Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya

Overall Project Protocol
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Project Personnel	Institution	Role
Omar Galárraga, PhD	Brown University, Rhode Island USA	Multiple Principal Investigator (Contact MPI)
Becky Genberg, PhD	Johns Hopkins University, Maryland USA	Multiple Principal Investigator
Juddy Wachira, PhD	Moi University School of Medicine, Eldoret, Kenya	Co-Investigator, Local PI
Jamil Said, MBChB	Moi University School of Medicine, Eldoret, Kenya	Co-Investigator
Sonak Pastakia, PhD, PharmD	Purdue University College of Pharmacy Academic Model Providing Access to Healthcare, Eldoret, Kenya	Co-Investigator
Tina Tran, PharmD	Temple University School of Pharmacy, Pennsylvania USA Academic Model Providing Access to Healthcare, Eldoret, Kenya	Co-Investigator
Suzanne Goodrich, MD	Indiana University School of Medicine, Indiana USA Academic Model Providing Access to Healthcare, Eldoret, Kenya	Co-Investigator
Jon Steingrimsson, PhD	Brown University, Rhode Island USA	Co-Investigator
Youjin Lee, PhD	Brown University, Rhode Island USA	Co-Investigator
Raj Vedanthan, MD	Icahn School of Medicine at Mount Sinai, New York USA	Co-Investigator
Joe Hogan, ScD	Brown University, Rhode Island USA	Co-Investigator
Paula Braitstein, PhD	Academic Model Providing Access to Healthcare, Eldoret, Kenya University of Toronto, Dalla Lana School of Public Health, Toronto, Canada	Co-Investigator
Catherine Kafu, MPH	Academic Model Providing Access to Healthcare, Eldoret, Kenya	Project Manager – Kenya
Marta Wilson-Barthes, MSPH	Brown University, Rhode Island USA	Project Manager – USA

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Summary

Title:	Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya
NIH Award Number:	1R01MH118075-01A1
Study Description:	Sustained viral suppression remains a key challenge for HIV treatment and prevention. Barriers such as lack of convenient access and economic instability have a major impact on retention in care for persons living with HIV (PLWH). The aim of this project is to evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and viral suppression among PLHIV in rural western Kenya. We will use a cluster randomized controlled intervention design to randomize at least 40 existing microfinance groups (with a majority of members who are living with HIV) to receive microfinance plus either (A) integrated community-based care, or (B) standard care. We will also recruit a matched control group (C), receiving standard care without participation in microfinance activities. The hypothesis is that integrated community-based care, within group microfinance, will improve viral suppression and retention in care compared to microfinance with standard of care and to standard of care alone. We will use qualitative and quantitative mediation analysis to evaluate mechanisms through which microfinance and ICB care impact outcomes, and analyze incremental cost-effectiveness of the intervention in terms of cost per HIV suppressed person-time, cost per patient retained in care, and cost per disability-adjusted life-year saved.
Objectives:	Primary Objective: The primary objective of this project is to demonstrate the effectiveness of an integrated community-based care approach for improving viral suppression and related outcomes among HIV-positive individuals participating in microfinance groups.
Endpoints:	Primary Endpoint: The primary endpoint for this study will be achievement of viral suppression (HIV-RNA < 400 cp/mL) at 18 months. Secondary Endpoints: A secondary endpoint will be retention in care, defined as the proportion of scheduled visits that were attended during the study period. Other secondary endpoints will be absolute mean change in systolic blood pressure and absolute mean change in HbA1c level from 0 to 18 months.
Study Population:	The population eligible for study participation will include HIV-positive patients, at least 18 years of age, who are active members of an AMPATH Group Integrated Savings for Health Empowerment (GISHE) group. (An active group is one that was formed at least 6 months prior to study start, is consistently meeting as scheduled, and is actively engaging in saving and loaning. An active member is one who has been consistently attending group meetings during the 6 months prior to study enrollment and who is actively engaging in saving and loaning.) Eligible participants will be required to be currently receiving HIV-related care through AMPATH, have an AMPATH Medical Record System (AMRS) ID, have initiated

	antiretroviral therapy at least 6 months prior to the study baseline, and be willing and able to provide informed consent for study participation. The eligible study population will also include participants who meet the same aforementioned criteria but are not participating in an AMPATH GISHE group (to serve as the matched comparison arm).
Phase or Stage:	Phase III Clinical Trial
Description of Sites/Facilities Enrolling Participants:	All research activities related to the clinical trial will be conducted within microfinance groups and Ministry of Health Facilities affiliated with the Academic Model Providing Access to Healthcare (AMPATH) in western Kenya. The intervention will be delivered in counties where AMPATH is already supporting active microfinance groups, specifically in Busia county and Trans Nzoia county. The Academic Model Providing Access to Healthcare (AMPATH) is based in western Kenya (~350km northwest of Nairobi) with primary headquarters in Uasin Gishu County. AMPATH is a joint partnership between Moi University School of Medicine, Moi Teaching and Referral Hospital, and a consortium of universities led by Indiana University and including Brown and University of Toronto. AMPATH has enrolled over 150,000 HIV+ patients in 156 Ministry of Health facilities in western Kenya. All HIV and tuberculosis (TB)-related care and treatment are free for patients. The HIV clinical care protocols used by AMPATH are consistent with WHO and Kenyan National (NASCOP) guidelines and entail routine 12-month viral load monitoring, with more intensive monitoring for unsuppressed patients. Care is supported and data are managed via AMPATH's electronic medical record system (AMRS). All care delivered in this study will be in line with clinical protocols in place within AMPATH. Moreover, AMPATH is already supporting more than 1349 MF groups (with over 27,249 people) as part of their Group Integrated Savings for Health Empowerment (GISHE) program and the Bridging Income Generation with Group Integrated Care (BIGPIC) randomized clinical trial.
Description of Study Intervention/Experimental Manipulation:	A cluster randomized controlled design will be used to perform an evaluation of integrated community-based care incorporated into existing microfinance groups, where all study participants are persons living with HIV (PLWH). Cluster randomization will be conducted at the level of existing GISHE groups and will be stratified by county. We will obtain informed consent from each individual participating in the trial, and randomize GISHE groups in a 1:1 ratio to receive either microfinance plus integrated community-based care for HIV, diabetes and hypertension (MF+ICB) or microfinance and standard facility-based care (MF+SOC). The intervention (MF+ICB) will be delivered within groups during regularly-scheduled microfinance group meetings and include the following: (1) integrated care visits by a clinical offer monthly during the first 6 months of the trial, and then quarterly for the remaining months (7-18), which will include one-on-one vital signs screening, consultation with a clinical officer, medication distribution (antiretroviral therapy for HIV

	and medications for hypertension and diabetes as needed), and point-of-care laboratory testing (creatinine, blood glucose and hemoglobin A1C, and viral load as it becomes available); (2) one-on-one referrals to facilities for emergency or acute care needs that are not able to be addressed in the community; and (3) group level health education discussion. Microfinance group members randomized to the standard of care arm (MF+SOC) will meet in their GISHE groups as usual and receive regular care for HIV and other chronic conditions at an AMPATH facility. Match control participants will continue to receive regular care at an AMPATH facility.
Participant Duration:	For each participant, the enrollment and follow-up period for the trial will be 18 months.

Acronyms

AMPATH	Academic Model Providing Access to Care
AMRS	AMPATH Medical Records System
ART	Antiretroviral therapy
CARG	Community ART Group
CDM	Chronic Disease Management
BIGPIC	Bridging Income Generation with Group Integrated Care
FPI	Family Preservation Initiative
GISHE	Group Integrated Savings for Health and Empowerment
ICB	Integrated Community-Based Care
IREC	Institutional Research & Ethics Committee
MF	Microfinance
PLWH	People Living With HIV
VS	Viral Suppression

1. Introduction

1.1 Background

Despite gains in antiretroviral therapy (ART) coverage for people living with HIV (PLHIV) and reductions in HIV-related morbidity and mortality, significant gaps remain: only 50% of PLHIV in sub-Saharan Africa are virally suppressed.[1] It is well known that retention in HIV care is a critical and necessary step in the continuum leading to viral suppression (VS). We have documented individual and system-level barriers to full engagement in care in western Kenya: distance to facilities, inefficient vertical care delivery, and limited means for transport and food.[2–4] For PLHIV, microfinance (MF) and other income-generating activities can effectively improve ART adherence and viral suppression through strengthened food security and household economic conditions,[5–7] while community-based ART delivery for PLHIV significantly reduces barriers related to distance and inefficient care delivery.[8,9] Integrating HIV into primary care improves the efficiency of care delivery while addressing the growing burden of non-communicable disease (NCDs) among PLHIV.[10] However, most Kenyans are uninsured and pay out of pocket for non-HIV-related healthcare, borrow from friends/family, or pay through harambee (Kiswahili for "pulling resources together").[11] What is still not known is how to alter care delivery to help support PLHIV to be continually engaged in care once they achieve relatively stable health initially afforded by ART.

Retention in HIV care within current care delivery models in SSA continues to be sub-optimal.[12-14] The primary barriers for retention in HIV care in western Kenya are distance to facilities, inefficient vertical care delivery, and limited means for transport and food. Access barriers are heightened in remote locations because travel is more difficult and transportation fees are prohibitively high relative to income.[15] Overcoming these barriers is critical for PLHIV as care interruption leads to gaps in ART and eventual unsuppressed viral load, allowing for disease progression and increased transmission, and increased risk of drug resistance.[16] Barriers to access and retention to care are interrelated, and require creative delivery models that address multilevel determinants, including economic and access issues.

