with household members/food preparers, and one to two (2-4) FGDs with VHTs. The adolescent FGDs were grouped according to their gender and age categories; 10-14 years, and 15-19 years while the household member and food preparers were grouped according to gender (male or female). Each FGD comprised of 8-12 members from each participant category and the key informant interview recruited 20-30 participants. The interviews were recorded in addition to the note-taking by the research assistants. Audio recordings of all interviews and FGDs were transcribed verbatim by competent and experienced social scientists.

All participants in the FGD received transport reimbursement of 10,000 shillings and either a bar of soap or scholastic materials (books/pens/set). We provided refreshments during FGDs. We also interviewed policy makers from the ministries of; Health (NCD and AIDS control programme), education and sports, gender, labour and social development, district/parish officials, VHT coordinators and Local leaders, dietitians/nutritionists with good understanding of the local community context (Jinja and Kampala) and health researchers in areas of CVDs. The participants for the individual key informant interviews (KII) received 50,000 Uganda shillings.

5.4 Documents review

A review of literature about healthy diet and appropriate physical exercises was conducted to identify relevant literature, curricula and education material on diet/nutrition, recommended healthy lifestyles, community health, and role of community health workers/VHTs) in Uganda. This was done in order to ensure that the adapted FCA intervention conforms to current policies and health education materials in Uganda.

5.5 Data analysis

The data collected from FGDs and KIIs were analysed using two approaches; deductive and inductive. The deductive approach was guided by Consolidate Framework for Implementation Research (CFIR) Framework application and the inductive approach (this was open coding to find new emerging themes). Using the CFIR framework that has five domains and 39 constructs (<https://cfirguide.org/constructs/>), we explored the barriers and facilitators of adapting and implementing FCA in the Ugandan context. Then, the themes were mapped onto the CFIR constructs. The inductive approach involved open coding to find other new emerging themes. An electronic data management package (NVivo 14) was used to code the data under identified themes and subthemes.

5.6 Co-designing of the final version of the intervention (FCA) suitable to Ugandan setting

Following the documents review, data collection and analysis, the study team developed a draft of an FCA fit for the Ugandan context and the required tools. These were presented at a validation workshop involving investigators and experts for review. A dissemination workshop for stakeholders including; policy makers,

civil society organizations members, development and implementing partners, youth and adolescents, advocate, health officials and municipal officers and community members was organised to share the near final FCA. The final version of the FCA was developed after this workshop taking into account the feedback from the different stakeholders.

6.0 Implementation and evaluation phases

These two phases will be implemented concurrently. The study will evaluate the following; effect of the intervention on health and implementation science outcome, the process and the economics/cost and cost effectiveness.

6.1 Study Design for the evaluation of effectiveness of the intervention

The evaluation phase, the study will use a hybrid type II cluster randomized controlled trial design (Curran et al., 2012, Clemson et al., 2017, Cully et al., 2012) to evaluate the clinical effectiveness and the implementation outcomes. The clinical effectiveness of the FaCe-D study will be determined at 12 months while the implementation outcome will be assessed through to 18 months (Figure 1). The cluster will be the village and the adolescents in a household will be the main study participant. This study will involve 32 villages, stratified into 16 urban and 16 rural clusters, with each cluster consisting of 40 adolescents. The clusters within each stratum will be randomly assigned to either treatment group or wait-list control group. Each cohort will be followed for 18 months, with the clinical effectiveness of the intervention assessed during the first 12 months (Figure 1).

a) First 12 Months (Effectiveness Phase):

- The immediate (**treatment**) arm will receive the FaCe-D intervention, comprising dietary and exercise interventions delivered by Village Health Teams (VHTs) – **details in section 4.6**

b) The **wait-list control arm** will receive the standard of care, with VHTs performing their usual roles) of health promotion in both communicable and non-communicable diseases as outlined by the Ministry of Health guidelines. In brief, the standard of care involves visit by the VHT at least once a quarter to check home hygiene and environment, children immunisation status and other health promotion activities. The VHT may or may not involve the entire family/household.

c) Last 6 Months (maintenance Phase):

- In the immediate (**treatment**) arm, the FaCe-D intervention will continue under the supervision of public health facilities. During this phase, VHTs in the intervention clusters will scale up the intervention to include all households within the village. This stage will focus on evaluating implementation science outcomes, particularly adoption, fidelity and maintenance.
- In the **wait-list control arm**, all clusters will begin implementing the FaCe-D intervention, ensuring that every participant benefit from the program.

6.2. Randomisation of clusters

At a meeting organised by the study team, VHTs and LC1 representing each village will draw a piece of paper written on the arm of the study the study their village will belong to. Each paper piece will be unfolded and read to all members in the room and recorded as the final arm. We will use systematic random sampling to select households to participant in the study. The LC1 working with the VHT will present a list of the households with adolescents aged 10 -19 years to the study team. Using the list, we will select every nth participant to obtain the 40 households. If the village has less than 40 eligible households, we will include all consenting households. If a household is found to have more than one adolescent, all those consenting will

be selected to participate. This event will be attended by other key stakeholders, including community advisory boards, youth councillors, health center in-charges, the district health officer, and the city health officer, all contributing to the collaborative effort to promote transparency

6.3. Sample size

A minimum sample size of 1280 adolescents was determined using STATA “*clustersampsi*” package for cluster randomized controlled trials. This calculation considered a baseline proportion of adolescents with ideal cardiovascular health of 53% based on a South African study among the rural population (Nsanya et al., 2019). With this sample size, the intervention will have 90% power to detect an improvement of at least 10% absolute difference in proportion of adolescents with ideal cardiovascular health considering 32 clusters of average size 40, an intra-class correlation coefficient of 0.005 and a significance level of 0.05.

6.4. Study setting

We will undertake this implementation research in two sub-counties located within Kampala and Jinja districts in Uganda, which reflects some diverse environments where adolescent populations live. The urban site is in Nakawa division, Kampala district, Central Uganda. It comprises of Bugolobi and Kiswa parishes and Mbuya parishes. The rural sites are in Budondo and Mafubira sub-counties in Jinja district, Eastern Uganda, covering Buwenda and Namulesa parishes. Mafubira has both peri-urban and rural parishes. We have chosen Buwenda and Namulesa rural parishes, characterized by lower population density, agricultural livelihoods, and limited infrastructure, typical of rural areas. The study settings offer a contrasting representation of urban and rural environments. Nakawa division, Kampala, has a population of 318,447 and 248,583 households, characterized by a predominantly middle-income earning population engaged in formal employment and living an urban lifestyle. We will aim to enroll adolescents from both the affluent and less-affluent households. In contrast, Jinja district has a population of 584,119, primarily comprising rural subsistence farmers with few formal sector wage earners and an estimated annual household income of US\$100.

6.5 Study population of the implementation and evaluation phase

The target population is adolescents aged 10-19 years. In our study, if a household has more than one adolescent, we will include all of them, provided they meet the inclusion criteria and consent to participate. This component of the study that involves quantitative data collection will focus mainly on the adolescents aged 10-19 years however the household head/parent/caretaker and food preparer will be required to consent and also participate in completing the food diaries and health economics questionnaires.

6.5.1 Adolescent inclusion and exclusion criteria:

The participant will be enrolled in the cluster randomized control trial only if they meet the following

- Aged 10 -19 years
- Household head/Parent have provided consent/permission
- Planning to continue staying in the study village for the next 12 months

The participant will be excluded from the study if they are;

- In boarding school or planning to join boarding school
- Pregnant or lactating
- Known to have a chronic condition such as CVD, diabetes, asthma, cancer or mental illness
- Not able to assent or consent.

6.5.2 Household head/ Parent/Caretaker/food preparers inclusion and Exclusion criteria

The participant will be included in the study if they are;

- Stay in the household for at least 2 weeks in a month
- Planning to continue staying in the study village for the next 12 months

The participant will be excluded from the study if they are;

- have a mental illness impairing their ability to consent
- very ill requiring admission

6.6 Intervention after obtaining stakeholder views

FCA was adapted from the effective iHealth-T2D intervention for prevention of type 2 diabetes (T2D) among high-risk South Asians (Kasturiratne et al., 2020). We co-designed the FaCe-D intervention together with stakeholders during the formative phase of this study, detailed elsewhere (*UVRI REC approval number GC/127/991*). FaCe-D intervention will be delivered collaboratively by the Village Health Team (VHTs) and adolescent peer champions. Our intervention leverages the existing VHT network and taps into the influential role of peer champions among adolescents. VHTs provide vital link between households and the formal healthcare system, while peer champions offer a unique opportunity to harness social influence and promote behavioural change among adolescents.

The selection of VHTs and peer champions as intervention deliverers was justified by our findings from the formative phase, which revealed that adolescents primarily seek health information from their peers, and VHTs require reinforcement to effectively engage adolescents. This collaborative approach addresses these gaps, and will enhance the intervention's acceptability, effectiveness, and sustainability within the Ugandan context.

The study intervention comprises four components; three of which will be implemented by VHT members and peer champions at family level, and these include: a) monthly home visits, b) health diet education and food preparation demonstration to the family by VHTs, and c) health education, peer mentorship and monitoring of physical activity by adolescent peer. The fourth component that will be implemented by the study team is short messages (text, audio and video) to study participants to reinforce lifestyle modification and behavioural change (Table 1). Each component is explained in detail below;

Monthly Home Visits: Under the home visit component, VHT members and peer champions will conduct regular visits to 10-12 households per month, approximately 3-4 homes per week. The frequency of visits will be twice a month for the first month, followed by monthly visits for the subsequent 11 months. Each home visit, lasting 45-90 minutes, will involve VHT and peer champion-led, interactive training sessions to educate adolescents and their families on healthy diet modification strategies. These sessions will emphasize balanced eating principles, including increasing fruit and vegetable intake, whole grains, lean protein sources, and healthy fats and the benefits of physical activity. They will take basic measurements of weight, height and blood pressure, reviewing previous diet and physical activity plans, and support the family in developing a healthy menu. Additionally, VHT members will conduct food demonstrations and utilize education materials, VHT registers, weighing scales, blood pressure machines, and portable stadiometers. In the first three months after enrolment, before the introduction of the intervention, home visits will engage the entire family and preferably take place on Saturdays and Sundays when most family members are present, with the VHT member discussing and determining the most convenient day of the week for each family. Following each visit, VHT members will complete the modified VHT register; a Ministry of Health tool that includes NCCD variables.

Physical activity: During the study, adolescents will be required to incorporate a daily 60-minute exercise routine. The study participants will be encouraged to begin with at least 15 minutes of daily exercise and gradually increase the duration to reach the recommended level. While findings from the formative phase showed a preference for jumping rope for girls and football for boys. The VHTs and peer champions will be encouraged to work with each family to identify and make the local play materials, such as ropes and dodgeballs, “blada” game, “Ssonko” game etc. using readily available materials. Additionally, information materials and physical activity videos will be shared with all families. These activities will be documented in the physical activity (PA) diary and the level of activity recorded in the VHT register. Each adolescent will be provided with a Physical Activity diary that will be completed every seven days starting on the day when the VHT/Peer champion visits their home. The PA diary will be carbonated so that a copy is picked by the VHT and one retained with the participant. To support physical activity, at community level, each village will receive two balls (football and netball). To promote participation and team spirit, jersey shirts will be provided to best performing adolescents in each village, that is those who successfully meet the WHO recommended physical activity level for three consecutive months. Parents will also have the option to purchase full jerseys for their children if they wish. Existing village facilities, such as playgrounds, schools, mosques and churches, will be utilized to minimize costs and maximize community engagement. The VHT and peer champion will work with Community members to organise village/ group physical activities on a quarterly basis. In addition to promoting and studying physical activity adoption in the individuals (adolescents), the study will encourage regular exercise among families and community members through quarterly community physical activities organised by the VHT and peer champion. For the first three months, these activities will be held monthly to establish momentum. VHTs, Local Council 1 (LC1) members, and other local resourceful persons will lead and report on these activities. These community-led physical activities will be conducted without any budget allocation from the study team. Instead, the team will be invited as guests to participate and provide support. To motivate participation, a Physical Activity Day will be held to recognize and reward outstanding performance.