As health systems transition to implementing the WHO 2015 recommendations to "treat all" with ART, differentiated models of HIV care delivery fill an urgent need to alleviate burden on already-strained systems while they expand to enroll new patients on ART, and to bolster and support retention and adherence to ART for those already in care.[17-19] The differentiated model most relevant to the current application – the community-based ART adherence club with quarterly group care for symptom checks and medication refills – has increased retention and viral suppression in South Africa while decongesting facilities; however, the effectiveness of this model on clinical outcomes has not been demonstrated with a randomized design.[20]

The burden of NCDs in PLHIV is increasing due to improved life expectancy of PLHIV who are adhering to ART.[21-24] Consequently, the magnitude of patients requiring chronic disease management in settings with strained health systems will continue to increase and overwhelm traditional care delivery models. HIV management may become sustainable if services are integrated into care for NCDs. While medication adherence clubs for HIV, diabetes and hypertension have been implemented in Kenya, the impact of integrated care on clinical outcomes remains uncharacterized.[25,26]

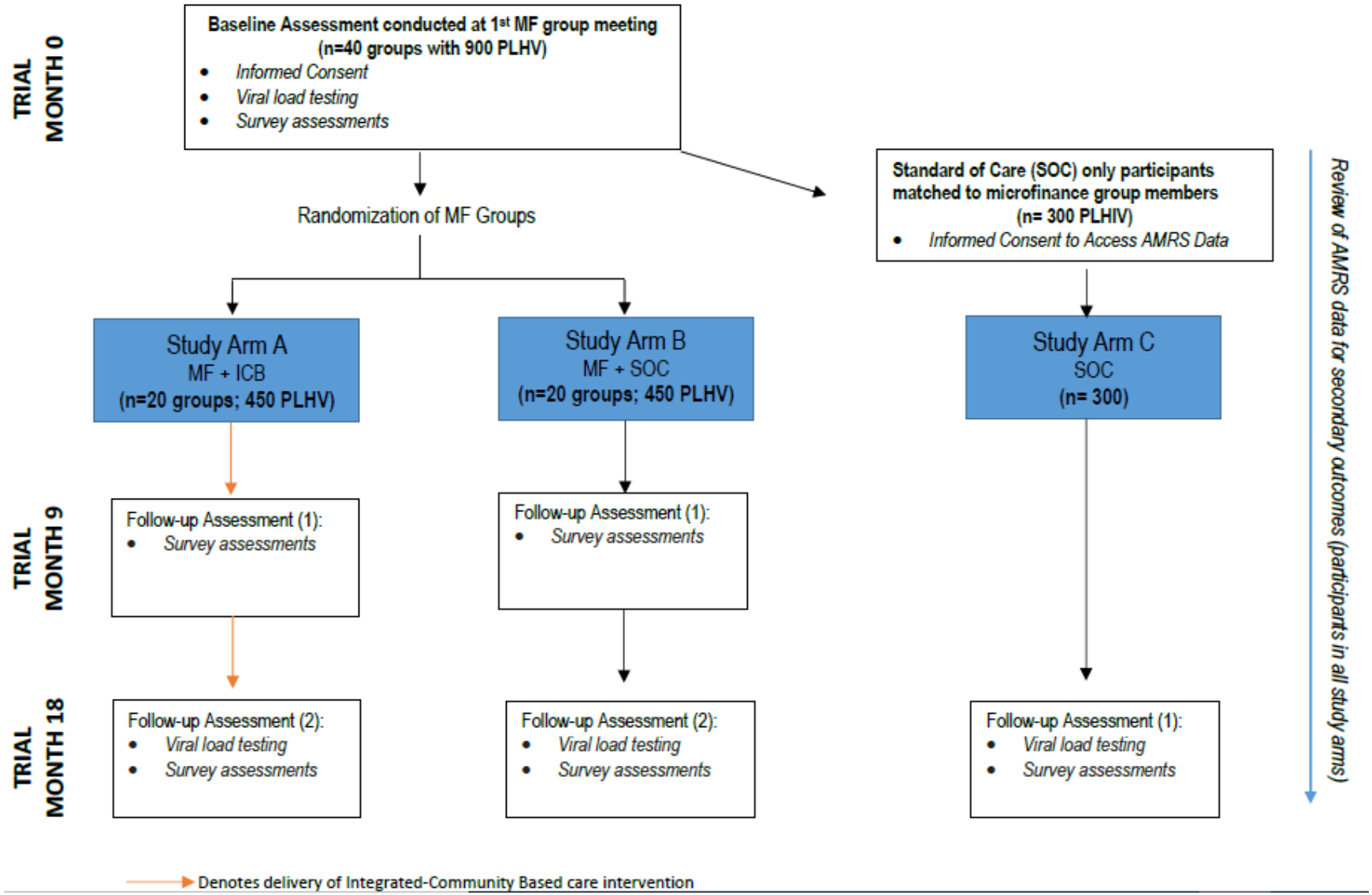
The Academic Model Providing Access to Healthcare (AMPATH)[27] provides HIV care free-of-charge to

more than 3.5 million PLHIV across 69 urban and rural clinics in Western Kenya. AMPATH also provides NCD care through its Chronic Disease Management (CDM) program that includes medications, lab tests, and clinical consultations, available to all regardless of HIV status.[28,29] AMPATH's current community-based NCD care and group-based microfinance program relies on earnings from the microfinance to fund subsidized services. Microfinance has been shown to be a sustainable and effective approach for improving economic outcomes for over 170 million poor people worldwide, and it provides unparalleled opportunities for delivering health-related services to hard-to-reach populations.

1.2 Objectives and Rationale

Our long-term goal is to help achieve epidemic control and the global targets of 90-90-90 through improved care delivery based on rigorous implementation research. The overall objective of this project is to demonstrate the effectiveness and longer-term sustainability of an innovative differentiated care delivery model for improving HIV treatment outcomes. The central hypothesis is that the integration of HIV care delivery into community-based primary care within group-based microfinance will improve retention and rates of viral suppression (VS) among people living with HIV (PLWH) in rural low-income settings in western Kenya via two related mechanisms: improved household economic status and easier access to care. The hypothesis is based on our strong feasibility and acceptability evidence of community-based care with group microfinance for NCDs,[30] the longstanding acceptability (since 2010) of our microfinance activities (currently >1300 groups and >43,000 people),[31] and community-based HIV care delivery in our program.[32] The rationale is that we need to implement and rigorously test specific differentiated care approaches in order to achieve sustained and sustainable approaches to achieve the 90-90-90 goals.

Figure 1. Schema of the cluster randomized trial



2. Overview of key activities during the cluster randomized trial

	Pre-baseline	Baseline Month 0	Visit 1 Month 1	Visit 2 Month 2	Visit 3 Month 3	Visit 4 Month 4	Visit 5 Month 5	Visit 6 Month 6	Visit 7 Month 9	Visit 8 Month 12	Visit 9 Month 15	Visit 10 Month 18
Enrollment: • Eligibility Screening • Informed Consent • Ascertain viral load data from patient medical records • Alignment of patient/participant clinical appointments with ICB care schedule	X	X										
Randomization of GISHE groups to integrated community-based care intervention or standard facility care	X											
Matching of standard care (SOC) patients to enrolled microfinance group participants on age, gender, county	X	X	X	X	X							
Administration of ICB care intervention (to MF+ICB groups only)		X	X	X	X	X	X	X	X	X	X	X
Collection of microfinance group performance/participation data (in MF+ICB and MF+SOC only)		X			X			X	X	X	X	X
Review AMRS medical record to coordinate care needs and delivery		X	X	X	X	X	X	X	X	X	X	X
Facility visits to collect retention in care information for Arm B participants of non-AMRS sites					X			X		X		X
Survey Assessments (All MF groups at 0, 9, 18 months; All SOC participants at 0 and 18 months)		X							X			X

3. Aim 1 RCT Methods: Participants, intervention, and outcomes

3.1 Study setting

The same study protocol will be implemented at multiple independent investigational sites in Busia and Trans Nzoia counties in western Kenya, where participants regularly meet to attend microfinance group meetings in the community. Microfinance groups invited to participated in the trial can include but are not limited to Group Integrated Savings for Health and Empowerment (GISHE) groups run by AMPATH's Family Preservation Initiative (FPI) income generation program.

3.2 Description of the intervention and trial arms

The study intervention **(Study Arm A)** will deliver integrated care for HIV, diabetes, and hypertension in the community to enrolled microfinance group members during regularly scheduled GISHE group meetings. The intervention will be delivered by a clinical team comprised of the same cadre of workers who deliver care in AMPATH-supported facilities (clinical officer, pharmacy technician, peer navigator, social worker), and include the following components:

> (1) a one-on-one clinical consultation between an AMPATH clinical officer and a microfinance group member, during which the clinical officer will conduct vital signs screening, perform an HIV-related clinical evaluation, perform an NCD-related clinical evaluation, distribute antiretroviral therapy for HIV, and distribute medications for diabetes and hypertension, as needed.
>
> (2) one-on-one referrals of the patient by the clinical officer to a health facility for emergency or acute care needs that cannot be addressed in the community (i.e., becomes virally unsuppressed/viremic, presents with new opportunistic infection, is lost to follow up, has moved out of study county, or another reason).
>
> (3) group-level health education during which the clinical officer will discuss positive HIV management habits and health lifestyle habits for managing chronic conditions, and GISHE group members will be able to ask questions together.

The integrated care intervention activities will be delivered during the microfinance group meeting (either before or after microfinance activities based on group preference). For one-on-one activities, each participant will be invited to a private location near their group meeting location (e.g., private room in a community hall, empty classroom in an empty school) to meet with the clinical officer. For group-level health education activities, groups will convene in their regular GISHE meeting location (e.g., in an empty community hall, outdoors away from other crowds).

Integrated care visits will occur monthly during months 1-6 of the trial, and then quarterly for the remaining months (7-18). Initial intervention group visits (months 1-6) will focus on acute non-HIV related needs and screening for NCDs, such as diabetes and hypertension. Facilities will be informed that participants will be receiving HIV care outside of clinic for the duration of the study, unless additional care is required (i.e., referral to facilities for worsening HIV, acute care, hospitalization, etc.). Care protocols will be put in place for handling new opportunistic infections, suspected viral resistance, malignancy screening and diagnosis.

Study Arm (B): Standard of Care with Microfinance. An attention-matched control design is inherent in this study since groups randomized to the control condition will meet as usual in their microfinance groups, and they will also receive regular standard of care from their usual AMPATH facility. In microfinance groups randomized to the standard of care condition, participants will receive the same services for HIV and other chronic diseases as those in the intervention arm but at their usual health facility. Microfinance groups in the control condition will receive clinical care services during their regularly scheduled clinic appointments, and pick up antiretroviral therapy and other medications for diabetes and/or hypertension as needed from the pharmacies following their prescribed refill schedule.

Study Arm (C): Standard of Care Alone. N=300 adult patients who receive standard of care at AMPATH facilities (from the approximately 25,000 that visit monthly) will be selected to serve as a non-randomized matched comparison to microfinance group participants. Inclusion criteria will be the same as criteria for individuals in Arms A and B, with the exception of not currently participating in any microfinance group or any community ART group. Standard-of-care-alone participants will be matched and enrolled following section 5.2 of this protocol.

3.3 Eligibility criteria[1]

3.3.1 Inclusion criteria

GISHE groups must meet the following eligibility criteria for study participation:

- An active AMPATH GISHE group (i.e., a group that was formed at least 6 months prior to study enrollment, is consistently meeting as scheduled, and is actively engaging in saving and loaning)
- An AMPATH GISHE group with a majority of group members who are AMPATH HIV patients and have disclosed their status

Members of GISHE groups that meet the above eligibility criteria will be eligible to participate if they meet the following criteria:

- Currently 18 years of age or older
- Living with HIV
- Is a member of an active AMPATH GISHE group (i.e., an active group is one that was formed at least 6 months prior, is consistently meeting as scheduled, and is actively engaging in saving and loaning)
- Is an active member of an active AMPATH GISHE group (i.e., an active member is one who has been consistently attending group meetings during the 6 months prior to study enrollment and who is actively engaging in saving and loaning)
- Is currently receiving HIV-related care through AMPATH and has an AMPATH Medical Record System (AMRS) ID
- Initiated ART at least 6 months prior to study enrollment
- Willing and able to provide informed consent for participation in the study including providing consent to allow access to AMRS data.

3.3.2 Exclusion criteria

Microfinance groups will be ineligible if they are (1) a non-AMPATH microfinance group, or (2) an AMPATH community-ART group (CARG).

[1] See the Addendum to the overall project protocol starting on page 100 for changes made to the eligibility criteria.

Members of eligible microfinance groups will be ineligible if they are (1) pregnant, (2) have an active HIV-related opportunistic infection or serious comorbidity such as cancer or conditions that require immediate hospitalization, or (3) a current participant of an AMPATH CARG.

3.4 Outcomes and endpoints

OBJECTIVES	ENDPOINTS	JUSTIFICATION
PRIMARY		
To evaluate the extent to which delivering integrated community-based care for HIV, diabetes and hypertension within microfinance groups affects viral suppression (VS) among people living with HIV (PLWH). Our working hypothesis is that A>B>C in terms of viral suppression, where (A) represents microfinance groups receiving integrated community-based care, (B) represents microfinance groups receiving facility-based care, and (C) represents facility-based care without microfinance.	The *primary* endpoint will be achievement of HIV viral suppression (HIV-RNA <400 copies/mL) at 18 months.[2]	Viral load is considered the gold standard for HIV treatment monitoring because it is an objective, biological measure of sufficient adherence to antiretroviral therapy (ART).
SECONDARY		
To evaluate the extent to which delivering integrated community-based care for HIV, diabetes and hypertension within microfinance groups affects retention in care among people living with HIV (PLWH). Our working hypothesis is that A>B>C in terms of retention in care, where (A) represents microfinance groups receiving integrated community-based care, (B) represents microfinance groups receiving facility-based care, and (C) represents facility-based care without microfinance.	The *secondary* endpoint will be retention in care, defined as the proportion of scheduled visits that were attended during the 18-month study period.	When persons with HIV are retained in care, they have better outcomes in terms of receiving antiretroviral therapy, achieving virologic suppression, improving survival, and reducing HIV transmission.
To evaluate the extent to which delivering integrated community-based care for HIV, diabetes and hypertension within microfinance groups affects systolic blood pressure among people living with HIV (PLWH). Our working hypothesis is that A>B>C in terms of systolic blood pressure, where (A) represents microfinance groups receiving integrated community-based care, (B) represents microfinance groups receiving facility-based care, and (C) represents facility-based care without microfinance.	The *secondary* endpoint will be absolute mean change in systolic blood pressure (mm Hg) over the 18-month study period.	Mean change in systolic blood pressure has shown to be associated with longer-term cardiovascular benefit, even when traditional control thresholds are not met.
To evaluate the extent to which delivering integrated community-based care for HIV, diabetes and hypertension within microfinance groups affects hemoglobin A1C (HbA1c) level among people living with HIV (PLWH).	The *secondary* endpoint will be absolute mean change in hemoglobin A1C (HbA1c) level (mmol/mol) over the 18-month study period.	Mean change in HbA1c has shown to be associated with longer-term cardiovascular benefit, even when traditional control thresholds are not met.

[2] See the Addendum to the overall project protocol starting on page 100 for changes made to the primary endpoint.

OBJECTIVES	ENDPOINTS	JUSTIFICATION
Our working hypothesis is that A>B>C in terms of HbA1c level, where (A) represents microfinance groups receiving integrated community-based care, (B) represents microfinance groups receiving facility-based care, and (C) represents facility-based care without microfinance.		

3.4.1 Sample size

At least forty (40) existing microfinance group clusters with n=900 people living with HIV (PLWH) will be randomized in a 1:1 ratio to either Study Arm A (MF+ICB) or Study Arm B (MF+SOC). Half of the cluters will be randomized to receive MF+ICB, resulting in approximately 450 PLWH in 20 groups in each of the MF+ICB and MF+SOC arms.

The number of participants enrolled in Study Arm C (SOC) will be 300 people living with HIV currently receiving care at an AMAPTH facility and not participating in group microfinance. As participants will not be randomized to the SOC arm, we will match SOC individuals to individuals in MF groups (in a 1:3 ratio) such that individuals have similar characteristics with respect to key individual and cluster-level variables.[73,74] To match individuals, we will use covariates associated with both microfinance enrollment and viral suppression. We will use coarsened exact matching, and check statistical balance of preexposure covariates for an explicitly stated specification. Section 5.2 of this protocol (Enrollment of patients receiving facility-based care and not engaged in microfinance) details the steps that will be used to match and enroll 300 standard of care facility patients.

3.4.2 Power calculation

For the sample size calculations, the standard deviation of the group size was set to 5, type-one error rate to 0.05, a two-sided test, and the intra-class correlation coefficient to 0.05. Based on studies of the effect of financial interventions we expect at least 15% increase in viral suppression between MF+ICB and MF+SOC, between MF+SOC and SOC only, and between MF+ICB and SOC only groups.[13,45] The power calculations used viral suppression in MF+SOC ranging from 20 to 50% and, as in the BIGPIC trial, accounted for 15% dropout.[43] For all the different scenarios considered, the power to detect a 15% increase in viral suppression was greater than 80% for testing all three hypotheses.

4. Aim 1 RCT Methods: Enrollment

4.1 Enrollment of microfinance group members

After identifying eligible microfinance group members, project personnel will use Adult Consent Form I (Appendix I) to obtain written informed consent from eligible GISHE group members (who will later be randomized to Study Arm A or to Study Arm B). For eligible GISHE group participants, informed consent will be collected in-person during a regularly scheduled GISHE group meeting.

Among microfinance group members, the Aim 1 enrollment period will begin on November 1, 2020 and end when the enrollment target of n=900 GISHE group members has been met. Obtainment of written informed consent will be recorded in REDCap.

<u>General Steps for Obtaining Written Informed Consent</u>

- The informed consent process should always occur in a private, confidential, and safe location.
- Elaborate on the objectives and purposes of the study and why the potential participant may qualify. Review the procedures that will be required of the participant. This includes naming the procedures, the time duration of the study, and location of where it will take place. Describe all of the risks and benefits for the procedures that are involved. Ensure that the potential participant has sufficient time to ask questions.
- If the subject is willing to participate under his or her own free will or the subject's legally authorized representative (LAR) agrees to the subject's participation, informed consent should be documented in the following ways:

a. The subject or the subject's legal representative signs, personally dates and prints his or her name in block letters on the consent form; and

b. The person who conducts the informed consent process signs, personally dates and prints his or her name in block letters on the consent form.

- Provide a paper copy of the signed and dated ICF to the subject and/or the subject's LAR.

- Store all signed informed consent forms securely in compliance with local IRB approvals and following the study's Aim 1 Data Management Protocol.

4.2 Enrollment of patients receiving facility-based care and not engaged in microfinance [3]

Among AMPATH patients not participating in group microfinance, the Aim 1 enrollment period will begin on August 1, 2021 and end when the enrollment target of n=300 standard care patients has been met. Obtainment of written informed consent will be recorded in REDCap. The following steps specify the process that will be used for matching and enrolling 300 standard of care patients.

Step 1. Using AMPATH's Medical Record Systems (AMRS), the project's data manager will filter all patient records in AMRS so that only those SOC patients who meet the following eligibility criteria are selected:

- Age: 18 years of age or older
- County of residence: Busia or Trans Nzoia
- County where patient receives care: Busia or Trans Nzoia
- HIV Status: currently living with HIV
- ART Status: Has been taking ART medications for $\geq$ 6 months
- Pregnancy Status: Not currently pregnant at most recent HIV care visit
- CARG Status: Not a member of a community ART group (CARG)

Filtering all AMRS patients by eligibility criteria will create a master list (**List 1**) of AMRS patients who can be matched to enrolled microfinance group members. List 1 will need to contain at least 1200 patients (300 SOC patients with 4 potential backups).

Step 2. Each time a group of GISHE participants are newly enrolled in Study Arm A or B (e.g., monthly or quarterly), the study's Data Assistant will send a list of the newly enrolled GISHE group members to the Data Manager so that the Data Manager can match these GISHE participants 3:1 to eligible SOC patients from List 1. The list of newly enrolled GISHE group members will contain, at minimum, the following information:

- Harambee Study ID
- AMRS ID (if available)
- CCC Number (if available)
- Universal ID (if available)
- County of Residence (Busia or Trans Nzoia)
- Age
- Gender

[3] See the Addendum to the overall project protocol starting on page 100 for changes made to the standard of care matching process.

- Name of health facility where patient receives routine HIV care

The Data Manager should match SOC patients from List 1 to enrolled GISHE group members on:
(1) County of Residence,
(2) Age (within +/- 5 years of the GISHE participant's age),
(3) Gender, and
(4) Health Facility

The Data Manager should also match the originally matched SOC patient to 4 backup SOC patients who have the same county, gender, age, and health facility as the original SOC patient. If exact matching for the original SOC patient is not possible, county and gender should be identical for all 4 ordered backups and then select each backup SOC patient whose age is closest to the original SOC patient. **List 2** should contain, at minimum, the following information:

- Harambee Study ID of matched GISHE participant
- Age, sex, county, and health facility of matched GISHE participant
- AMRS ID of 5 matched SOC patients (1 originally matched SOC patient and 4 ordered backups)
- CCC Number of the 5 matched SOC patients (if available)
- Universal ID of the 5 matched SOC patients (if available)
- Age, sex, county, and health facility of all 5 matched SOC patients

The Data Manager should return List 2 to the Data Assistant. In addition to the Harambee Study IDs, AMRS IDs, and other relevant IDs (e.g., CCC Number), List 2 should be formatted as in below example screen shot that contains faux data:

	A	B	C	D	E	F	G
1	id	case	idmatch	age	county1	sex	facility
2	1	1	1	32	1	0	Teso
3	1278	0	1_1	32	1	0	Teso
4	3336	0	1_2	32	1	0	Teso
5	3433	0	1_3	32	1	0	Teso
6	3609	0	1_4	32	1	0	Teso
7	4189	0	1_5	32	1	0	Teso
8	2	1	2	59	1	1	Port Victoria
9	763	0	2_1	59	1	1	Port Victoria
10	996	0	2_2	59	1	1	Port Victoria
11	1408	0	2_3	59	1	1	Port Victoria
12	1520	0	2_4	59	1	1	Port Victoria
13	2031	0	2_5	59	1	1	Port Victoria
14	3	1	3	22	1	0	Khunyangu
15	905	0	3_1	22	1	0	Khunyangu
16	2023	0	3_2	22	1	0	Khunyangu
17	4176	0	3_3	22	1	0	Khunyangu
18	6207	0	3_4	22	1	0	Khunyangu
19	6541	0	3_5	22	1	0	Khunyangu

In the example screenshot: **id** = deidentified dummy ID; **case** = 1(GISHE participant) / 0(SOC Patient); **sex** = 1 (male) / 0 (female); **county1** = 1(Busia) / 0(Trans Nzoia); **facility** = name of health facility where patient receives HIV care. The **idmatch** variable indicates the

GISHE participant (e.g., idmatch = 1) and the 5 SOC of patients to whom they were matched (e.g., idmatch = 1_1, 1_2, 1_3, 1_4, 1_5).

Step 3. Working closely with the AMPATH Retention Team, Harambee Data Assistant will use the AMRS ID from the list of matched SOC patients (**List 2**) to retrieve a given patient's contact information from their AMPATH medical record.