Diet modification: VHTs shall have a list with structured health education topics for delivery during every home visit. Health education topics shall cover information related to a heart healthy diet and preventing NCD risk. Using available food in the home, dry rations or charts, the VHT member and peer champion will then carry out demonstrations on healthy foods and their preparation. Documentation of details of meal consumption will be done by the household head or a member delegated by the household head. Families will be encouraged to set up kitchen gardens using the available space. A community-based demonstration garden will be identified as (these already exist within the study communities) to showcase locally available, dietary diverse foods. The Health Kitchen initiative will utilize traditional local foods in the locality to demonstrate healthy meals catering to various dietary needs. These sessions will occur at LC1, VHT, or public community spaces, showcasing balanced eating principles at least once in 6 months. To support diet modification, the study will provide food charts to each family and VHT, along with food diaries for training. Demonstration foods will be provided during VHT training, accompanied by video clips sharing healthy cooking practices.

Phone reminders: To re-enforce the health lifestyle education and health literacy, the study will utilize phone reminders through short, informative, and engaging SMS messages sent twice weekly - midweek and weekend. These messages will be drawn from the health education topic for that month. We will purchase two phones, one for Jinja and another for Kampala Research Assistants for monitoring and clarifying any queries related to the messages. To ensure accessibility, messages will be sent to participants' preferred

contacts, including household members, adolescents, or neighbours, accommodating those with limited technology access. Additionally, participants can call the designated study line as needed. To foster community interaction, participating villages will be encouraged to create WhatsApp groups for sharing experiences, information, and coordinating study activities, although this is not a mandatory intervention component. This multifaceted approach will ensure consistent communication, promote health awareness, and re-enforce the education by VHTs.

Table 1: Summary of the Intervention component and processes

Component	Description	Frequency	Duration	Person Responsible	Materials/Tools	Goals
1. Monthly Home Visits	VHT & peer champion visits for education, Anthropometric measurements and planning/goal setting	Twice monthly (first month), then monthly (2 nd Month to 11 th Month)	45-90 minutes	VHT Members, Peer Champions	VHT Registers, Education Materials, Weighing Scales, Blood Pressure Machines, review diet and physical activity plans	Promote healthy lifestyles Develop healthy menu
2. Physical Activity	Participation in physical activities of their choice Adolescents: 60-minute daily exercise; Adults: 30-60 minutes, 3-5 times/week	recommended daily	Between 30 -60 minutes	Peer Champions, VHT Members to support participants identify enjoyable physical activity (PA) activity and develop a PA plan	Physical Activity Diaries and education materials	Reduce NCD risk factors
3. Diet Modification	Health Diet education, food demonstrations, kitchen garden setup	Monthly education Quarterly demonstrations	45-90 minutes	VHT Members, Peer Champions	Nutrition Charts/Posters, Food dairies and food Demonstration Kits, Kitchen Garden Guides,	Reduce NCD risk factors
4. Phone Reminders	SMS (twice/week: Wed, Sat) and WhatsApp (once/week: Sun) for engagement, health literacy	Twice a week	--	Study Team	Mobile phones, SMS/WhatsApp software	Leverage existing VHT network

6.7. Outcomes

The outcomes include; the effectiveness and implementation science outcomes.

6.7.1 Primary effectiveness outcomes:

The primary effectiveness outcome of the study is the Ideal Cardiovascular Health (ICH) using the American Heart Association (AHA) Life's Simple 7 metrics **smoking status, body mass index (BMI), physical activity, Blood pressure, fasting blood glucose, cholesterol, and diet**. The study seeks to establish the proportion of adolescents and their family members meeting at least five ICH metrics, to enhance the overall ICH score, and to reduce the proportion of individuals exhibiting poor cardiovascular health metrics after 12 months of study intervention. These metrics will be classified into three categories: ideal (5-7 metrics met), intermediate (3-4 metrics met), and poor (0-2 metrics met). This classification will provide a clear understanding of the FaCe-D intervention's impact on cardiovascular health, based on seven key components: Each of these metrics will be assessed and scored based on a previous study by Pahkala-et-al-2013 as shown in **table 2**:

Table 2 Definition of Ideal Cardiovascular Health Metrics (<20 Years of Age) as Defined by the American Heart Association

	Ideal Metric, AHA Definition	Ideal Metric, Definition in this Study
Health behaviors		
Smoking	Never tried; never smoked whole cigarette	Never smoked a cigarette
Body mass index	<85th percentile	<85th percentile
Physical activity	≥60 min of moderate- or vigorous-intensity activity every day	>60 min of moderate-intensity activity/d (>30 MET h/wk)
Diet	4–5 components*: Fruit and vegetables: ≥4.5 cups/d Fish: 2 or more 3.5-oz† servings/wk Fiber-rich whole grains: 3 or more 1-oz-equivalent servings/d Sodium: <1500 mg/d Sugar-sweetened beverages: ≤450 kcal (36 oz)/wk	4–5 components*†: Fruit and vegetables: ≥450 g/d Fish: ≥200 g/wk Fiber-rich whole grains: 2 or more 28.35-g servings of whole-grain bread/d Sodium: <1500 mg/d Sugar-sweetened beverages: ≤450 kcal/wk
Health factors		
Total cholesterol	<170 mg/dL (<4.40 mmol/L)	<4.40 mmol/L
Blood pressure	<90th percentile	<90th percentile
Plasma glucose	<100 mg/dL (<5.6 mmol/L)	<5.6 mmol/L

MET indicates metabolic equivalents.

*Intake goals expressed for a 2000-kcal diet. Scaled accordingly for other levels of energy intake.

†The criterion of having ≥2 of the ideal diet components was applied to form the diet-modified ideal cardiovascular health score.

†1 oz=28.35 g.

6.7.2. Overall Scoring and the Cardiovascular Health Categorization

To create the Life Simple 7 score, a value of 1 will be assigned for each metric if the criterion was met as per table. The total score for an individual can range from 0 to 7 points. A score of 5-7 points will be considered ideal cardiovascular health, and a score of <5 points will be considered not Ideal health. With moderate cardiovascular health (3-4 points) and poor cardiovascular health (0-2 points). Therefore, the main outcome (ideal cardiovascular health) will be a binary variable coded 1 for a score of 5-7 points representing ideal health, and 0 for a score of less than 5 points representing non-ideal health.

6.7.3 Secondary effectiveness outcomes

These will include anxiety scores, depression scores and sleep quality among adolescents. Screening for anxiety and depression among adolescents aged 10-17 years will be conducted using the Mini International Neuropsychiatric Interview for Children and Adolescents version 7.0.2 (MINI-KID 7.0.2). The MINI-KID 7.0.2 is a structured diagnostic interview designed to assess the presence of 24 DSM-V child and adolescent psychiatric disorders as well as the risk of suicide. The MINI-KID is proven to generate reliable and valid

psychiatric diagnoses for children and adolescents. For this study, we will utilize the anxiety and depression modules. Sleep quality will be measured using the single item sleep quality scale (SQS) by Snyder *et al* (2018). The SQS has favorable measurement characteristics compared to lengthier more frequently administered sleep questionnaires like the Pittsburg Sleep Quality Index (PSQI). The single item SQS is very easy to administer and has been validated and widely used in different population. Participants will be asked to report on their sleep quality over a 7-day recall period, taking into consideration core components of sleep quality such as number of hours slept, the ease of falling asleep, and frequency of waking up during the night (except to go to the bathroom). The SQS is assessed on a 10-point visual analog scale (0 = terrible and 10 = excellent), with higher scores indicating better sleep quality. The total score will be interpreted as follows: 0 = terrible, 1–3 = poor, 4–6 = fair, 7–9 = good, and 10 = excellent.

6.7.4 Implementation science outcomes

The data collection and analysis for these outcomes will be guided by the Reach, Effectiveness, Implementation, Adoption and Maintenance (RE-AIM) framework (Glasgow *et al.*, 2019). Reach is the proportion of persons who participate in the intervention, effectiveness is about the effect of the intervention. Adoption refers to what extent the participants and other stakeholders take up the intervention, implementation refers to what extent the intervention is delivered as planned, and maintenance is about sustainability.

1. **Reach:** How many family members attended the health education talk provided by the VHT? How many family members increased their engagement in physical activity? How many households changed diet – reduced salt consumption?
2. **Effectiveness:** Did CVD risk behaviours decrease among adolescents and their families, and which components accounted for reduced risk? Did the intervention reduce BMI among adolescents and family members with abnormal BMI? Did the intervention reduce BMI among adolescents and family members with abnormal BMI? Did BP among adolescents and family members with elevated BP or hypertension improve?
3. **Adoption:** How many family members participated in FCA activities? How many family members attended the health education talk provided by the VHT? How many family members participated in our recommended level of exercise? How many family members followed our dietary recommendation? Did the number of household members reach FCA expectations? How many of the VHTs and peer champions participated implemented the intervention.
4. **Implementation:** Was the intervention implemented with fidelity? Were appropriate intervention components offered to adolescents and families? How many of the 13 VHT visits were conducted? How many of the recommended topics for discussion were done by the VHT. What are the reasons to explain why intervention components was or was not implemented according to plan?
5. **Maintenance:** How well was the intervention absorbed into the routine practices of adolescents and families? What are the barriers and facilitators to maintaining the intervention after the study? What are the barriers and facilitators for scaling the intervention up to the national level? What systems have been put in place to ensure maintenance.

The data for evaluating implementation science outcomes will be collected both quantitatively and qualitatively from all participating adolescents in the household who will have been reached by the intervention, household heads and food preparers. We will purposively sample boys and girls, and women and men of different ages. The participants will have participated in the intervention for at least 6 months. Recruitment of adolescents and their families will be supported by the VHTs (trained on the intervention) and local leaders. Representatives from policy makers and local government district level in health departments, non-government organisations, community leaders will be identified and invited to participate as key informants.

6.8. Study Duration and Data Collection

The overall duration of the study is five years, with the implementation and evaluation phase lasting approximately two years. The demographic data will be collected at baseline (month 0), while the rest of the data on Life's simple 7 metrics will be collected at baseline, month 6, month 12 (end of effectiveness phase) and month 18 (end of maintenance phase). In this phase, study field workers (with a medical background supported by a social science research scientist) will collect data using the study tools while the VHTs will continue to use a modified Ministry of Health (MoH) register (see VHT modified register appendix 5) to collect data during the monthly visits to the families/households. The data from the modified VHT register will be extracted using the data abstraction tool. The data on anxiety, depression and sleep quality among adolescents will be collected at baseline, 6 and 12 months.

The study timeline is illustrated in Table 1.

Table 1: FaCe-D Study schedule

TIMEPOINT (Month)	-3	Implementation and evaluation phase								
		0	3	6	9	12	15	18	21	24
		Effectiveness phase						Maintenance	Closure	
Protocol training, VHT training, SOP development and household mapping	X									
Inform consent		X								
INTERVENTION										
16 clusters (Intervention)										
16 clusters (Wait list)										
DATA type/tool:										
Screening tool	X									
Demographic and Medical History	X									
FaCe-D CVH (Life Simple 7)	X		X		X				X	
Anxiety, depression screen (MINI KID) and sleep quality (SQS tool)	X		X			X				
Food diary data abstraction	X	X	X	X	X	X	X			
Physical activity diary data abstraction	X	X	X	X	X	X	X			
FFQ	X	X	X	X	X	X	X			
PROCESS EVALUATION (KIs and FGDs)				X		X			X	
Costing data/Health economics data		X		X		X			X	

6.9. Training

Training of study teams, Village Health Teams (VHTs), peer champions, and other healthcare providers is crucial for effective implementation.