Step 4. In both Trans Nzoia and Busia counties, the AMPATH Retention Team will then call each matched SOC patient on List 2 and introduce them to the Harambee RA who will - invite them to enroll in Study Arm C. If there is no phone number available for the first identified SOC patient in AMRS (e.g., idmatch = 1_1 for GISHE Participant with idmatch = 1), then the RA will visit the facility that the client belongs to and obtain the contact information available. If a phone number is still not identifiable, then the team member should proceed with contacting the next matched SOC patient for that GISHE participant (e.g., idmatch = 1_2 for GISHE participant with idmatch = 1).

Step 5. To maximize efficiency, each original SOC patient and each backup SOC patient on List 2 should be contacted no more than twice to be invited to enroll in Aim 1. If a SOC patient is not able to be reached on the second attempt, the AMPATH Outreach Team of Harambee Data Assistant should proceed with contacting the next relevant patient on List 2. SOC patients who are unable to be reached after 2 attempts should not be contacted at a future date to be invited to enroll. Because a total of n=900 GISHE participants and total of n=300 SOC patients will be enrolled during Aim 1 (GISH Participants matched 3:1 to SOC patients), only one-third of matched SOC patients from List 2 list should be enrolled.

Step 6. For SOC patients who indicate that they are interested in enrolling in Aim 1, Harambee RA will first confirm eligibility over the phone and then schedule a time to complete informed consent procedures in-person using Adult Consent Form II (Appendix II). RA will complete in-person informed consent at a mutually convenient location agreed upon by the RA and the SOC patient (e.g., at an AMPATH-supported health facility during the patient's regularly scheduled HIV care visit).

4.3 Recruitment and retention strategies

Community mobilization and microfinance group engagement: AMPATH staff from Family Preservation Initiative (FPI), GESPs (community supervisors of GISHEs) and Harambee project personnel will conduct community mobilization meetings with microfinance group leaders to inform them about the study and randomization process. Additionally, research personnel will complete a mapping exercise during project Year 1 to assess feasibility of group engagement and willingness to participate. Only after obtaining acceptance from the groups for the study's community entry will groups be approached to complete enrollment procedures and baseline assessments.

Participant recruitment and retention in microfinance groups**:** FPI staff who have long-standing relationships with many of the MF group leaders will work with the investigative team in Kenya to recruit as many members as possible during the enrollment period. The intervention will be provided when more than half of the group members agree to participate. Microfinance group members who do not wish to participate will not be excluded from any ongoing microfinance group activities.

Attending microfinance group meetings is on its own an incentive for retention in care since care will be provided in conjunction with the on-going routine meetings where participants buy shares and take turns borrowing money from a common savings pool. By combining care with microfinance, financial

incentives are built into the structure of this local, grassroots activity, and thus will not be expected to require long term (external) donor support to be sustainable.

In the MF + ICB groups (Study Arm A), we anticipate that the community-based care intervention itself will be a substantial incentive for attending study visits and for ongoing study participation.

Additionally, the following factors will also serve to increase participant retention in Study Arms A and B:

- Microfinance is a strong motivator for participation, regardless of whether participants receive community- or facility-care
- The social network created by the microfinance groups is a good source of information such that peers will play an active role in recruitment and retention efforts
- Our previous community-based care interventions show that participation and retention rates are high because participants' need for transportation to and from a clinical site is minimized (Arm A)
- The study assessments will be conducted at community locations that are convenient for participants
- We will hire appropriately-trained staff members to conduct recruitment and retention activities; many staff members have already been working with the MF groups for a number of years

Participant retention in the SOC arm: Research personnel will attempt to contact identified eligible SOC participant up to 2 times to invite them to enroll in Aim 1. Research personnel will attempt to contact each enrolled SOC participant up to two times to complete the 18-month follow up assessment (i.e., viral load and surveys). In the event that a participant cannot be located, their most recent viral load measurement will be ascertained from the patient's AMRS data to estimate viral suppression at 18 months.

5. Aim 1 RCT Methods: Randomization [4]

Group randomization will occur after all consenting participants complete baseline assessments using a computer-generated sequence to randomize MF groups to receive either integrated community-based care (ICB) or standard of care. The randomization process will be conducted centrally by biostatisticians at Brown University.

6. Aim 1 RCT Methods: Intervention Delivery [5]

Integrated care visits will occur monthly during months 1-6 of the trial, and then quarterly for the remaining months (7-18). Initial intervention group visits (months 1-6) will focus on acute non-HIV related needs and screening for NCDs, such as diabetes and hypertension. Facilities will be informed that participants will be receiving HIV care outside of clinic for the duration of the study, unless additional care is required (i.e., referral to facilities for worsening HIV, acute care, hospitalization, etc.). Protocols

[4] See the Addendum to the overall project protocol starting on page 100 for changes made to the randomization process.

[5] See the Addendum to the overall project protocol starting on page 100 for changes made to the schedule and format of intervention delivery.

for handling new opportunistic infections, suspected viral resistance, malignancy screening and diagnosis will follow established AMPATH care protocols.

Prior to each intervention visit in the community, the clinical officer will review patient medical records to confirm each microfinance group members care needs at the upcoming visit. If an ART refill is needed at the upcoming visit, the clinical officer will work with the AMPATH pharmacist to prepare the ART medications and package them in a brown paper bag. If a NCD medication refill is needed at the upcoming visit, the clinical officer will work with the AMPATH pharmacist to prepare the NCD medication and package them in a brown paper bag.

The study intervention **(Study Arm A)** will deliver integrated care for HIV, diabetes, and hypertension in the community to enrolled microfinance group members during regularly scheduled GISHE group meetings. The intervention will include the following components (Figure 2):

(1) a one-on-one clinical consultation between an AMPATH clinical officer and a microfinance group member, during which the clinical officer will conduct vital signs screening, perform an HIV-related clinical evaluation, perform an NCD-related clinical evaluation, distribute pre-packaged antiretroviral therapy for HIV, and distribute pre-packaged medications for diabetes and hypertension, as needed.

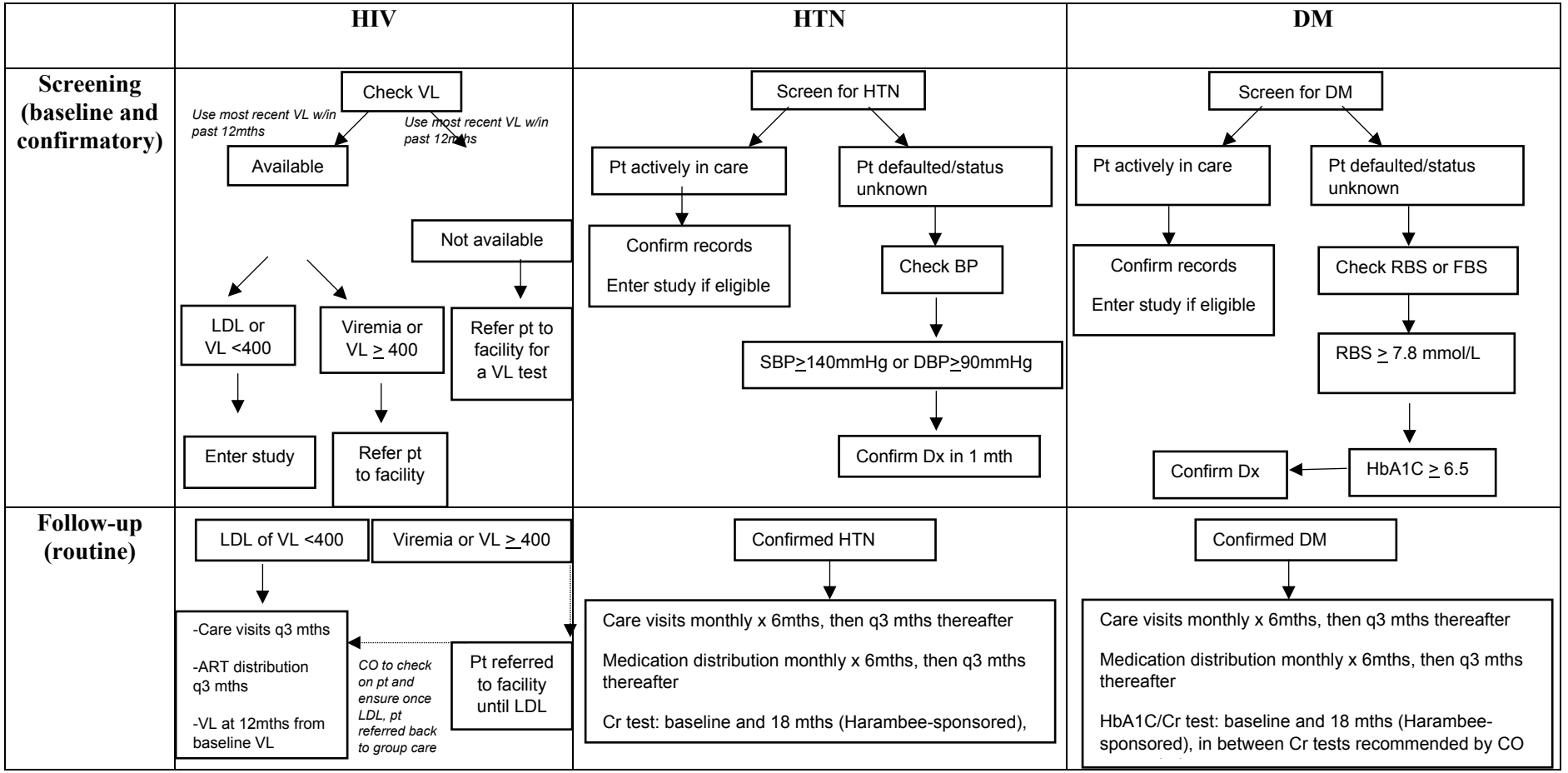
6.1 Medication refills

- All antiretroviral therapy will be provided to microfinance group members free of charge in accordance with AMPATH care protocols and national policies.
- NCD medication costs will be charged to the patient following the discounted costs set by the Kenya Medical Supplies Agency (KEMSA). The cost(s) of NCD medications during ICB care visits will be the same as the NCD medication costs at the AMPATH facility. The amount of NCD medications packaged and brought to the community visit will be enough to last until the next integrated care visit. Each NCD patient will be allowed to buy the quantity of NCD medication they can afford at the time of the visit (i.e., the entire refill or only a portion of the refill). If a given patient chooses to purchase only a portion of their NCD refill, the clinician will give the patient a prescription for the remaining quantity that the patient can then choose to fill at a pharmacy prior to the next integrated, community care visit. After each ICB care visit the clinician will take back all remaining drugs, as well as any and all funds received from NCD medication refills. A written receipt will be given to each patient who purchased a supply of NCD medication, and a copy of the receipt will be taken back to facility and entered into the Revolving Fund Pharmacy records.

6.2 Point of care testing

- Viral load testing: The most recent viral load test result available in the patient's medical record with the 12 months prior to their enrollment date will serve as the patient's baseline viral load. If no test result is available, no viral load test result will be performed. For all microfinance group members in the integrated care arm, study staff will collect a blood sample during the 18-month study visit in the community to measure endline viral load and assess the study's primary outcome. AMPATH care protocols require PLWH to receive a viral load test every 12 months such that some patients may have an additional viral load test result in their medical record during the middle of the trial. These results will not be used in the effectiveness analyses.

Figure 2. Harambee Study Clinical Flow (Study Arm A) *Updated May 09, 2021*



Referral (prn)	Patient with viremia or ≥ 400 Patient with clinical symptoms that require ↓ Referral recommendation as needed based on clinical judgement Documentation must be completed: VL (if applicable) % clinic visits successfully	Patient with emergencies requiring immediate management at a tertiary health facility (ie. hypertensive emergency, DKA/HHS) ↓ Referral recommendation as needed based on clinical judgement Documentation must be completed: % clinic visits successfully attended (successful	Patient with emergencies requiring immediate management at a tertiary health facility (ie. hypertensive emergency, DKA/HHS) ↓ Referral recommendation as needed based on clinical judgement Documentation must be completed: % clinic visits successfully attended (successful

VL = viral load; LDL = undetectable viral load; BP = blood pressure; Tx = treatment; Dx = diagnosis; RBS = random blood sugar; Cr = creatinine; DKA = diabetic ketoacidosis; HHS = hyperosmolar hyperglycemic state; mth=month; prn= pro re nata ("as needed").

- Creatinine test: A creatinine test will be conducted among all microfinance group members in the integrated care arm during the baseline visit in the community and during the final 18-month visit in the community. The baseline and endline tests will be sponsored by the study and conducted using Creatinine cartridges and a point-of-care iStat machine that the study team will be responsible for transporting to the group meeting location. The clinical officer may recommend a patient seek additional creatinine tests at a facility during the trial, which will be charged to the patient.
- Random blood sugar (RBS): A random blood sugar test will be conducted among all microfinance group members in the integrated care arm during the baseline visit in the community and during the final 18-month visit in the community. The baseline and endline tests will be sponsored by the study and conducted using a glucose strip and glucometer that the study team will be responsible for transporting to the group meeting location. The clinical officer may recommend a patient seek additional creatinine tests at a facility during the trial, which will be charged to the patient.
- HbA1C test: A hemoglobin A1C test will be conducted among all microfinance group members in the integrated care arm during the baseline visit and during the final 18-month visit in the community if their RBS > 7.8 mmol/L or if their FBS > 6.1 mmol/L. The baseline and endline tests will be sponsored by the study.
- Systolic and diastolic blood pressure will be assessed during each clinical evaluation conducted in the community using a routine blood pressure cuff.

(2) one-on-one referrals of the patient by the clinical officer to a health facility for emergency or acute care needs that cannot be addressed in the community (i.e., becomes virally unsuppressed/viremic, presents with new opportunistic infection, is lost to follow up, has moved out of study county, or another reason).

(3) group-level health education during which the clinical officer will discuss positive HIV management habits, and health lifestyle habits for managing chronic conditions, and GISHE group members will be able to ask questions together.

For one-on-one activities, each participant will be invited to a private location near their group meeting location (e.g., private room in a community hall, empty classroom in an empty school) to meet with the clinical officer. For group-level health education activities, groups will convene in their regular GISHE meeting location (e.g., in an empty community hall, outdoors away from other crowds).

Clinical encounter data, medication distribution data and data on referrals will be recorded in REDCap in the community and then transferred to the patient's medical record by the clinical officer when the clinical officer returns to the facility.

7. Aim 1 RCT Methods: Data collection, management, and analysis

7.1 Data Collection

The trial involves the collection and use of the following types of data. With the exception of viral load data which will be ascertained from and/or entered directly into patient medical records, data will be collected using mobile tablets with secure encryption and cloud-based data capture.

1. We will measure HIV viral load at study enrollment and at 18-months for all enrolled trial participants.

1.1 Baseline viral load will reflect the most recent viral load measurement available in the patient's medical record within the 12 months prior to their enrollment date.
1.2 18-month viral load will be assessed using blood draws taken during the 18-month assessment in the community (for microfinance group members) and at the facility (for non-microfinance group members).

2. For clinical secondary outcomes, we will measure systolic blood pressure and hemoglobin A1c at baseline and 18-months for all 900 microfinance group members enrolled in the trial. Blood pressure will be measured in the community by the clinical officer using a blood pressure arm cuff. HbA1c will be measured in the community by the clinical officers using a point of care test.
3. For non-clinical secondary outcomes, we will measure retention in care on an ongoing basis for all enrolled trial participants. Retention in care will be based on study records (REDCap) for intervention recipients and on medical records for facility care patients.
4. For exploratory outcomes and mediation analyses, we will collect survey data from all enrolled trial participants: at enrollment and 18-months for all trial participants, with an additional round of survey data collection at month 9 for all microfinance group members. Surveys will be administered by a research assistant to participants in a private location in-person. Surveys will assess demographics, health insurance enrollment and utilization, social support (Oslo Social Support Scale-3), quality of life (adapted version of the MOS-HIV scale), psychological distress (Patient Health Questionnaire-4), self-reported ART adherence (based on the adapted ACTG Adherence Questionnaire), self-reported adherence to NCD medications (based on the extent of DOSE-Nonadherence Questionnaire), barriers to accessing care, patient satisfaction with care, felt HIV stigma (9-item measure of felt stigma validated in Kenya). The survey instrument is included in Appendix III. For exploratory outcomes, we will collect data on microfinance group performance (e.g., saving and lending activities, loan default rates) for all microfinance group participants. Microfinance group performance data will be collected on a quarterly basis and recorded via REDCap. The microfinance data collection tool is included in Appendix IV.

7.1.1 Baseline assessments

Trained research assistants will conduct baseline assessments at the first regularly scheduled MF meeting following study start date. During the baseline visit, **participants in GISHE groups** will:

- Complete informed consent procedures which include consenting to provide access to their AMRS data (Appendix I)
- Be screened for hypertension and diabetes following routine AMPATH protocols (Appendix VIII)
- Complete the survey assessments (Appendix III)

Participants who receive standard of care at AMPATH facilities and agree to enroll in the study (Study Arm C), will also complete a baseline assessment at a facility or mutually agreed upon convenient location. During the baseline visit, **SOC participants** will:

- Complete informed consent procedures which include consenting to provide access to their AMRS data (Appendix II)
- Complete the survey assessments (Appendix III)

AMRS IDs will be verified for all trial participants at enrollment. In addition, a separate contact form will be completed for participant follow-up and kept separately from other study documents.

7.1.2 Follow up assessments

For study participants in MF groups (MF + ICB and MF+SOC), follow up assessments to evaluate primary and secondary outcomes will be conducted in the field at 9- and 18- months. During follow up assessments, MF group participants will:

- Provide a blood draw for HIV viral load testing (study month 18 only)
- Provide a systolic blood pressure reading (study month 18 only)
- Provide an HbA1c point of care test, if clinically indicated (study month 18 only)
- Complete the survey assessments (study month 9 and 18)

Trained research assistants will work with the clinical teams to collect survey assessment data on mobile tablets. Clinical teams will record blood pressure and HbA1c results in the patient's medical records and in the study REDCap records. At 18 months, clinical officers and research assistants will transport blood samples from the community to the Eldoret reference lab for analysis. For participants who do not attend MF group meetings during assessment time points (months 9 and 18), research assistants will use participant's contact information to schedule follow-up meetings to collect data if participants are willing to meet outside of the regularly scheduled MF meeting time. We will access and review AMRS for data on secondary outcomes (i.e., retention in care and chronic disease composite score).

For study participants receiving SOC (Study Arm C), follow up assessments to evaluate primary and secondary outcomes will be conducted at AMPATH facilities when the patient returns for their HIV clinic visit at 18-months. During follow up assessments, SOC patients will:

- Provide a blood draw for HIV viral load testing
- Complete the survey assessments

7.1.3 Fidelity monitoring

During the first six months of the study, intervention staff will meet weekly to review study progress, care protocols, and any issues that have arisen during the ICB care delivery activities. Following the initial six months, the project manager will visit 4 randomly selected intervention groups (MF+ICB) monthly to monitor activities and ensure that procedures for care delivery are being followed. Using a checklist for adherence to study protocol, the project manager will rate each session. Staff in groups with low ratings will be retrained and monitored for the following 3 months. During the random audit, any staff member found in violation of study protocol will be suspended and retrained.

7.2 Statistical analysis [6]

The primary analysis of interest is comparing viral suppression at 18 months between the MF+ICB (Study Arm A) and MF+SOC groups (Study Arm B). As a secondary hypothesis, we will test MF+ICB vs SOC alone and MF+SOC vs SOC alone. To test both the primary and the secondary hypotheses we will use a generalized mixed effects model.[33] For the primary outcome, the model we will use is

$$log(P(Y_{ij} = 1|I_j, S_j, VB_{ij}, c_j)) = \beta_0 + \beta_1 I_j + \beta_2 S_j + \beta_3 VB_{ij} + c_j,$$

[6] See the Addendum to the overall project protocol starting on page 100 for changes made to the statistical analysis plan.

where, Y_{ij} is viral suppression at 18 months for participant i in cluster j, I_j is the indicator if cluster j is randomized to the MF+ICB arm, S_j is an indicator if cluster j comes from the SOC individuals, VB_{ij} is the baseline viral load for participant i in cluster j, and c_j is the random effect associated with cluster j. The estimator $\beta_1$estimates the difference between the MF+SOC and MF+ICB arms and positive values indicate higher viral suppression in the MF+ICB arm. To test the primary hypothesis we will perform a hypothesis test for H_0: $\beta_1 = 0$. To test the secondary hypothesis we will perform a hypothesis test for H_0: $\beta_2 = 0$ and H_0:$\beta_1 - \beta_2 = 0$.

For the secondary outcomes, we will modify the above model to reflect that retention in care is a proportion and the absolute mean change in systolic blood pressure and HbA1c level are each a continuous outcome. Dropout from the study will be handled using inverse probability weighting.[34] The design, analysis, and interpretation of the results from the trial will follow the recommendations given by the CONSORT statement on cluster randomized trials.[35] All data will be de-identified prior to the analysis phase.

8. Aim 2: Mixed methods to assess mechanisms through which MF and community-based care affect patient outcomes

8.1 Study Population and recruitment

For **qualitative mediation analyses**, we will conduct qualitative in-depth with 40 participants from the Aim 1 randomized controlled trial (n=20 from the MF+ICB arm and =20 from the MF+SOC arm). Following the Aim 1 trial's 18-month assessment, research assistants will provide information to a purposively selected sample of n=40 participants and invite them to join the qualitative data collection. Following the Aim 1 trial's 18-month assessment, research assistants will also invite n=10 current AMPATH staff who delivered the intervention to participate in in-depth interviews. Individuals who are interested in participating in the Aim 2 interviews will complete the informed consent form in Appendix V.

8.1.1 Inclusion criteria for trial participants:

- consented to participate in the intervention study (Aim 1) and completed at least the baseline and 18-month assessment;
- participated in at least 2 MF group meetings during the study period; and
- able and willing to provide informed consent for the qualitative study.