6.8.1. Training of study teams

All study staff will undergo a five-day protocol training, covering data collection tools and research ethics. They will also be training on how to carry out the testing for blood sugar and cholesterol using the point of care machines.

6.9.2 Training of VHTs, peer champions and health facility workers

All VHTs will receive refresher training using the current VHT training curriculum provided by the MoH, as well as training on completing the modified MoH village register, which includes measurement of weight, physical activities, and blood pressure. Training sessions will utilize visual aids and local language to ensure effective communication and sharing culturally adapted examples, making healthy eating more relatable and achievable.

Peer champions, selected from among the adolescents in the participating households will undergo training similar to VHTs. However, their role will be distinct, serving as bridges between fellow adolescents and VHTs, complementing but not duplicating VHT responsibilities. This targeted training will enable peer champions to effectively support their peers.

Health facility staff will receive refresher training on NCD prevention, management, and CVD risk assessment. By equipping study teams, VHTs, peer champions, and healthcare providers with the necessary skills and knowledge, this comprehensive training will facilitate effective implementation and ensure the success of the study.

6.9.3 VHT Monitoring and Supervision:

Effective monitoring and supervision will ensure VHT motivation, standardization, and accountability. Activities will occur at multiple levels: Peer-to-peer, VHT Coordinators, Community Advisory Board (CAB) members, designated health workers, district or ministry representatives, and study team representatives. VHTs will present a report to the study staff at the health facility every two weeks and during this visit she/he will meet with both the study staff and designated health worker in-charge of VHTs to review performance and completeness of data. A monitoring and supervision checklist (Appendix 6) and data quality framework will aid these activities. The study team will conduct direct observation using checklists, monthly review meetings, random checks, field incident and referral tracking, and GIS location and timestamps (where possible).

6.9.4 VHT Facilitation and Support:

Each VHT will receive a monthly facilitation of 80,000 Uganda Shillings, issued in two instalments (40,000 Uganda Shillings) upon presentation of the VHT register with records/evidence of visits conducted and signing an accountability form. Additionally, VHTs will receive: An Umbrella, Bag, T-shirt for identification, Equipment and tools, including Food charts, Handbook, VHT register, Notebooks and pens, weighing scale, Stadiometer and Blood pressure machine, these provisions will support VHTs in their critical role in the FaCe-D study and will be left with the VHTs after the study end after discussion with the ministry of health team. The peer champions will receive a total facilitation and transport of 40,000 Uganda shillings issued in one instalment upon presentation of a Home visit report to the health facility once a month.

7.0 Statistical Analysis

Data on baseline characteristics of the study participants will be analysed using descriptive summary statistics including mean (standard deviation) and median (interquartile range) for the continuous variables, and frequencies and percentages for the categorical variables. The intervention effect on cardiovascular disease risk outcomes among the study adolescents will be determined using mixed-effects regression model. The model will be used to account for within cluster variations. The model is illustrated below.

$$E(\theta_{jk}) = \alpha + \beta X_{jk} + \mu_j$$

Where j is a cluster (1 to 32), k is an individual, θ is the expected outcome (e.g., ideal cardiovascular health), α is the outcome in the control group, β is the intervention effect, X_{jk} is an indicator for whether individual k is in cluster j receiving the intervention, μ_j is a random effect for cluster j . The above model can be naturally extended to accommodate all types of outcomes by replacing the expected outcome $E(\theta_{jk})$ with $E(\mu_j)$ for a mean (continuous) outcome, $\log(\lambda_{jk})$ for rate (count) outcome, and $\text{logit}(\pi_{jk})$ for proportion (binary) outcome (e.g., ideal cardiovascular health). The baseline measures of the outcomes will be included a priori in the model to adjust for their effects. Additional covariates (potential confounders) will include participants individual level factors (like age, sex, education and others) and household level factors (like head of household age, sex, education and others). Intervention effect will be measured using Odds ratio

(OR) for binary outcomes (the main outcome, ideal cardiovascular health), mean difference (MD) for continuous outcomes, and incidence rate ratio (IRR) for count outcomes. All these measures of the intervention effect will be presented with 95 % confidence interval (CI). Wald test p-value will also be reported to indicate the strength of evidence for the intervention effect. In addition, intra-cluster correlation (ICC) will be estimated.

8.0 Process evaluation of the FaCe-D study

Our team will evaluate the process of implementing the FaCe-D study intervention based on the grounds of a broad social behavioral approach to support adolescents and their families' engagements and capacity building for healthy lifestyles and diet literacy. We will place the needs, experiences, attitudes and perspectives of the adolescents and their families at the center of the implementation and process evaluation of the intervention as well as investigate participants' motivations and decision-making processes related to preferences and needs of adolescents and their families to engage in health literacy, lifestyle and behavioral change.

The findings from the process evaluation will enhance the social construction and acceptability of the FaCe-D intervention, link outcomes to policy and advocacy, and impact on sustainability of CVD health (Amuyunzu-Nyamongo, 2010). The process evaluation will also provide an opportunity to document the implementation process and make recommendations to refine the delivery procedures and the FCA intervention (Moore et al., 2015).

A qualitative approach will underpin the collection of social behavioral information in two chosen districts (Kampala and Jinja) in Uganda. We seek to understand the importance of context, especially when comparing rural (Jinja) and urban (Kampala) areas in Uganda. We will yield an in-depth socio-cultural understanding of adolescents and their families on reported outcomes, their motivations, preferences, needs, beliefs, expectations, identities, hopes, views on feeding habits, physical activities, and decision-making processes in order to better understand stakeholder (adolescents and their families, VHTs/healthcare provider, policy maker, community leader) positioning during implementation of the FaCe-D intervention; so as to inform policy and practice, ensure effective service user education, position service users and their families to understand the intervention, and interpret study outcomes, and facilitate its further implementation (Maher & Sekajugo, 2011).

8.1. The aim of the process evaluation

The aim is to investigate the contextual and process factors that influence the reach, adoption, appropriateness, effectiveness, fidelity, acceptability, scalability (uptake) and sustainability of FaCe-D intervention for improving the cardiovascular health among adolescents and their families in Uganda.

8.2. Research questions guiding the process evaluation

1. What are the perceptions and experiences of participants (adolescents, parents and community members), health care providers and policy makers on the FaCe-D intervention for improvement of CVD health among adolescents and their families?
2. What are the barriers and facilitators to implementation of the FaCe-D intervention?
3. What are the barriers and facilitators to acceptability and sustainability of the FaCe-D intervention for improvement of CVD health among adolescents and their families?
4. What are the factors that can potentially influence the scaling up of the FaCe-D intervention for improvement of CVD health among adolescents and their families in Uganda?

5. how has the FaCe-D intervention helped improve the literacy, lifestyle and behavioural change among adolescents and their families and communities in Uganda?
6. What can be done to enable acceptability/uptake of the FCA intervention by adolescents and their families in Uganda?

8.3. The specific objectives of the process evaluation

1. To explore the perceptions and experiences of participants (adolescents, household members and community members), health care providers and policymakers on the FaCe-D intervention for improvement of CVD health among adolescents and their families.
2. To explore the contextual and process factors (barriers and facilitators) for acceptability and scale-up of the FaCe-D intervention at the family and community level.
3. To evaluate and appraise the procedures followed during implementation of the FaCe-D intervention to improve CVD health among adolescents in their communities.
4. To determine the feasibility for the adoption of FaCe-D intervention and its scale-up.
5. To recommend healthy lifestyles, behaviours, feeding practices and physical activities preferred and adopted by adolescents and their families in context of cultural beliefs, values, attitudes and practices of the community.

8.4. The outcomes of process evaluation

Widely, process evaluations are used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes (Van Hout et al., 2020). The process evaluation in FaCe-D study is therefore focused on identifying the contextual factors that affect, adoption, fidelity, maintenance and effectiveness of the FaCe-D as an intervention. This synergistic approach to evaluate, understand and respond will support the FaCe-D intervention to inform surveillance, policy and practice development, and efforts to involve and educate family members and communities on matters that reduce the risks of CVD among the children in Uganda.

8.5. Methods and design for the process evaluation

8.5.1 study design

This study will adopt a behavioral social science-qualitative research design (Djamba & Neuman, 2002). We will understand how and why our efforts to implement FCA may succeed or fail, and how patients and providers experience and make decisions to participate or not, in our intervention (Bokhour et al., 2018). Therefore, key questions on attitudes, how our intervention can be implemented, its effectiveness, and adoption at different sites will be explored using this design. Therefore, at the end, we will be able to reveal organizational and interpersonal dynamics affecting the intervention; explaining practice change; discerning barriers and facilitators to uptake of the intervention; identifying what strategies are being used to foster organizational change, how successful they are perceived to be, and how they make a difference; and in identifying contextual factors and provider perceptions that affect implementation and sustainability(Morgan & Harmon, 2001).

8.5.2 Study Population

The study population for the process evaluation will include adolescents, household heads, parents/care takers), food preparers community members and leaders, policy makers, local government and VHT/ peer champions. The primary food preparer will be determined through discussion with the members who will identify the person who prepares most meals. Only one primary food preparer per household will be included in the study, provided they meet the inclusion criteria and can consent to participate

8.5.3 Data Collection for the process evaluation

Data collection will explore the experiences, perceptions, attitudes, and practices of a wide variety of stakeholders during the process of FaCe-D intervention implementation to develop an understanding of the impact of broader structural and contextual factors on the implementation process. Data shall be collected using focus group discussions among adolescents and their families (care takers)/community members, key informant interviews with community leaders, policy makers, ministerial/local government and VHTs. These will be selected using the purposive sampling methods.

Observations shall be made on the procedures followed and activities done before, during and after health education sessions. Daily activities including preferred physical activities and feeding practices will be recorded by adolescents and these shall be retrieved and reviewed by the VHT every week. This will help to assess fidelity and self-efficacy in the context of the intervention, assess the barriers and facilitators and recommendations to improve the intervention adaptation process (Lessard et al., 2016). Socio-behavioural qualitative data will be collected by a team of trained Social Scientist Researchers. The data collection/interviews will continue until data saturation is reached. The intervention will take into consideration the age, gender and other socio-demographic characteristics of the participants before engaging them in physical activities. We will collect data at three time-points. That is; at baseline within the first month of joining the intervention to collect data on the perceptions and attitude of the participants, at midline (6 months) in the intervention in order to collect data of the experiences including challenges and achievements/benefits that are attributable to our intervention, and to learn from their experiences to improve the delivery of the intervention. Also, we shall conduct exit interviews with patients as end line data collection with the aim of gathering information for scalability of our intervention.

Table 3 below summarises the data collection techniques that will be used for the study.

Table 3: Process evaluation Objectives and outcomes

Factors affecting Fidelity as key evaluation outcome at baseline (within 3 month of implementing the intervention), (12 months and 18 months)			
Objective	Key questions	Methods to be used	Population and sampling
-To evaluate and appraise the procedures followed during the implementation of the FaCe-D intervention to improve CVD health among adolescents in their communities.	-What are the barriers and facilitators to implementation fidelity of the FaCe-D intervention?	8 Field observations 4-10 Key informant interviews (KII) 6-12 Focus group discussions (FGDs)	VHT home visits and education sessions on physical activities, food preparation. Family and community members' involvement in FaCe-D intervention. Health care providers, Local/community leaders, VHTs and District Health Teams. Adolescents, family members and community members
Factors affecting adoption as a key evaluation outcome at baseline (3 months of joining the intervention) and end line (12 months)			
-To explore the barriers and facilitators for acceptability/uptake of the FCA intervention	- What enables acceptability/ uptake of the FCA intervention by	4-10 Key informant interviews (KII)	With health care providers, Local/community leaders,

FCA intervention at the family, community and health provider level.	adolescents and their families ?	6-12 Focus Group Discussions	VHTs and District Health Teams. Adolescents, family members, community members and VHTs and peer champions
Maintenance as a key evaluation outcome at (12 months ad 18 months)			
-To explore the contextual and process factors (barriers and facilitators) for scaling-up of the FaCe-D intervention at the adolescent.family, community, health provider and national levels?	- What are the barriers and facilitators to maintaining the intervention in families and communities? -What are the barriers and facilitators to scaling the intervention up to the community and national levels?	4-10 Key informant interviews 6-12 Focus Group Discussions (FGDs)	With health care providers, Local/community leaders, VHTs and District Health Teams. Adolescents, family members and community members
Effectiveness as a key evaluation outcome at midline (6 months) and end line (12 months)			
-To establish if there has been improvement in the diet and health lifestyle literacy among adolescents and their families	- Can the FaCe-D intervention help improve the diet and health lifestyle literacy, among adolescents and their families	4-10 Key informant interviews (KII) 6-12 Focus group discussions (FGDs)	Local, Ministerial policy makers and District Health Teams Adolescents, family members and community members
-To explore the perceptions and experiences of participants on the FCA intervention improvement of CVD health among adolescents and their families.	-What are the perceptions and experiences of participants on the FCA intervention for the CVD health among adolescents and their families?	6-12 Focus group discussions (FGDs) 4-10 Key informant interviews (KII)	Adolescents, family members and community members with Local, Ministerial policy makers and District Health Teams

8.5.4. Data Management and analysis

Field notes from study procedure observations will be analysed thematically to provide a description of process and content involved in adapting and delivering the intervention. Recordings from the dairies will be interpreted and discussed with the participants and these shall be used to inform other steps to improve the uptake of the intervention. Audio recordings of interviews and FGDs will be transcribed verbatim by competent and experienced social scientists. Translation from the local language into English and back translation will be done in cases where interviews are conducted in local languages. An electronic data management package (NVivo 14) will be used to manage the data and a thematic approach shall be used to analyze the data (Zamawe, 2015). The research team will take time to read the texts several times to identify the themes and emergent subthemes. The data shall be coded under respective themes and subthemes. The RE-AIM Framework will, therefore, guide the evaluation of the process basing on the identified barriers and facilitators to the adoption, acceptability, feasibility, fidelity effectiveness and sustainability of the FCA intervention at individual, interpersonal, community and structural levels.

8.6 Credibility and transferability

Our proposal to conduct the process evaluation considers research ethics. The credibility and reliability of our data will be anchored in the ability to triangulate our data. Triangulation will occur across methods (focus group discussions, key informant and in-depth interviews, observations and activity dairies). In addition, our

9.0 Economic evaluation

A trial-based cost-effectiveness analysis will be conducted to establish the incremental costs, incremental benefit and the incremental cost-effectiveness ratio (ICER) for using the FaCe-D intervention for prevention of cardiovascular diseases among adolescents and their families. A societal perspective which includes costs to healthcare payer, patients and their household will be adopted to capture the broader impact of the intervention. The purpose of this evaluation is to assist decision-makers in determining whether the implementation of FaCe-D intervention, as demonstrated in this trial would be cost-effective if implemented on a routine basis. The analysis will follow the Consolidated Health Evaluation Reporting Standards (CHEERS) statement, for reporting economic evaluation studies to inform health policy.

9.1. Cost estimation and analysis

A three-stage approach will be followed to determine the total and unit cost estimates, based on the study trial design. The first stage will include identification of incremental resources used during the study implementation. Relevant cost categories and cost centres such as start-up versus recurrent costs, direct versus indirect costs, personnel, training and travel costs will be used to classify resources used during study implementation. Costs will further be identified and categorised by perspective. The next stages will involve quantification and valuation of incremental resources used during the study implementation. In order to capture the full value of the alternatives, we shall further categorize costs into financial and economic costs. Financial costs are monetary outlays paid out for acquisition or implementation of the alternatives, while economic costs will comprise the value of services and inputs regardless of the sources of funding and take into account the value of donated goods. For fixed costs such as building equipment. A top-down approach will be employed to allocate shared costs to the intervention using allocation proxies.

To determine the resources associated with the healthcare payer for implementing the intervention, information will be gathered from project financial records and through interviews with the program financial managers and project team. The data collection will be conducted prospectively throughout the study implementation period. Intervention costs will be carefully assessed and separated cost related research. Given a broader perspective, participant and household related costs will be collected separately in this study. A household level economic questionnaire will be used prospectively alongside other study case report forms. The questionnaire will focus on the direct and indirect costs associated with three components of the study intervention such as health diet, physical activity and regular screening. Direct costs include direct expenditure on food items, physical activities and regular screening for CVD following the intervention. Indirect costs will be determining the amount of time caregivers or parents spending in supporting their adolescents in the three main intervention areas. The valuation of time used will assume that national minimum wage rates represent the alternative cost of the caregivers' time.

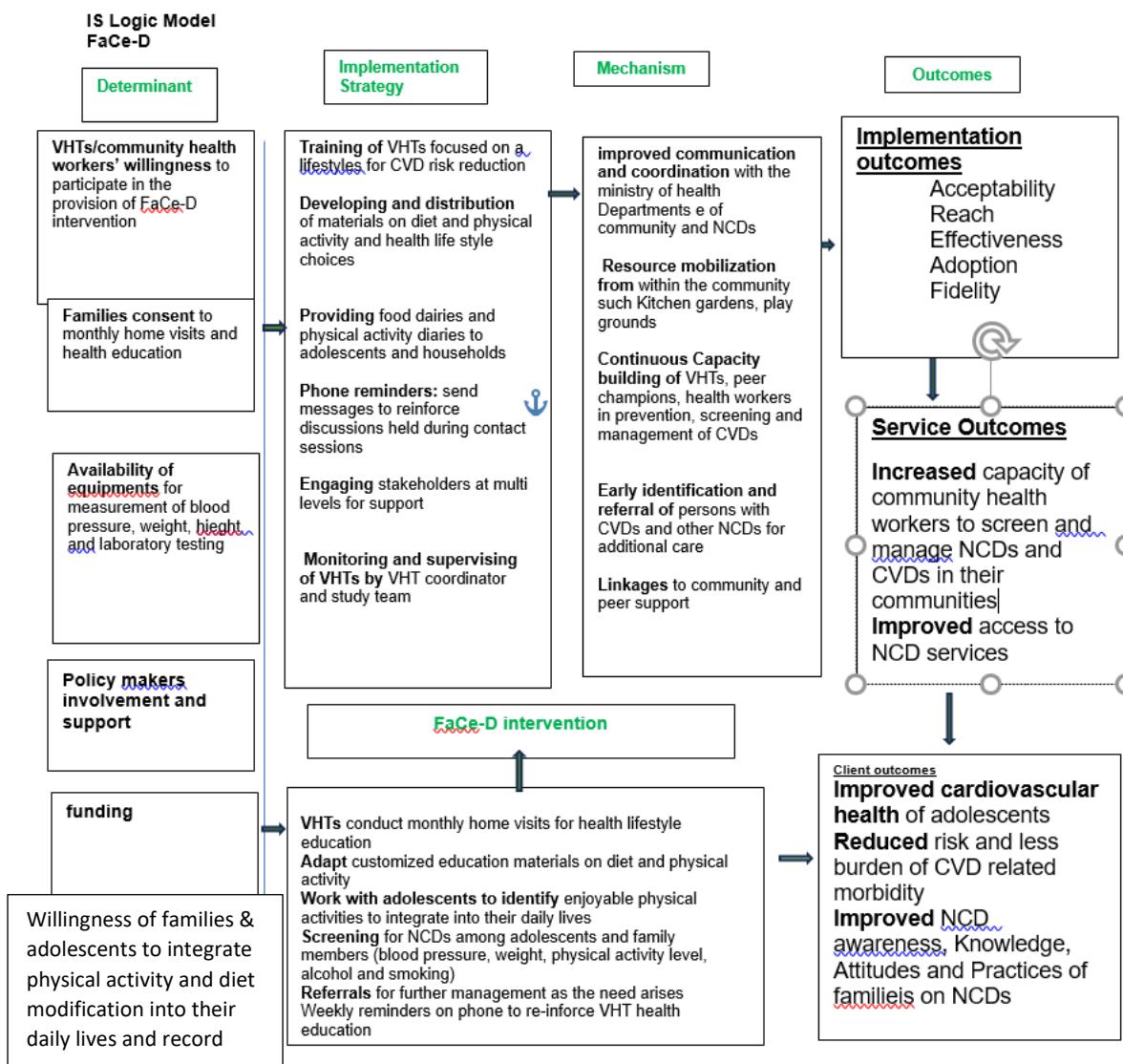
9.2 Measurement of cost effectiveness

The outcome evaluation will be based on estimable primary outcomes of the main trial as approved by the research team. We shall consider additional generic effectiveness measures applied in economic evaluation such as Disability adjusted life years (DALYs) averted due to prevention of CVD. DALY is a generic effectiveness measure that would allow as compare our economic evaluation results with other interventions within the health sector. As much as possible, we shall use the main-trial parameters and available global burden of disease studies to compute the DALYs averted.

9.3 Cost-effectiveness analysis

The final outcome of this evaluation will be incremental cost, incremental effectiveness and the incremental cost-effectiveness ratio (ICER) of the intervention. The estimated ICER will be compared against a recommended cost-effectiveness threshold by World Health Organization for in the low-middle income countries. For instance, the intervention will be deemed highly cost-effective if the ICER is less than one time the gross domestic product (GDP) per capita or, deemed cost-effective if the ICER is between one and three times the GDP per capita of Uganda. All costs will be adjusted to a stable year dollar price. A selected discount rate will be used to value the present value of future resources to be used in the implementation of the intervention. Sensitivity analyses will be conducted to check the impact of parameter uncertainty on the results. Parameters will be varied based on selected ranges. One-way sensitivity analysis will be performed on all parameter inputs to generate Tornado plots representing the most influencing parameters. While probabilistic sensitivity analyses will be performed using monte Carlo simulation to generate cost-effectiveness acceptability curves and portray the robustness of the model. All modelling will be performed using a Microsoft-excel based decision analytical model and were possible TreeAge software will be used for probabilistic sensitivity analyses.

10.0 IS Logic model



10.1 Implementation strategies

With reference to the logic model of implementation of FaCe-D study, the implementation strategies will include the stakeholder engagement, training of the village health teams and peer champions, development and distribution of health education materials, participants' handbooks, food and physical activity dairies. We will also work with the ministry of health teams in the department of community and non-communicable disease to monitor and supervise the VHTs through fostering communication and improved coordination and strengthening referral and linkages while drawing on the resources within the community.

11.0 Governance and Ethics

Compliance: The study will be subject to research ethics oversight from the Uganda Virus Research Institute Research Ethics Committee. Uganda National Council of Science and Technology (UNCST) and the University of British Columbia Behavioural Research Ethics Board. Ethical considerations: We will conduct the research by the principles of Good Clinical Practice and LSHTM research governance and integrity guidelines. (<https://www.lshtm.ac.uk/research/research-governance-integrity>). The study will be conducted with a team of qualified professionals who possess the necessary knowledge and skills including training in Human subject's protection.

Informed Consent: All study participants including adolescents and their family members will be provided with adequate information to fully understand the purpose, procedures, potential benefits, and risks associated with participating in the study. Written informed consent /assent will be obtained from both the adolescents and their parents or legal guardians, while respecting their autonomy and ensuring their comprehension of the intervention. Participants will be free to decline to join the study or to withdraw at any time. Parental/guardian consent will be obtained from all adolescents aged 10-17 years followed by their individual assent. Adolescents for whom parental/guardian consent cannot be obtained will be excluded for the study. All interviews and informed consent procedures will be conducted in the local languages understood by the participants to ensure comprehension of the study.