8.1.2 Inclusion criteria for key stakeholder and care providers:

- Delivered care in the intervention arm of the trial for at least 6 months;
- 18 years of age or older; and
- Able and willing to provide informed consent to participate.

Data for all Aim 1 participants (n=900 microfinance groups + 300 SOC) collected via the survey measures (Appendix III) administered at baseline, 9-month, and 18-month follow-up visits will be used for the for the Aim 2 **quantitative mediation analyses**.

8.2 Aim 2 (mixed methods mediation analysis) procedures

In depth interviews (IDIs) with trial participants will take place in a private and quiet location with the use of an interview guide. A semi-structured guide (Appendix VI) will include questions to assess the following domains: 1) Experiences related to MF groups, 2) Barriers/facilitators to accessing HIV care, including household economic conditions, food security, geography/distance, social support, and HIV-related stigma; 3) How participation in MF and/or community-based care impacts retention in care,

adherence to ART; 4) Satisfaction with HIV care delivery (community-based or facility-based); 5) Suggested improvements for care delivery models.

In depth interviews (IDIs) with intervention delivery personnel will take place in a private location, outside of their work location if preferred. Interviewers will be trained members of the AMPATH social behavioral team. Semi-strucutred interview guides (Appendix VII) with staff will focus on the following domains: 1) Satisfaction with job; 2) Challenges to delivering HIV care in the community; 3) Suggested improvements; 4) Context-specific issues delivering care in this setting related to geography, community, etc. Interviews will be conducted in Swahili or English by a trained member of the research staff and audio-recorded with permission. All interviews will be transcribed and translated in full. Transcriptions will be entered into a text organization software program for analysis.

8.3 Aim 2 statistical analyses

Quantitative mediation analyses. We will use causal mediation analysis to evaluate the importance of causal pathways between microfinance and integrated community-based care and viral suppression and retention. We will use the data described in Aim 1 collected at baseline, 9-month, and 18-month follow-up visits. The primary analysis will focus on two main mediators: household economic conditions and access to care. We will estimate the mediation effect of each mediator separately using the difference method and account for multiple comparisons using a Bonferroni correction. The generalized linear models needed to implement the difference method will adjust for key confounders such as education, location, gender, and age. We will perform a sensitivity analysis of the assumption of no unmeasured mediator-outcome confounders. As a secondary analysis, we will use causal mediation analysis to evaluate the mediation effect of food security, social support, and HIV-related stigma. We hypothesize that there will be similar improvements in household economic conditions between the two MF and MF+ICB groups, but that barriers in access to care will be more improved in the MF+ICB arm. Differences in these mechanisms will provide important information regarding the additive impact of integrated community-based care on the hypothesized relationships.

Qualitative mediation analyses. Text from the n=50 interviews will be coded into a hierarchical, branching structure in which broad concepts are first identified, along the domains identified in the interview guides and our conceptual model, and then themes and variations within those themes will be defined and text will be labeled according to these definitions. Coded data from intervention participants will be compared to identify mechanisms through which MF and community-based care impacted retention in HIV care and adherence to ART, and the additive impact of the community-based care delivery in the intervention group. Specifically, data will compare between the intervention arms the added benefits of community-based care, beyond those relevant to both groups from the MF activities. We will triangulate findings using data from the qualitative study to explain and expand on findings from the quantitative mediation analysis.

9. Aim 3. Cost-effectiveness analysis

Aim 3 will perform a cost-effectiveness analysis to test the working hypothesis that microfinance groups with integrated community-based care (MF+ICB) are more cost-effective compared to microfinance without ICB (MF+SOC) and standard care (SOC).

9.1 Aim 3 procedures

Costs attributable to the intervention will be collected during the randomized controlled trial (Aim 1) for each relevant study period at 6, 12, and 18 months. Costs will be recorded using a cost tracking tool developed specifically for this study. We will estimate differences in the intervention arms (MF+ICB and MF+SOC) and the controls (SOC). The differences in costs among the control and intervention arms will be defined as the incremental costs **(ΔC)**. Cost estimates for the controls will be obtained from

AMPATH's existing electronic medical records (AMRS) as well as accounting and administrative records, and interviews with n=5 key informants such as administrative directors, comptroller, and local managers. In particular, we will use project and administrative records to conduct a cohort-based, micro-costing approach. We will assess cost differences between the control and intervention arms including the total costs of the medications (ART, NCD control, etc.), as well as transportation and wait time costs. For each participant, we will review the AMRS to determine the actual utilization of ART, non-ART drugs, laboratory tests used, and clinic visits for each patient.

9.2 Aim 3 statistical analyses

Costs will be calculated from three distinct perspectives. First, we will take the perspective of AMPATH as a provider of care. Total costs will be defined as the sum of fixed and variable costs. Variable costs for each patient will be calculated by multiplying the number of units of each good or service used by the unit cost. Costs of ART will be obtained from the official AMPATH/PEPFAR supplier in Kenya. Unit costs for non-ARV drugs will be estimated by reviewing invoices and interviewing key informants. Clinical care unit costs will be estimated by multiplying the time of the clinical interaction (based on time motion logs) by the amount spent on staff salaries by level (medical officer, nurse, etc.) and overhead. All costs incurred by the project, not directly attributable to individual participants will be considered as part of the fixed costs. These are usually costs that are exercised regardless of the volume of participants (cleaning, maintenance, utilities, etc.). Fixed costs will also include any equipment bought (new testing machines, motorcycle, rent/space costs, etc.) which will be discounted at a rate of 5% per year to account for depreciation. Total fixed costs will be allocated to all the participants proportionally. Second, we will take into account costs from the patients point of view, which will include time and transport costs to the place where care is received (i.e., the clinic for the SOC vs. the microfinance meeting place for the MF+ICB group). Third, we will perform a potential cost-saving estimation from the point of view of government and donors where financial outlays are compared into the future to gauge the extent to which the proposed intervention can be financially self-sustained.

Effectiveness: We will use the changes in primary and secondary outcomes, as explained in Aim 2; namely: viral suppression and retention-in-care. The incremental effectiveness **(ΔE)** will be defined as the difference in outcomes between the SOC and the intervention groups.

Incremental Cost-Effectiveness Ratio (ICER) will be defined as incremental cost over incremental effectiveness (ΔC/ΔE). In addition, we will model incremental costs per disability-adjusted life year (DALY) averted to make the results comparable to the international cost-effectiveness literature. We will model the effects over the life span using the Sullivan method discounting future effects. For the net benefits estimation, we will transform costs into constant 2018 USD using the Kenyan consumer price index and the international average exchange rate to convert from Kenyan shillings (KES) to USD. We will compare the cost per DALY saved to the Kenyan income per capita (GDPpc) and deem the intervention extremely cost-effective if $/DALY is less than 1*GDPpc, highly cost-effective if $/DALY is less than 2*GDPpc, and cost-effective if $/DALY is less than 3*GDPpc.

Sensitivity Analysis: We will use sensitivity analyses to describe the scope and nature of the inherent uncertainties surrounding the cost-effectiveness estimates. Each parameter in the model will be varied across a plausible range of in a series of one-way sensitivity analyses and those that exhibit the largest magnitude of influence either in effects, costs, or the resultant cost-effectiveness ratio, will be varied together in multi-way sensitivity analyses. In addition, we will conduct threshold analysis, whereby we will point out the values at which the intervention options may no longer be cost-effective; we will use a probabilistic uncertainty analysis for the variables that have an underlying probability distribution.

The final cost-effectiveness results will be measured with incremental cost effectiveness ratios comparing the SOC with each of the additional interventions. In addition, given that each of the innovations may have an optimal level of scale and diffusion, and potential cost savings from the perspective of each of the actors. To estimate return on investment we will use a cost-utility approach that we have successfully used for HIV testing and can be adopted for HIV treatment retention interventions.

10. Protection of human subjects

This study involves research that is classified as non-exempt human subjects research. All procedures of this research will be conducted in accordance with 45 CFR Part 46 and will be approved by the Moi University School of Medicine IRB (the IRB of record) and the Brown University Institutional Review Board (the prime award recipient).

10.1 Risks to human subjects

Participation in this study involves no physical risk above the risks ordinarily encountered in daily life. There may be several non-physical risks associated with study participation.

1. There is a small risk of loss of privacy or confidentiality for participants in the trial (Aim 1) and in the qualitative study (Aim 2). Individuals will provide information regarding sensitive topics, such as their experiences with HIV care. All data will be de-identified to ensure no loss of privacy or confidentiality as described in the Data Safety and Monitoring Plan. All informed consent documents will provide participants with information regarding the potential risks of loss of privacy.

2. Participants may experience psychological discomfort during the qualitative interviews (Aim 2) or during care sessions (Aim 1), however this should not be beyond what would be experienced during the course of routine care. Interviewers, research assistants and providers will be trained to handle emotional responses to the topics. We will take steps to minimize the psychological discomfort of participating in this study.

3. There is a small risk of stigma related to study participation. Individuals will be recruited into the study based on their HIV-status. In order to ensure that participants are not stigmatized based on participation in the study, we are intentionally operating our study within already existing microfinance groups. Microfinance groups are only eligible for study participation if at least 70% of their members are HIV positive. Therefore, there should be no additional stigma associated with our study.

4. Potential risks for this study include a minimal physical risk of bruising or discomfort from needle sticks during venipuncture to collect blood. However, every precaution will be taken to reduce the risk of the blood draw by hiring seasoned and proficient phlebotomists. From our prior experience performing blood draws as part of RCTs, the discomfort associated with venipuncture is trivial.

10.1.1 Adequacy of protection against risks

10.1.2 Informed consent

Informed consent will be written consent for participation in the trial and in the qualitative interviews. Written informed consent will be obtained by trained study staff in a private place in or near the regularly scheduled MF group (for trial participants) or the AMPATH clinic (for SOC participants and

clinic personnel involved in the qualitative interviews). Informed consent documents will be translated into Swahili or other local language and back-translated for accuracy. Informed consent will be read aloud to participants and they will be given the opportunity to ask questions before agreeing to participate. The participants will have the opportunity to read the form and take as much time as they need to do so. The participants will be offered a copy of the form to keep. The interviewer or research assistant will ask the participants if they agree to take part in the study and if they agree, both will sign and date the document. If participants are not literate, they will be asked to mark the page in the presence of a witness (another study staff member so as to not violate participant confidentiality). Interviewers and counselors will document that consent was provided prior to beginning any study procedures.

Our study team has prior experience in obtaining informed consent for research and clinical trials within the cultural context of Kenya. The informed consent procedure has been designed to maximize understanding of potential risks. Participants may decline to participate at any point.

10.1.3 Maintaining privacy and avoiding stigmatization

In order to minimize potential risk of stigma, our recruitment will occur during regularly occurring microfinance meeting times. We expect that this technique will be very effective at minimizing any attention that may be paid to study participants due to the presence of our study staff in the village. We will only discuss the nature of the study with the study participants and will train field staff to appropriately respond to queries about study activities from individuals not enrolled in the study. Study visits to the regularly scheduled microfinance group meetings will occur in unmarked vehicles in order to reduce the unlikely possibility of stigmatizing study participants.