Privacy and confidentiality: All data collected will be treated with confidentiality. Data including identifying information such as the consent and assent forms will be stored in secure cabins under lock and key. Computer databases will be encrypted, and data will be anonymized and stored without participant identifiers in accordance with Good Clinical Practice. Data will be stored at MRC/UVR & LSHTM – Uganda research unit but will be accessible to all partners. There will be no need to transfer data so no need for data transfer agreement.

12.0 Safeguarding

We are committed to safeguarding the welfare of minors and vulnerable adults during project implementation. Our protocol will follow key principles: empowerment, prevention, proportionality, protection, partnership, and accountability, ensuring the safety of beneficiaries, stakeholders, and staff. The project management team, led by Dr. Ivan Namakoola as the safeguarding officer, will oversee compliance. A trained safeguarding focal person will be appointed at each project site. All staff will be informed about the protocol, and copies will be shared with relevant stakeholders. Personal and sensitive data will be securely collected and stored, with an annual review to ensure compliance with any operational developments.

13.0 Dissemination plan

We will disseminate the results at parish (group of villages that were involved in the study), at the district level and to the technical working groups at the ministry of health through their routine meetings. We will however arrange a meeting bringing together different stakeholders to share the results and hear their

feedback and next steps. Dr. Birungi, Dr. Muddu and Dr. Ouma have organized several meetings to disseminate results to policymakers at the Ministry of Health and other relevant Ministries, and some of this effort has resulted into policy shift. In recent years, study team members have disseminated research findings in top journals (e.g., *Lancet*, *Lancet Global Health*, *AIDS and Behavior*, *JAIDS*, and *PLOS Medicine*). Study team members have collectively published over 100 peer-reviewed journal articles in the past five years, and have given presentations at universities, research conferences such as at the meetings of the *International AIDS Society*, and research seminars and workshops. The team have experience disseminating research findings through academic publications. Lastly, our primary dissemination strategy will be to produce multiple peer-reviewed publications (which will also be posted and freely available on institutions' websites) and conference presentations.

Figure 2: FaCe-D implementation districts



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14.0 Appendices

Appendix 1: Summary of the data to be collected

Time/ Activity	Data to be collected	tool	Frequency	By whom
Identification of participants for implementation phase	Households with adolescents	VHT registers Local/Village leaders registers	once	Study team
At enrollment	Demographic data including family and treatment history diabetes or hypertension, or chronic conditions, number of family members present blood pressure, height & weight, BMI and Cardiovascular Health matrix will be calculated based on seven simple risk factors (Life's Simple 7) Any chronic illness	Enrollment and Biomedical indicators tool Cardiovascular health matrix BMI wheel GPAQ	At baseline	Study field worker
During VHT visit	Weight and blood pressure Lifestyle data: physical activity, 7 –days food diary data (self-carbonating) Materials given out to the family	Village registers Adolescent physical Activity diary 7-day food diary	Every home visit	VHT
At 12 months and 18 months)	blood pressure, & weight, height BMI and CVD health and risk to be calculated Do a point of care Cholesterol measurement and a fasting Blood Glucose Any new chronic illness illnesses present Lifestyle data (physical activity, 7 –days food diary data & 24-hour recall food recall Anxiety, depression and sleep quality	End of study tool	end of the study	Study field worker
Costing data	Costing tool	Questionnaire	0, 6, 12,18	
Process evaluation	Implementation science outcomes listed below		6, 12,18	Social scientist team

Appendix 2: FaCe-D study Screening tool

Screening Date:

--	--	--	--	--	--

Participant's Initials:

--	--	--	--	--	--

Screening ID:

--	--	--	--	--	--	--	--

Participants must meet ALL of the inclusion criteria and NONE of the exclusion before filling the enrolment form

Screening (Inclusion) Criteria - tick Yes or No

1. Is the participant aged ≥ 10 and 19 years of age? Yes, No

2. Has the participants parent/caretaker provided consent? Yes, No

3. Has the participants Household head provided consent? Yes, No

4. Is the participant planning to stay in this village for the next 12 months Yes No

Screening (Exclusion) Criteria - tick Yes or No

5. Is the participant in boarding school? Yes, No

6. Is the participant know to have any chronic conditions? Yes, No

7. Is the participant pregnant or lactating? Yes, No NA

8. Is the participant Very sick, requiring immediate hospital care/admission? Yes, No

Proceed to next steps only if yes to question 9

9. Has the patient met all of the inclusion criteria and none of the Exclusion criteria? Yes, No

If Yes to question 9 proceed to consent process and thereafter for Baseline clinical measurements and if possible point of care Tests form before completing the enrolment form

I am confident that the information supplied in this tool/ form is complete and accurate data.

Data collector's Initials:

Date of signature:

D	d	m	m	m	y	y	y	y

Appendix 3: FaCe-D Enrolment (CVH and Mental Wellbeing) Tool

FaCe-D ICH and Mental Wellbeing Tool

Location Data		
Question	Response	Code
Village		
District		
Interviewer name/ ID		
Date of completion of tool (Day, month, and year)		
Time of interview		

Demographics		
Question	Response	Code
Participant name		
Sex		
Age		
Study step		
Contact phone number		
Phone ownership		
Highest level of education		
Ethnic group		
Marital status		
Work status		
Average household income		
Number of people who live in household including respondent		
Medication for any chronic illness apart from diabetes, hypertension, cardiovascular disorder, or mental disorder	Yes 1 No 2 if yes, please specify	

Step 1 Behavioral measurements

Tobacco use		
Now I'm going to ask you some questions about smoking/tobacco use.		
Question	Response	Code
Do you currently smoke any tobacco products, such as cigarettes, cigars or pipes?	Yes 1 No 2 if no, go to code xx	
Do you currently smoke tobacco products daily?	Yes 1 No 2 if no, go to code xx	
	In Years. If known go to code xx	

Do you remember how long ago it was that you started smoking? If they know age please list <i>Don't know 77</i>	In Months. If known go to code xx	
	In Weeks. If known go to code xx	
	Age in years:	
On average, how many of the following products do you smoke/use each day/week? <i>Don't Know 99</i>	Manufactured cigarettes	
	Hand-rolled cigarettes	
	Pipes full of tobacco	
	Cigars	
	Number of Shisha sessions	
	Other	
	Other (please specify):	
During the past 12 months, have you tried to stop smoking?	Yes 1	
	No 2	
In the past, did you ever smoke any tobacco products?	Yes 1	
	No 2	
In the past, did you ever smoke daily?	Yes 1	
	No 2	
How old were you when you stopped smoking?	Age (years) If not known 99 If known go to code xxx	
How long ago did you stop smoking? <i>Don't Know 99</i>	In Years. If known go to code xx	
	In Months. If known go to code xx	
	In Weeks. If known go to code xx	
Do you currently use any smokeless tobacco products such as (<i>snuff, chewing tobacco</i>)?	Yes 1 No 2 if no, go to code xx	
Do you currently use smokeless tobacco products daily?	Yes 1 No 2 if no, go to code xx	
On average, how many times a day/week do you use <i>Don't Know 99.</i>	Snuff by mouth: Daily. Weekly	
	Snuff by nose: Daily. Weekly	
	Chewing tobacco: Daily. Weekly	
	Other	
	Other (please specify):	
In the past, did you ever use smokeless tobacco products such as <i>chewing tobacco, etc.</i> ?	Yes 1 No 2 if no, go to code xx	
During the past 30 days, did someone smoke in your home? <i>Smokers should exclude themselves.</i>	Yes 1 No 2	

During the past 30 days, did someone smoke in closed areas in your workplace (in the building, in a work area or a specific office)?	Yes 1 No 2 Don't work in closed area	
--	--	--

Alcohol Consumption		
The next questions ask about the consumption of alcohol		
Question	Response	Code
Have you ever consumed any alcohol such as beer, wine, spirits or local brew?	Yes 1 No 2	
In the past, have you stopped drinking due to health reasons, such as a negative impact on your health or on the advice of your doctor or other health worker?	Yes 1 if yes, go to code xx No 2 if no, go to code xx	
During the past month, how frequently have you had at least one standard alcoholic drink? <i>For a few sips of alcohol during the past 12 months, the answer should be "Never".</i>	Daily 1 5-6 days per week 2 3-4 days per week 3 1-2 days per week 4 1-3 days per month 5 Less than once a month 6 Never 7	
During the past month, what was the largest number of standard alcoholic drinks you had on a single occasion?	Largest number Don't know 99	
During the past month, how frequently have you had at least one locally brewed drink? <i>For a few sips of local brew during the past 12 months, the answer should be "Never".</i>	Daily 1 5-6 days per week 2 3-4 days per week 3 1-2 days per week 4 1-3 days per month 5 Less than once a month 6 Never 7	
During the past month, what was the largest number of locally brewed drinks you had on a single occasion?	Largest number Don't know 99	
During the past month, how often have you failed to do what was normally expected from you because of drinking?	Daily or almost daily Weekly Never	

Diet		
The next questions ask about the fruits and vegetables that you usually eat. A serving is approximately the size of your fist.		
Question	Response	Code
In a typical week, on how many days do you eat fruit?	Number of days Don't know 99. If zero days go to code xx	
How many servings of fruit do you eat on one of those days?	Number of servings Don't know 99	
In a typical week, on how many days do you eat vegetables?	Number of days. If zero days go to code xx Don't know 99	
How many servings of vegetables do you eat on one of those days?	Number of servings Don't know 99	
Dietary salt, oil, and sugar		
With the next questions, we would like to learn more about salt, oil, and sugar in your diet. Dietary salt includes ordinary table salt, unrefined salt such as sea salt, iodized salt, salty stock cubes and powders, and salty sauces such as soy sauce. Oil includes vegetable oil, olive oil, ghee, butter, nut oils, and blue band. Sugar includes refined and unrefined sugar, honey, and other sweeteners.		
How often do you add salt or a salty sauce such as soy sauce or additive like aromat to your food right before you eat it or as you are eating it?	Always Often Sometimes Rarely Never Don't know 99	
How often is salt, salty seasoning or a salty sauce added in cooking or preparing foods in your household?	Always Often Sometimes Rarely Never Don't know 99	
How often do you eat processed food high in salt? These are foods that have been altered from their natural state, such as packaged salty snacks, canned salty food, fast food, sausages, cheese, bacon and processed meat	Always Often Sometimes Rarely Never Don't know 99	
How much salt or salty sauce do you think you consume?	Far too much Too much	

	Just the right amount Too little Far too little Don't know 99	
Do you do any of the following on a regular basis to control your salt intake?		
Limit consumption of processed foods	Yes 1 No 2	
Look at the salt or sodium content on food labels	Yes 1 No 2	
Buy low salt/sodium alternatives	Yes 1 No 2	
Use spices other than salt when cooking	Yes 1 No 2	
Avoid eating foods prepared outside of a home	Yes 1 No 2	
Do other things specifically to control your salt intake	Yes 1. If yes go to code xx No 2	
Other (please specify)		
How often do you add oil or fat such as blue band, ghee, pork fat, and olive oil to your food right before you eat it or as you are eating it?	Always Often Sometimes Rarely Never Don't know 99	
How often is oil or any other fat like ghee and butter added in cooking or preparing foods in your household?	Always Often Sometimes Rarely Never Don't know 99	
Do you do any of the following on a regular basis to control your oil intake?		
Limit consumption of processed foods	Yes 1 No 2	
Look at the fat or hydrogenated oil content on food labels	Yes 1 No 2	
Buy low fat alternatives	Yes 1	

	No 2	
Cook without oil or oil-based additives	Yes 1 No 2	
Avoid eating foods prepared outside of a home	Yes 1 No 2	
Do other things specifically to control your oil/ fat intake	Yes 1. If yes go to code xx No 2	
Other (please specify)		
How often do you add sugar or other sweeteners like honey to your drinks right before you drink them or as you are drinking them?	Always Often Sometimes Rarely Never Don't know 99	
How often is sugar or other sweeteners like honey added in cooking or preparing foods in your household?	Always Often Sometimes Rarely Never Don't know 99	
Do you do any of the following on a regular basis to control your sugar intake?		
Limit consumption of processed foods	Yes 1 No 2	
Look at the sugar content on food labels	Yes 1 No 2	
Buy low sugar alternatives	Yes 1 No 2	
Prepare drinks or food without sugar or honey	Yes 1 No 2	
Avoid eating foods prepared outside of a home	Yes 1 No 2	
Do other things specifically to control your sugar intake	Yes 1. If yes go to code xx No 2	
Other (please specify)		

Physical activity		
Next, I am going to ask you about the time you spend doing different types of physical activity in a typical week. Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food.		
Question	Response	Code
Do you do any vigorous-intensity sports, fitness or leisure activities that cause large increases in breathing or heart rate like running or football?	Yes 1 No 2 if no, go to code xx	
In a typical week, on how many days do you do vigorous-intensity sports, fitness or leisure activities?	Number of days	
How much time do you spend doing vigorous-intensity sports, fitness or leisure activities on a typical day?	Hours: minutes	
Do you do any moderate-intensity sports, fitness or recreational (<i>leisure</i>) activities that cause a small increase in breathing or heart rate such as brisk walking, cycling, swimming, or volleyball?	Yes 1 No 2 if no, go to code xx	
In a typical week, on how many days do you do moderate-intensity sports, fitness or leisure activities?	Number of days	
How much time do you spend doing moderate-intensity sports, fitness or leisure activities on a typical day?	Hours: minutes	
Sedentary behaviour		
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, traveling in car, bus, train, reading, playing cards or watching television, but do not include time spent sleeping.		
How much time do you usually spend sitting or reclining on a typical day?	Hours: minutes	

Blood pressure history		
Have you ever had your blood pressure measured by a doctor or other health worker?	Yes 1 No 2 if no, go to code xx	
Have you ever been told by a doctor or other health worker that you have raised blood pressure or hypertension?	Yes 1 No 2 if no, go to code xx	
Were you first told in the past 12 months?	Yes 1 No 2	
In the past month, have you taken any drugs (medication) for raised blood pressure prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for raised blood pressure or hypertension?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for your raised blood pressure?	Yes 1 No 2	

Diabetes history		
Have you ever had your blood sugar measured by a doctor or other health worker?	Yes 1 No 2 if no, go to code xx	
Have you ever been told by a doctor or other health worker that you have raised blood sugar or diabetes?	Yes 1 No 2 if no, go to code xx	
Were you first told in the past 12 months?	Yes 1 No 2	
In the past month, have you taken any drugs (medication) for diabetes prescribed by a doctor or other health worker?	Yes 1 No 2	
Are you currently taking insulin for diabetes prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for diabetes or raised blood sugar?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for your diabetes?	Yes 1 No 2	

Cholesterol history		
Have you ever had your cholesterol (fat levels in your blood) measured by a doctor or other health worker?	Yes 1 No 2 if no, go to code xx	
Have you ever been told by a doctor or other health worker that you have raised cholesterol?	Yes 1 No 2 if no, go to code xx	
Were you first told in the past 12 months?	Yes 1 No 2	
In the past month, have you taken any oral treatment (medication) for raised total cholesterol prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for raised cholesterol?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for your raised cholesterol?	Yes 1 No 2	

Cardiovascular disease history		
Have you ever had a heart attack or chest pain from heart disease (angina) or a stroke (cerebrovascular accident or incident)?	Yes 1 No 2	
Are you currently taking aspirin daily or almost daily to prevent or treat heart disease?	Yes 1 No 2	
Have you ever seen a traditional healer for raised cholesterol?	Yes 1	

	No 2	
Are you currently taking any herbal or traditional remedy for your raised cholesterol?	Yes 1 No 2	
Are you currently taking statins (medicines to lower cholesterol) daily or almost daily regularly to prevent or treat heart disease?	Yes 1 No 2	

Mental health history		
Have you ever seen a doctor, counselor, psychologist, psychiatrist or other health worker for a mental health disorder like depression or anxiety?	Yes 1 No 2 if no, go to code xx	
Have you ever been told by a doctor or other health worker that you have a mental health disorder?	Yes 1 No 2 if no, go to code xx	
Were you first told in the past 12 months?	Yes 1 No 2	
In the past month, have you taken any drugs (medication) for a mental health disorder prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for a mental health disorder?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for a mental health disorder?	Yes 1 No 2	

Step 2 Physical Measurements

Blood pressure		
Reading 1	Systolic (mmHg)	
<i>Record first measurement after the participant has rested for 15 minutes. Wait 3 minutes before taking second measurement.</i>	Diastolic (mmHg)	
Reading 2	Systolic (mmHg)	
<i>Record second measurement. Record third measurement after participant has rested 3 minutes.</i>	Diastolic (mmHg)	
Reading 3	Systolic (mmHg)	
<i>Record third measurement</i>	Diastolic (mmHg)	
During the past month, have you been treated for raised blood pressure with drugs (medication) prescribed by a doctor or other health worker?	Yes 1 No 2	
Height and weight		
For women: Are you pregnant? If pregnant, skip height, measurements	Yes 1 No 2	
Height in centimeters with one decimal point		
Weight in kgs with one decimal point		

Step 3 Biochemistry

Blood glucose		
Time of last meal (24-hour clock). It is essential that participant has not had anything to drink or eat apart from water in the last 8 hours immediately before the blood test.		
Fasting blood glucose in MMOL/L or MG/DL		
Today, have you taken insulin or other drugs (medication) that have been prescribed by a doctor or other health worker for raised blood glucose?	Yes 1 No 2	
Blood lipids		
Total cholesterol in MMOL/L or MG/DL)		
During the past month, have you been treated for raised cholesterol with drugs (medication) prescribed by a doctor or other health worker?	Yes 1 No 2	
Triglycerides in MMOL/L OR MG/DL)		
HDL Cholesterol in MMOL/L OR MG/DL)		

Appendix 5 MINI KID

MAJOR DEPRESSIVE EPISODE (MINI KID, pages 6-7)

No	Question	No		Yes	
A1 a.	At any time in your life, did you feel sad or depressed? Felt down or empty or hopeless? Felt grouchy or annoyed? Did you feel this way most of the time, for at least 2 weeks?				
b.	For the past 2 weeks, did you feel this way, most of the day, nearly every day?				
A2 a.	At any time in your life, were you bored a lot or much less interested in things (like playing your favourite games)? Have you felt that you couldn't enjoy things? Did you feel this way most of the time, for at least 2 weeks?				
b.	For the past 2 weeks, did you feel this way, most of the day, nearly every day?				
A3	Over the two weeks, when you felt depressed/grouchy/ uninterested:	Past two weeks		Past Episode	
a.	Were you less hungry or hungrier most days? Did you lose or gain weight without trying?	No	Yes	No	Yes
b.	Did you have trouble sleeping almost every night ("trouble sleeping" means trouble falling asleep, waking up in the middle of the night, waking up too early or sleeping too much)?				
c.	Did you talk or move slower than usual? Were you fidgety, restless or couldn't sit still almost every day? Did anyone notice this?				
d.	Did you feel tired most of the time?				

e.	Did you feel bad about yourself most of the time? Did you feel guilty most of the time?				
f.	Did you have trouble concentrating or thinking or did you have trouble making up your mind almost every day?				
g.	Did you feel so bad that you wished that you were dead? Did you think about hurting yourself? Did you have thoughts of death? Did you think about killing yourself?				
A4.	Did these sad, depressed feelings cause a lot of problems at home? At school? With friends? With other people? Or in some other important way?				
A5.	In between your times of depression, were you free of depression or sadness for at least 2 months?	NA	NA		
W. Rule out medical, organic or drug causes for all disorders		No	Yes	Uncertain	
W1	Were you taking any drugs or medicines or in withdrawal from any of these?				
a.					
b.	Did you have any medical illness?				
W2	IF W1a OR W1b IS CODED YES, in the clinician's judgment, is likely to be a direct cause of the patient's disorder?				
W2 su m	Has an "organic"/ medical/drug related cause been ruled out?				
	How many episodes of depression did you have in your lifetime? (<i>Between each episode there must be at least 2 months without any significant depression</i>)				

GENERALIZED ANXIETY DISORDER

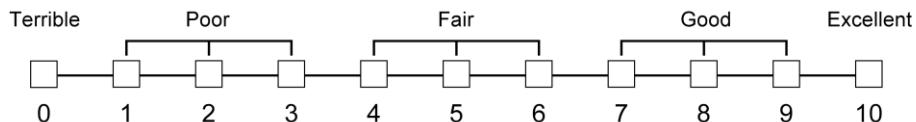
No	Question	No	Yes
U1	For the past six months, have you worried a lot or been nervous?		
a	Have you been worried or nervous about several things, (like school, your health, or something bad happening)? Have you been more worried than other kids your age?		
b	Do you worry most days? IS THE PATIENT'S ANXIETY RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT?		
U2	Do you find it hard to stop worrying? Do the worries make it hard for you to pay attention to what you are doing?		
U3	When you are worried, do you, most of the time:		
a	Feel like you can't sit still?		
b	Feel tense in your muscles?		
c	Feel tired, weak or exhausted easily?		

d	Have a hard time paying attention to what you are doing? Does your mind go blank?		
e	Feel grouchy or annoyed?		
f	Have trouble sleeping ("trouble sleeping" means trouble falling asleep, waking up in the middle of the night, wakening up too early or sleeping too much)?		
ARE 1 OR MORE U3 ANSWERS CODED, YES?			
U4	Do these worries or anxieties cause a lot of problems at school or with your friends or at home or at work or with other people?		
W.	Rule out medical, organic or drug causes for all disorders	No	Yes
W1	Were you taking any drugs or medicines or in withdrawal from any of these?		
a			
b	Did you have any medical illness?		
W2	IF W1a OR W1b IS CODED YES, in the clinician's judgment, is either likely to be a direct cause of the patient's disorder?		
W2 sum	Has an "organic"/ medical/drug related cause been ruled out?		
	Sleep quality		

INSTRUCTIONS:

- The following question refers to your overall sleep quality for the **majority of nights in the past 7 days ONLY**.
- Please think about the quality of your sleep **overall**, such as how many hours of sleep you got, how easily you fell asleep, how often you woke up during the night (except to go to the bathroom), how often you woke up earlier than you had to in the morning, and how refreshing your sleep was.