Every effort will be made to ensure that privacy is maintained during the ICB care delivery visits in the intervention groups. All data collected during Aims 1 and 2 will be de-identified as described in the Data Safety and Monitoring Plan.

10.1.4 Minimizing psychological discomfort

In order to minimize risks from psychological discomfort or potential loss of confidentiality, potential participants will have study procedures fully explained before giving consent, with explanations about the potential risks involved in participation. All participants will have the opportunity to ask questions prior to consenting to participate. While we expect this strategy to be effective in minimizing psychological discomfort due to study procedures, we will offer referrals to mental health services offered at AMPATH for any participant in need. In cooperation with the Department of Psychiatry at Moi University School of Medicine and Moi Teaching and Referral Hospitals, AMPATH holds a special weekly clinic to meet the mental health needs of patients. Patients can be referred from any site for evaluation and treatment. A mental health nurse also provides onsite counseling one day per week at rural clinics at Mosoriot, Burnt Forest, and Turbo. The weekly clinics and onsite counseling provide treatment to patients with a variety of disorders, including depression, psychosis, and substance abuse.

10.1.5 Minimizing risk to due to venipuncture

In order to minimize risk due to venipuncture we will only hire and train staff with experience collecting blood samples. Our phlebotomists will make every effort to minimize physical discomfort due to the blood draw procedures.

10.2Data safety and monitoring plan

The first aim of this study involves a cluster randomized trial as well as secondary analysis of data from electronic medical records and recorded as part of usual care. This data will be managed and secured following standard operating procedures within AMPATH. Only the AMPATH data manager will have access to the identifiable data. A unique study identifier will be used to identify participants. Only the principal investigators (MPI Drs. Galarraga and Genberg and PI Wachira) and the data manager will have access to the file linking the unique study identifier to identifiable data. All data will be de-identified prior to analysis. All data files will be kept securely with password protection. Similar procedures will be put in place to safeguard data collected from surveys for Aim 2.

The second aim will also involve in-depth interviews that will include digital recordings, transcripts and notes by the interviewer. The interviewer and the MPIs will have access to this data. Transcripts sent out for translation will have no identifiable information included. We will use a service that has a history of experience working with AMPATH and other medical data. Qualitative data will also be stored on secure servers, protected by password and encryption. The data will not include identifying information. Any information used to recruit and schedule appointments, such as first name, mobile numbers, or addresses will be destroyed following data collection.

The third study aim will involve in-depth costing interviews and working meetings organized in six major steps: (1) accessing and organizing the annual financial reports into logical sub-categories; (2) reorganizing the subcategories into input cost categories to create a financial cost profile; (3) estimating the annual equivalent payment for program equipment; (4) documenting donations to the program implementation; (5) including any portion of the organizational costs not attributed to specific programs; and (6) including the results of Steps 3-5 into an expanded cost profile. Note that the costing interviews will not be audio recorded, and instead only aggregate costing numbers will be agreed upon and completed in already pilot-tested Excel spreadsheets which we have successfully used in similar projects.

All research personnel will adhere to the comprehensive Data Safety and Monitoring Plan that was submitted to and approved by the NIH Program Officer for this project.

10.3Potential benefits of the proposed research to the participants and others

There is no direct benefit of the proposed research to study participants. However, if the intervention is successful, individuals in the intervention study may benefit from HIV and NCD care delivered in a more convenient setting. More regular engagement in HIV care is associated with many improved patient outcomes and individuals in the study will have the opportunity to receive more convenient HIV care with a trained clinical staff member. It is possible that individuals in western Kenya as a whole will benefit from this study as it is designed to test a differentiated model of care delivery. If we can successfully intervene and engage patients with HIV into more regular HIV care and increase viral suppression among people living with HIV, there will be important benefits for individual patient outcomes, as well as at the population level in terms of reduction in HIV incidence. Given these potential benefits, we believe the risks for participation are reasonable.

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Appendix I: Adult Consent Form 1

(For microfinance group members who are asked to enroll in Aim 1)

Title of Research:	Harambee: Integrated Community-Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	23 February 2021

What you should know about this study

Unachopaswa kujua kuhusu utafiti huu

- You are being asked to join a research study.
  Unaulizwa kujiunga na utafiti huu.
- This consent form explains the research study and your part in the study.
  Fomu hii ya idhini inalezea kuhusu utafiti na jukumu lako kwenye utafiti.
- Please read it carefully and take as much time as you need.
  Tafadhali isome kwa umakini na uchukuwe muda mwingi kadri unavyohitaji.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
  Wewe ni mtu ambaye amejitolea. Unaweza kuchagua kutoshiriki kabisa katika utafiti. Ikiwa unachagua kujiunga na utafiti, una hiari wa kutoka kwenye utafiti huu wakati wowote. Hakutakuwa na adhabu yoyote ukiamua kutoka kwenye utafiti.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.
  Kwa wakati wa utafiti, tutakueleza mara moja endapo tutapata kujua kuhusu habari yoyote mpya ambayo inaweza kuathiri ikiwa unataka kuendelea kuwa kwenye utafiti.

What is the purpose of research study?

Je, ni nini kusudi la utafiti huu?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Kusudi la utafiti huu ni kuweza kujua ikiwa kupeana huduma ya HIV na huduma zingine za afya katika jamii, badala ya kwenye kituo cha afya, itawasaidia watu wanaoishi na HIV kuishi maisha yenye afya. Utafiti huu pia unataka kujua ikiwa kutoa huduma ya HIV na huduma zingine za afya kwa watu ambao ni wanachama katika vikundi vya mikopo midogo itawasaidia watu wanaoishi na HIV kuishi maisha yenye afya.

Why we are asking you to participate?

Je, ni kwa nini tunakuuliza ushiriki?

You are being asked to participate in this study because:

Unaulizwa kushiriki katika utafiti huu kwa sababu:

1) You are at least 18 years old
   Una angalau umri wa miaka 18
2) You are an HIV patient
   Wewe ni mgonjwa anayeishi na HIV
3) You have been taking antiretroviral (ART) medications for the past 6 months or longer
   Umekuwa ukitumia dawa za ART kwa miezi 6 iliyopita au zaidi
4) You receive care for HIV at an AMPATH HIV clinic
   Unapokea huduma ya HIV katika kliniki ya AMPATH
5) You have an AMPATH identification number
   Una nambari ya kitambulisho cha AMPATH
6) You have been a member of an active microfinance group for the past 6 months or longer
   Umekuwa mwanachama wa kikundi cha mikopo midogo na kinachoendelea na kazi zake kwa miezi 6 iliyopita au zaidi
7) You do not have serious infections or illnesses that require immediate care or hospitalization
   Hauna maambukizo makali au magonjwa yanayohitaji huduma ya haraka au kulazwa hospitalini
8) You are not a member of a community ART group (CARG)
   Wewe sio mshiriki wa kikundi cha kupokea madawa ya ARVs katika jamii
9) You are not pregnant
   Wewe si mjamzito

What will happen if you agree to participate in the study?

Je, ni nini itatokea ikiwa utakubali kushiriki katika utafiti?

If you agree to participate in the study, your microfinance group will be assigned to Group A or Group B. The chances that you will be in Group A or Group B are equal because they are picked by chance (like tossing a coin – the chances of getting each side are the same).

Ikiwa unakubali kushiriki kwenye utafiti, kikundi chako cha mikopo midogo kitapewa aidha katika kundi A au kundi B. uwezekano wa kuwa katika kundi A au B ni sawa kwa sababu unachaguliwa kwa bahati (kama vile katika kutupa sarafu- uwezekano wa kupata kila upande ni sawa).

If you are assigned to Group A, you will attend your regular microfinance group as normal. When you attend your microfinance group, you will also meet with AMPATH staff members and members of this research study. The AMPATH staff will take your vital signs (blood pressure, temperature, heart rate, height, weight, waist circumference, etc.) and give you medicine for your HIV for free. If you have high blood pressure or diabetes, you will receive medicine for a fee. The price you will pay for the blood pressure or diabetes medicines will be similar to prices at the AMPATH pharmacy. During your time in this study, AMPATH staff will also take samples of your blood to test your HIV levels (viral load) to see how healthy you are. The frequency of this blood test depends on your age and the amount of HIV virus in your body. At a minimum, we will take a blood sample at least once at the end of the study during your

microfinance group meeting. We will also test your blood sugar levels to know if you have diabetes. At a minimum, this will occur two times, one at the beginning (baseline) and another at the end of the study (18 months) at no cost to you. If you are found to have diabetes, you will pay a subsidized fee for any additional tests you may need. You will also speak with an AMPATH counselor. If you have any problems or concerns, the counselor will help you and refer you to the AMPATH clinic if you have an emergency.

Ikiwa umepewa Kundi A, utahudhuria kikundi chako cha kila mara cha mikopo midogo kama kawaida. Unapohudhuria kikundi chako cha mikopo midogo, utakutana pia na wafanyikazi wa AMPATH na wasaidizi katika utafiti huu. Wafanyikazi wa AMPATH watapima ishara zako za mwili (presha, kiwango cha joto mwilini, mapigo ya moyo, urefu, uzito, mduara wa kiuno, n.k.) na kukupatia dawa zako za HIV bure bila malipo. Ikiwa una ugonjwa wa presha au kisukari, utapokea madawa kwa malipo. Bei utakayolipia madawa ya ugonjwa wa presha au kisukari itakuwa sawia na bei kwenye duka la dawa la AMPATH. Wakati wa huu utafiti, mfanyikazi wa AMPATH pia atachukua sampuli za damu yako ili kupima viwango vya virusi vya HIV (viral load) kuona jinsi ulivyo heri wa afya. Mara ya kurudia vipimo hivi vya damu inategemea na umri wako na kiwango cha virusi vya HIV katika mwili wako. Kwa kiwango cha chini, tutachukua sampuli ya damu angalau maramara moja mwisho wa utafiti (miezi 18) katika kikundi chako bila malipo yeyote. Pia tutapima kiwango chako cha sukari ili kujua ikiwa una ugonjwa wa kisukari. Kwa kiwango cha chini, hii itatendeka mara mbili, moja hapo mwanzoni (baseline) na nyingine hapo mwishoni mwa utafiti (miezi 18) bila gharama yoyote kwako. Ikiwa utagundulika kuwa na ugonjwa wa kisukari, utalipa bei ya chini kidogo kwa vipimo vyovyote vya ziada unavyohitaji. Pia utazungumza na mshauri wa AMPATH. Ikiwa una shida yoyote au wasiwasi wowote, mshauri atakusaidia na akupatie rufaa uende kwa kliniki ya AMPATH endapo kuna udharura.

If you are assigned to Group B, you will participate in your regular microfinance group as normal and will continue to get HIV care and services for blood pressure and diabetes as normal; either at the AMPATH clinic or any health facilities when you go for your regular appointments.