1. During the **past 7 days**, how would you rate your sleep quality overall?
(Please mark only 1 box)



Appendix 6: Modified VHT register

Figure 2 Below: Proposed Modifications to the figure 1 to include NCDs

QUARTERLY HOUSEHOLD REGISTER																														
Village: <u>Lobongall</u>	Household Number: <u>59</u>			Head of Household: <u>Solomon Kabuas Abdallah</u>			Reporting Period: <u>April - June 2010</u>																							
Name of VHT Member: <u>Katumba Julius Caesar</u>																														
GENERAL INFO: All Household Members Above 5 Years					ADULTS		PREGNANT WOMEN			NCD																				
Household Members (Above 5 Years)	Sex M	Age	Died	Children not in School	Using FP Method	ART Treatment	Delivery Month	Antenatal Care Visits to H.C.	Danger Sign	Referred	Delivered at Home	Post Natal Check at H.C.	Using ITN	B 1	W 1	P 1	A 1	S 1	B 2	W 2	P 2	A 2	S 2	B 3	W 3	P 3	A 3	S 3	Food diary reviewed	
Solomon Kabuas Abdallah	✓	47			✓	✓		1																						
Katumba Julius Caesar	✓	42			✓	✓		2																						
Essentongo Yusuf	✓	28	✓					3																						
Kassali Sifafa	✓	21			X		October	✓	✓		✓	✓																		
Kamuddu Sharifa	✓	19			X																									
Ssemwanga Al-Muhib	✓	13																												
GENERAL INFO: Children 5 Years and Below					CHILDREN: 5 Years and Below					GENERAL INFO SUMMARY					NEED TO FOLLOW UP BY VHT															
Household Members (5 years and below)	Sex M	Age	Died	ART Treatment	Immunisation Has Card	Up-to-date	Received Deworm 1st	Received Deworm 2nd	Received Vitamin A 1st	Received Vitamin A 2nd	Yellow MUAC	Red MUAC/ Oedema	Using ITN	Using Family Planning Method	ART Treatment	No ANC Visits	Died during Childbirth	Delivered at Home	No Post Natal Check	Using ITN	Immunisation Up-to-date	Red MUAC/ Oedema	Using ITN	ART Treatment	1. Toilet/pit latrine status, if full advice	2. Children to complete Vitamin A 3.	Talk about diet/nutrition	4. Malnourished child to health facility	5. Support in case family lost a member	6. Refer NCD care (high Blood pressure)
Wakige Kibetuge Yolita	✓	2 yrs			✓	✓	✓	✓	✓	✓	✓	✓	✓																	
Katto Ssentongo Bakhir	✓	4 yrs			✓	✓	✓	✓	✓	✓	X	X	X																	
HOUSEHOLD: Water, Food and Sanitation					ADULTS SUMMARY					PREGNANT WOMEN SUMMARY					CHILDREN SUMMARY					GENERAL INFO SUMMARY										
Protected water source	✓				✓									Using Family Planning Method	ART Treatment	No ANC Visits	Died during Childbirth	Delivered at Home	No Post Natal Check	Using ITN	Immunisation Up-to-date	Red MUAC/ Oedema	Using ITN	ART Treatment	Less than 1 month M F	1 - 11 months M F	1 - 5 years M F	6 - 14 years M F	15 - 49 years M F	50 years and older M F
Safe drinking water	✓				✓																									
Kitchen	✓				✓																									
Drying rack for dishes	✓				✓																									
Rubbish pit	✓				✓																									
Latrine	✓				✓																									
Hand-washing area with soap near latrine	✓				✓																									
Follow up on anything the family is missing.																														

Appendix 7: Cardiovascular Health Matrix

CLICK TO ARTICLE	Table 1. Poor, Intermediate, and Ideal Definitions: Health Metrics in Children and Adolescents																																				
<table border="1"> <tr> <td colspan="2">Non-ideal Cardiovascular Health (metric score here = 0)</td> <td colspan="2">Ideal Cardiovascular Health (any score =)</td> </tr> <tr> <td>Metric</td> <td>Poor</td> <td>Intermediate</td> <td>Ideal</td> </tr> <tr> <td>Smoking status</td> <td>Tried >30 d ago</td> <td>...</td> <td>Never tried; never smoked whole cigarette</td> </tr> <tr> <td>BMI</td> <td>>95th percentile</td> <td>85th–95th percentile</td> <td><85th percentile</td> </tr> <tr> <td>Physical activity level</td> <td>None</td> <td>>0 and <60 min/d moderate or vigorous activity every day</td> <td>≥60 min/d moderate or vigorous activity every day</td> </tr> <tr> <td>Healthy Diet Score*</td> <td>0–1 components</td> <td>2–3 components</td> <td>4–5 components</td> </tr> <tr> <td>Total cholesterol</td> <td>≥200 mg/dL</td> <td>170–199 mg/dL</td> <td><170 mg/dL</td> </tr> <tr> <td>Blood pressure</td> <td>>95th percentile</td> <td>90–95th percentile</td> <td><90th percentile</td> </tr> <tr> <td>Fasting blood glucose</td> <td>≥126 mg/dL</td> <td>100–125 mg/dL</td> <td><100 mg/dL</td> </tr> </table>		Non-ideal Cardiovascular Health (metric score here = 0)		Ideal Cardiovascular Health (any score =)		Metric	Poor	Intermediate	Ideal	Smoking status	Tried >30 d ago	...	Never tried; never smoked whole cigarette	BMI	>95th percentile	85th–95th percentile	<85th percentile	Physical activity level	None	>0 and <60 min/d moderate or vigorous activity every day	≥60 min/d moderate or vigorous activity every day	Healthy Diet Score*	0–1 components	2–3 components	4–5 components	Total cholesterol	≥200 mg/dL	170–199 mg/dL	<170 mg/dL	Blood pressure	>95th percentile	90–95th percentile	<90th percentile	Fasting blood glucose	≥126 mg/dL	100–125 mg/dL	<100 mg/dL
Non-ideal Cardiovascular Health (metric score here = 0)		Ideal Cardiovascular Health (any score =)																																			
Metric	Poor	Intermediate	Ideal																																		
Smoking status	Tried >30 d ago	...	Never tried; never smoked whole cigarette																																		
BMI	>95th percentile	85th–95th percentile	<85th percentile																																		
Physical activity level	None	>0 and <60 min/d moderate or vigorous activity every day	≥60 min/d moderate or vigorous activity every day																																		
Healthy Diet Score*	0–1 components	2–3 components	4–5 components																																		
Total cholesterol	≥200 mg/dL	170–199 mg/dL	<170 mg/dL																																		
Blood pressure	>95th percentile	90–95th percentile	<90th percentile																																		
Fasting blood glucose	≥126 mg/dL	100–125 mg/dL	<100 mg/dL																																		

BMI indicates body mass index.

* The Healthy Diet Score is based on adherence to the following dietary recommendations: fruits and vegetables, ≥4.5 cups per day; fish, 2 or more 3.5-oz servings per week; sodium, ≤1500 mg/d; sugar-sweetened beverages, ≤450 kcal (36 oz) per week; and whole grains, ≥3 servings a day scaled to a 2000-kcal/d diet. Reprinted from Lloyd-Jones et al.¹ Copyright © 2010, American Heart Association.

Appendix 8 Health Economics questionnaire

Participant/household description

The interviewer should gather basic information about the characteristics of the participants and their household before and during implementation of the Face-D study. This information will enable us to uniquely identify the participant.

Participant/household details	
Participant/respondent's ID:	
Household ID:	
Participant name:	
Participant gender:	
District:	
Setting (Rural/Urban):	
Household income	
Data collector's name:	
Date contacted:	

Household/participant information on food expenditure.

This section will be used to record information on each participant and their household involved in the FaCe-D study implementation over 12months. The interviewer will ask for monthly information about household expenditure associated with food or healthy diet

In the last one month, has your household expenditure on food changed due to participation in this study? (Yes/No)

How did the expenditure change? (Increased, decreased, unchanged)

In the table below, identify the major food items, quantity and number of meals your household spent money on as a result of participating in this study within the last month.

Food item	Unit	Quantity	Unit costs	Total cost

In the table below, identify the major food items and indicate the number of meals based on the food items identified as a result of participating in this study within the last month. Indicate the amount of money your household spent.

Food item	Number of meals per week	Number of meals per week	Unit costs per meal

In the past month, did your household reduce or discontinue consumption of unhealthy food items? (Yes/no). If yes, indicate the food items, quantity and number of meals consumed compared to previous months

Food item	No. of meals in past month after the study	No. of meals per month before the study	Unit costs per meal

Household/participant information on physical activity.

In the last month, did you participate in any paid or non-paid physical activity due to participation in this study (Yes/no)

If yes, please indicate in the table below the type of physical activity or items/sessions, quantities and costs that you or your household spent on.

Physical activity items or session	Unit	Quantity/number of sessions	Unit cost	Total cost

In the last month, indicate the time you spent doing physical activity both paid or non-paid physical activity as a result of participating in this research study.

Name of Physical activity	Period of Physical activity (Daily/weekly)	How many days/weeks	How many hours per day/week	Total hours spent per month

Household/participant information on regular screening.

In the last month, did you go for regular screening (paid or non-paid) for any cardiovascular disease? (Yes/No)

If yes, please indicate the type of screening and frequency in the table below.

Name of screening/test	Number of tests	Unit cost per test/screen	Total cost

Appendix 9: VHT Monitoring and Supervision Checklist- FaCe-D

Supervisor Name		Designation	
VHT name		VHT Contact	
Village		Subcounty	
District		Date	

Supervision Task	Yes	No	N/A	Notes

One on one mentoring sessions (30-60 minutes) at participating health facility in the community or virtual; these allow all critical issues to be addressed. Review past performance, provide feedback, set goals, motivate and develop capacity.	Every month	
Peer to peer accountability to reinforce work goals and methods, ethics, safeguarding issues and share learnings and best practice. This increases the VHT's self-confidence and self-awareness.	Every month	
Observation of practice. This helps to evaluate the quality, style, personal presentation, and technical skills of the VHT, and feedback should be provided immediately. However, be mindful that the VHT may feel nervous. These may be sampled.	Every quarter	
VHT group meetings to share experiences, learnings, and best practice. High performing VHTs may also be recognized at the health facility when they are bringing back the reports	Every Quarter	
Community Participatory Data Analysis/ dissemination	Every 6 Months	

National Participatory Data Analysis/ dissemination	Annually	
Emergency support supervision as the need may arise.	As and when required	
GIS and time stamps where possible	Depending on availability of funds	

Appendix 10: Process evaluation Data collection tools

Adolescent including peer champions _ DATA COLLECTION

Capture demographics (religion, highest level of education, livelihood, age, marital status, children)

Knowledge, perceptions and attitudes about FCA (REACH)

What do you know about CVDs? Probe for common CVDs, risk factors, prevention etc

Tell me about the FCA intervention/what do you know about FCA/FaCe-D study? *Probe for; awareness about FCA, purpose of the study/FCA, source of information, adequacy of information, intervention components etc*

What are your views/perceptions about FaCe-D study/FCA? Probe for.

-*If it's the right strategy to prevent CVDs*

-*What are your expectations/hopes (the positives or negatives)?*

-*What are your views about doing physical activities daily, for 60 minutes? -What are the barriers and facilitators?*

-*What are your views about changing/improving your diet as recommended by the health workers (reducing sugar and salt intake, less oils and fried foods, fast and packed foods? -What are the barriers and facilitators?*

-*What are your views about VHTs home visits and health education? -What are the barriers and facilitators?*

-*What are your views on receiving health information about FCA intervention via text messages? -What are the barriers and facilitators?*

Acceptability (REACH & Adoption)

What factors influenced the decision to participate in the FaCe-D study? *Barriers and facilitators to acceptability*

What can be done to improve participation?

Full or partial participation (adoption)

Do you think you will be able to fully or partially participate in the FCA intervention? *Probe for willingness, what would be the barriers and facilitators for your choice?*

What can be done to enhance full participation in the intervention?

Any comments

Family members_ DATA COLLECTION

Capture demographics (religion, highest level of education, livelihood, age, marital status, children)

Knowledge, perceptions and attitudes about FCA (REACH)

What do you know about CVDs? Probe for common CVDs, risk factors, prevention etc

Tell me about the FCA intervention/what do you know about FCA/FaCe-D study? *Probe for; awareness about FCA, purpose of the study/FCA, source of information, adequacy of information, intervention components etc*

What are your views/perceptions about FaCe-D study/FCA? Probe for;

-*If it's the right strategy to prevent CVDs*

-*What are your expectations/hopes (the positives or negatives)?*

-*What are your views about doing physical activities daily, for 60 minutes? -What are the barriers and facilitators?*

-*What are your views about changing/improving your diet as recommended by the health workers (reducing sugar and salt intake, less oils and fried foods, fast and packed foods? -What are the barriers and facilitators?*

-*What are your views about VHTs home visits and health education? -What are the barriers and facilitators?*

-*What are your views on receiving health information about FCA intervention via text messages? -What are the barriers and facilitators?*

Acceptability (REACH & Adoption)

What factors influenced the decision to participate in the FaCe-D study? *Barriers and facilitators to acceptability*

What can be done to improve participation?

Full or partial participation (adoption)

Do you think you will be able to fully or partially participate in the FCA intervention? *Probe for willingness, what would be the barriers and facilitators for your choice?*

What can be done to enhance full participation in the intervention?

Any comments

VHTs_ DATA COLLECTION

Capture demographics (religion, highest level of education, livelihood, age, marital status, children)

Knowledge, perceptions and attitudes about FCA (REACH)

What do you know about CVDs? Probe for common CVDs, risk factors, prevention etc

Tell me about the FCA intervention/what do you know about FCA/FaCe-D study? *Probe for; awareness about FCA, purpose of the study/FCA, source of information, adequacy of information, intervention components etc*

What are your views/perceptions about FaCe-D study/FCA? Probe for;

-If it's the right strategy to prevent CVDs

-What are your expectations/hopes (the positives or negatives)?

What are your views about having community members including your family doing physical activities daily, for 60 minutes for adolescents and 3 days for 30 minutes for adults? *-What are the barriers and facilitators?*

What are your views about your community members including your family changing/improving your diet as recommended by the health workers (reducing sugar and salt intake, less oils and fried foods, fast and packed foods? *-What are the barriers and facilitators?*

What are your views about visiting peoples' homes to offer health education on living a healthy lifestyle? *-What are the barriers and facilitators?*

What are your views on receiving health information about FCA intervention via text messages? *-What are the barriers and facilitators?*

Acceptability (REACH & Adoption)

For the participants recruited, what are the factors that influenced the decision to participate in the FaCe-D study? *facilitators to acceptability*

For the participants that declined participating, what are the factors that influenced the decision to not to participate in the FaCe-D study? *Barriers to acceptability*

What can be done to improve participation?

Any comments

Policymakers_ DATA COLLECTION

Capture demographics (religion, highest level of education, livelihood, age, marital status, children)

Knowledge, perceptions, and attitudes about FCA (REACH)

What do you know about CVDs? Probe for common CVDs, risk factors, prevention, etc

Perceptions about FaCe-D study/FCA (*first explain the FCA intervention*)

What are your views about having adolescents and their families doing physical activities daily, for 60 minutes for adolescents and 3 days for 30 minutes for adults? *-What are the barriers and facilitators?*

What are your views about having adolescents and their families change/improve their diet as recommended by the health workers (reducing sugar and salt intake, less oils and fried foods, fast and packed foods? -*What are the barriers and facilitators?*

What are your views about VHTs visiting peoples' homes to offer health education on living a healthy lifestyle? -*What are the barriers and facilitators?*

What training or support is required to ensure the VHTs deliver the FCA intervention effectively?

What are your views on having adolescents and their families receive additional health information via text messages? -*What are the barriers and facilitators?*

For each of the barriers mentioned earlier, what can be done to address them?

Acceptability

What can be done to have more families embrace doing physical exercises and changing their diet as recommended by the health workers?

What specific resources/policies could support the implementation of the FCA intervention?

What specific policies could support the sustainability of the FCA intervention?

What specific resources could support the sustainability of the FCA intervention? (*probe for; whom to provide the resources*)

Any comments

FGDs_Community members_ DATA COLLECTION

Capture demographics (religion, highest level of education, livelihood, age, marital status, children)

Knowledge, perceptions, and attitudes about FCA (REACH)

What do you know about CVDs? Probe for common CVDs, risk factors, prevention, etc What do you know about CVDs? *Probe for common CVDs, risk factors, prevention etc*

Perceptions about FaCe-D study/FCA (*first explain the FCA intervention*)

What are your views about having adolescents and their families doing physical activities daily, for 60 minutes for adolescents and 3 days for 30 minutes for adults? -*What are the barriers and facilitators?*

What are your views about having adolescents and their families change/improve their diet as recommended by the health workers (reducing sugar and salt intake, less oils and fried foods, fast and packed foods? -*What are the barriers and facilitators?*

What are your views about VHTs visiting peoples' homes to offer health education on living a healthy lifestyle? -*What are the barriers and facilitators?*

What training or support is required to ensure the VHTs deliver the FCA intervention effectively?

What are your views on having adolescents and their families receive additional health information via text messages? -*What are the barriers and facilitators?*

For each of the barriers mentioned earlier, what can be done to address them?

Acceptability

What can be done to have more families embrace doing physical exercises in your community?

What can be done to have more families embrace changing their diet as recommended by the health workers?

Any comments



Appendix 11: Participants' education materials: Health plate and portion sizes

HEALTHY EATING PLATE

HOW TO STRUCTURE YOUR PLATE

1. In small amounts use healthy oils, sunflower, sesame, corn, olive oil, shea butter.
2. Avoid using cooking fats.

Drink plenty of water, tea, and coffee (with little or no sugar)
Atleast 1.5 litres a day. You can spice your water with mint, rosemary, ginger etc.

Eat a variety of whole grains (rice, millet, posho, sorghum, whole wheat bread), matooke, cassava, sweet potatoes.



Eat plenty of fruits of all colors in between meals as snacks and on meals.



Choose fish, chicken, beans, nuts, limit red meat and avoid processed meats (sausages, burgers etc.)

Salt measurements

- Recommended salt intake per day according to dash diet is 1 tea spoon (2300mg or 1500mg)



Portion Size Guide



Methods

of cooking

- Boiling
- Frying
- Steaming
- Stewing
- Roasting
- baking

Portion sizes for vegetables and fruits



The Palm = 3 oz.

The palm of your hand can be used to estimate protein intake. 1 palm is equivalent to a 3 oz. serving of protein. Examples of what you could measure a 3 oz. serving include pork, poultry, beef, fish, and chicken.



Fist = 1 cup

A fist is a great way of measuring carbohydrates. You can use this tool when measuring the intake of rice, cereals, salads, fruits, or popcorn.



Tip of Thumb = 1 Tablespoon

The tip of a thumb is equivalent to a serving of 1 tablespoon. This tool is used when measuring fat intake such as mayonnaise, cheese, salad dressings, creams, and peanut butter.



A Cupped Hand = 1/2 cup

1 hand cupped is equivalent to a 1/2 cup serving. You can use this tool for measuring food items such as pastas, potatoes, nuts, and even ice cream.



The Thumb Nail – 1 Teaspoon

The nail of the thumb is about 1 teaspoon serving of oils or fats. This can be used to measure salad dressings, olive oil, or butter.



Appendix 12: Physical Activity diary

4	Washing dishes										
5	Jumping										
6	Making the bed										
7	Dancing										

8	Running										
9	Ridding a tire										
10	Pushups										
11	Climbing a tree										

12	Cleaning										
13	Walking										
14	Climbing steps										
15	Gardening										

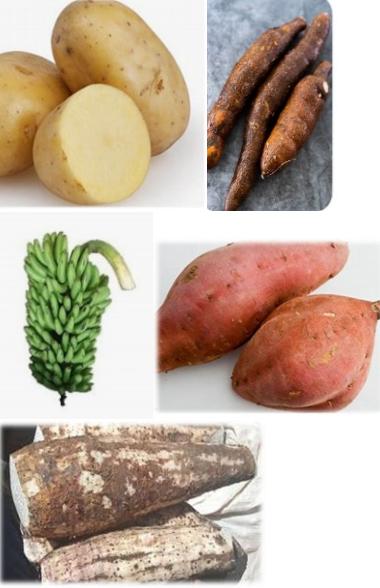
16	Okwepena(dodge ball)									
17	Cleaning the car									
19	Preparation of food									

20	Pushing the wheelbarrow										
21	Volleyball										
21	Others e.g. swimming, gymnastics, netball, basketball, boxing, rugby, karate, table tennis, Golf etc.										

Appendix 13: Food diary

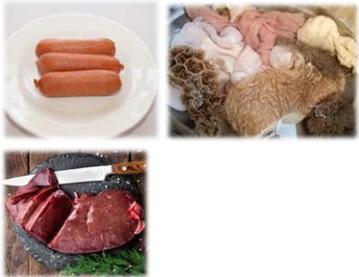
Food diary for Jan 2025... participants study ID.....

No	Food groups			Please write the foods you have consumed today and response for 7 days										
				Name	Types	PICTURES		1 st	2nd	3rd	4th	5 th	6 th	7 th to 30 th /31 st of the month
1	Energy giving foods	Whole grains e.g. unprocessed maize, millet, wheat, brown rice, whole wheat bread, sorghum						Adolescent						
								Household						
2		Refined grains and bakery products e.g. Processed maize, rice, bread,						Adolescent						
								Household						
3		starchy tubers or roots such as potatoes, yams, karo or cassava,						Adolescent						

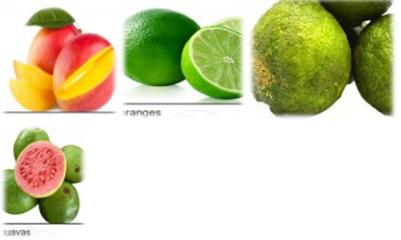
		matooke, Irish potatoes			Household						
4		Healthy oils e.g. sunflower, sesame, corn, olive oil, shea butter, ground nut oil, vegetable oil, avocado oil			Adolescent						
					Household						
5		Un healthy oils e.g., Ghee			Adolescent						

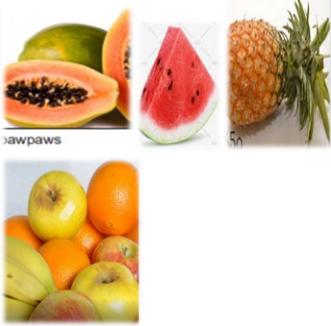
		,butter, margarine			Household						
6	Body building foods	Plant proteins Pulses e.g. Dry beans, broad beans, dry peas, chickpeas, cow peas, lentils, soya beans									

7	<p>Plant proteins</p> <p>Nuts and seeds e.g. Ground nuts, almonds, awusa nut, peanut, cashew nuts, sweet acacia, sesame seeds</p>							
8	<p>Animal proteins</p> <p>Meat e.g. white meat, red meat poultry (chicken, turkey) processed meat, organ meat (kidney, liver mixed offal's, intestines) animal skin/ear/feet/he</p>					.		

		ad , insects, tinned meats									
9		Fish and sea foods e.g. whole fish , fish meat, silver fish and shell fish			Adolescent						
					Household						
10		Milk and dairy e.g. fresh milk, sour milk, milk powder, cheese, yogurt and cream									

11		Eggs e.g. whole (boiled egg) or separated eggs(fried egg, scrambled eggs								
12	Vegetables	Dark Green leafy Vegetables e.g. dodo, bugga, spinach, cabbage, nakatti, sukuma wiki, ejobyo, pumpkin leaves.								

13	Other vegetables	Ginger, turmeric root, garlic, onions, tomatoes and broccoli, cucumber, asparagus and okra, carrots, green/yellow/red pepper, egg plants freach beans, mushrooms, tomatoes, avocado, pumpkin, bitter berries(entulla).							
14	Fruits	Mangoes, pumpkin, starchy fruits(bananas) , watermelon, pineapple, pawpaw, tangerines', oranges, passion fruits, jack fruits, apples, lemons, black plum, mapela, grapefruits, apples, tamarind.							

											
15	Sugars and sweets	Sugar, honey, syrups, candies, sweets, chocolates, sweet cakes			Adolescent						
					Household						
16	Beverages	Non-alcoholic e.g. Black tea, coffee, soda,			Adolescent						

		powdered drink mixes, artificial diluted or sweetened juices, non-dairy fermented juices.									
18		Alcoholic beverages e.g. beers, wine, whiskeys			Adolescent						
19	Others	Condiments, spices, soup stocks, broths, baking powder/soda ash, salt			Household						