Ikiwa umepewa Kundi B, utahudhuria kikundi chako cha kila mara cha mikopo midogo kama kawaida na utaendelea kupokea huduma ya HIV na huduma za ugonjwa wa presha na wa kisukari kama kawaida; aidha katika kliniki ya AMPATH au kituo chochote cha afya wakati unapotembelea kliniki yako jinsi ilivyopangwa.

If you are assigned to Group A or Group B, you will be asked to complete one survey 3 times during the study: once in the beginning, once in the middle (at 9 months), and once at the end of the study (at 18 months). This survey will ask questions about your household, access to food, access to HIV care, your medications, your community and your general health and well-being. In addition, we will also collect information every three months related to your microfinance activities including your saving and loaning activities.

Ikiwa umepewa Kundi A au Kundi B, utaulizwa kukamilisha maswali sawia mara 3 kwa wakati wa utafiti: mara moja mwanzoni, mara moja katikati (katika miezi 9), na mara moja mwisho wa utafiti (kwa miezi 18). Utafiti huu utauliza maswali kuhusu familia yako, kupatikana kwa chakula, kupatikana kwa huduma ya HIV, jamii yako na afya na ustawi wako kwa jumla. Kwa kuongezea, tutakusanya habari kila baada ya miezi mitatu inayohusiana na shughuli zako za kikundi cha mikopo midogo pamoja na shughuli zako za kuweka akiba na kukopa.

In addition, the research team will also collect information about you from your AMPATH and other medical records throughout the study. This information will include demographics (e.g. age, gender), diagnoses for HIV, your HIV health, HIV-related infections and other illness like blood pressure and/or diabetes, medication history, the number of times you attend your clinic appointments, the number of times you participate in a study visit, and the dates of these visits and appointments.

Kwa kuongezea, timu ya utafiti itakusanya pia habari kukuhusu kutoka kwa rekodi zako za AMPATH na rekodi zingine za matibabu wakati wote wa utafiti. Habari hii itajumuisha habari zako binafsi (k.m. umri, jinsia), hali ya HIV, afya yako na HIV, maambukizo yanayohusiana na HIV na magonjwa mengine kama Presha na / au ugonjwa wa kisukari, historia ya matibabu, mara ngapi unahudhuria kliniki yako jinsi ilivyopangwa, mara ngapi unashiriki kwenye utafiti huu mnapotembelewa, na tarehe ya mitembeleo yenyewe na ratiba jinsi ilivyopangwa.

We do not know whether receiving care in Group A or in Group B is better, or if they are the same. The purpose of the study is to answer this question. No matter which group you are in, you should continue to take your medicines according to your doctor's instructions.

Hatujui ikiwa kupata huduma katika Kundi A au katika Kundi B ni bora, au ikiwa ni sawa. Madhumuni ya utafiti huu ni kujibu swali hili. Haijalishi uko katika kikundi gani, unapaswa kuendelea kumeza dawa zako kulingana na maagizo ya daktari wako.

Explanation of Procedures

Maelezo ya Taratibu

The following steps will be followed if you agree to participate in the study:

Hatua zifuatazo zitafuatwa ikiwa unakubali kushiriki kwenye utafiti:

Step 1: Baseline Assessment

To be eligible for this study, you must meet our inclusion and exclusion criteria. A member of the research team will speak with you to make sure you can participate in this study.

Ili kuhitimu kushiriki katika utafiti huu, lazima ufikie vipengele vyetu vya kujumuishwa na kutengwa. Mshiriki wa timu ya utafiti atazungumza nawe ili kuhakikisha kwamba unaweza kushiriki katika utafiti huu.

If you agree to participate in the study today, we will confirm your HIV viral load from your AMPATH medical records. We will tell you the results of your blood test as soon as they are available. We will also perform a finger prick to test your blood sugar for diabetes. We may do another finger prick to confirm whether you have diabetes or not. We will tell you the result of the finger prick as soon as they are available. We will also measure your height, weight, temperature, waist circumference, and heart rate. To know if you have high blood pressure, we will measure your upper arm blood pressure as you sit quietly on a chair. If your blood pressure is high, we will measure your upper arm blood pressure again in 2 weeks and tell you the results as soon as they are available.

Ikiwa unakubali kushiriki kwenye utafiti leo, tutahakikisha kiwango cha virusi kwa damu yako kupitia redoki zako za AMPATH. Tutakuambia matokeo ya kipimo hicho cha (viral load) damu mara tu yatakapopatikana. Pia tutachomoza kidole chako ili kupima kiwango cha sukari kwa ajili ya ugonjwa wa kisukari. Tunaweza kuchomoza kidole chako kwa mara nyingine ili kudhibitisha ikiwa una ugonjwa wa kisukari au la. Tutakuambia matokeo ya kipimo hicho sukari mara tu yatakapopatikana. Pia tutapima urefu wako, uzito, kiwango cha joto mwilini, mduara wa kiuno, na kiwango cha mapigo ya moyo. Ili kujua ikiwa una ugonjwa wa Presha, tutapima Presha kwa mkono wako kwenye sehemu ya juu unapokaa kwa utulivu kwenye kiti. Ikiwa Presha yako iko juu, tutapima Presha kwa mkono wako kwenye sehemu ya juu tena katika wiki 2 na kukuambia matokeo mara tu yatakapopatikana.

Lastly, you will also complete a survey today that will ask you questions about your household, access to food, access to HIV care, your medications, your community and your general health and well-being.

Mwishowe, utakamilisha maswali leo ambayo yataulizia kuhusu familia yako, kupatikana kwa chakula, kupatikana kwa huduma ya HIV, jamii yako na afya na ustawi wako kwa jumla.

Step 2: Study Visits

Mitembeleo katika Utafiti

Group A**:** During the study, a clinical officer (CO) and research staff will come to your regular microfinance group meetings every month for the first 6 months of the study and then every 3 months for the last 12 months of the study. On days when the CO and research staff come to your group, they will:

Kundi A: Kwa wakati wa utafiti, daktari na wafanyikazi wa utafiti huu watakuja kwenye mikutano yenu ya kawaida ya kikundi cha mikopo midogo kila mwezi kwa miezi 6 ya kwanza ya utafiti na kisha kila miezi 3 kwa miezi 12 za mwisho wa utafiti. Katika siku ambazo daktari na wafanyikazi wa utafiti watakuja kwenye kikundi chako, wata:

- Attend to your health needs
  Shughulikia mahitaji yako ya kiafya
- Take your vital signs as described above
  Kupima ishara zako za mwili kama ilivyoelezwa hapo juu
- For HIV: count your pills and give you free medicines for your HIV
  Kwa HIV: hesabu tembe zako na kukupatia dawa za bure kwa ajili ya HIV
- For high blood pressure, measure your blood pressure at no cost to you and give you medicines at a subsidized fee
  Kwa ugonjwa wa Presha, pima Presha yako bila gharama yoyote kwako na kukupatia dawa kwa bei iliyopunguzwa
- For diabetes, measure your blood sugars and give you medications at a subsidized fee
  Kwa ugonjwa wa kisukari, pima kiwango chako cha sukari kwenye damu na kukupatia dawa kwa bei iliyopunguzwa
- Provide peer support if you are feeling unhappy or have any other issues that you want to discuss at no cost to you

Peana ushauri ikiwa unajisikia hauna furaha au una mambo mengine ambayo unataka kujadili bila gharama yoyote kwako

If there are any issues with your health that the CO cannot address, s/he will refer you to the nearest health facility so that you can receive the care that you need.

Ikiwa kuna shida yoyote na afya yako ambayo daktari hawezi kushughulikia, atakupea rufaa uende kwenye kituo cha afya kilicho karibu ili uweze kupata huduma unayohitaji.

Group B: You will continue to receive care at your usual AMPATH clinic. For hypertension and diabetes management, you will receive that care by a clinician at the nearest AMPATH clinic or any health facilities that is most convenient to you. Our team can provide you with a list of available clinic locations.

Kundi B: Utaendelea kupokea huduma katika kliniki yako ya kawaida ya AMPATH. Kwa matibabu ya ugonjwa wa Presha na Kisukari, utapokea huduma hiyo kupitia kwa daktari katika kliniki ya AMPATH iliyo karibu au vituo vyovyote vya afya ambavyo ni rahisi kwako kuvifikia. Timu yetu inaweza kukupatia orodha ya maeneo mbalimbali ya kliniki.

Your microfinance group will continue to meet at the normal time, days and location. Members of the same microfinance group will always be in the same group for this study.

Kikundi chako cha mikopo midogo kitaendelea kukutana kwa wakati wenu wa kawaida, kwa siku na eneo la kawaida. Wanachama wa kikundi sawia cha mikopo midogo watakuwa kwa kundi sawa katika utafiti huu.

What happens if I decide to stop my treatment?

Je, ni nini kitafanyika ikiwa nitaamua kuachana na matibabu yangu?

If you choose to stop receiving care in Group A or B before the end of the study, or if you decide you cannot complete all of the care visits:

Ikiwa unachagua kuacha kupokea huduma katika Kundi A au B kabla ya mwisho wa utafiti, au ikiwa unaamua hauwezi kukamilisha mitembeleo yote kwa ajili ya huduma:

- You will be asked to return to your usual clinic care at AMPATH and continue receiving care as you previously did before joining the study
  Utaulizwa urudi kwenye kliniki yako ya kawaida huko AMPATH na uendelee kupokea huduma kama hapo awali kabla ya kujiunga na utafiti
- We will contact you at the end of the study (18 months) to test your HIV viral load and blood sugar levels, measure your blood pressure, and to complete the surveys. Participation in these surveys is voluntary.
  Tutawasiliana nawe mwishoni mwa utafiti (miezi 18) ili kupima kiwango cha virusi vya HIV (viral load) na kiwango cha sukari kwenye damu, kupima Presha yako, na kukamilisha mahojiano. Kushiriki katika mahojiano haya ni kwa hiari.

If you choose to leave your microfinance group before the end of the study, or if you decide you cannot complete all of the microfinance visits:

Ikiwa unachagua kuondoka kwenye kikundi chako cha mikopo midogo kabla ya mwisho wa utafiti, au ikiwa unaamua hauwezi kukamilisha mitembeleo yote ya kikundi cha mikopo midogo:

- For Group A, you must decide whether you will want to (1) continue receiving care at the community during microfinance group meetings or (2) be referred back to receiving care at your AMPATH clinic as you previously did before joining the study.
  Kwa Kundi A, lazima uamue ikiwa utataka (1) kuendelea kupokea huduma katika jamii wakati wa mikutano ya kikundi cha mikopo midogo au (2) kupewa rufaa urudi kupokea huduma katika kliniki yako ya AMPATH kama hapo awali kabla ya kujiunga na utafiti.
- For Group B, you will continue receiving care at your usual AMPATH clinic.
  Kwa Kundi B, utaendelea kupokea huduma katika kliniki yako ya kawaida ya AMPATH.
- For both groups, we will contact you at the end of the study (18 months) to test your HIV viral load and blood sugar levels, measure your blood pressure, and to complete the surveys. Participation in these surveys is voluntary.
  Kwa makundi yote mawili, tutawasiliana nanyi mwishoni mwa utafiti (miezi 18) ili kupima kiwango cha virusi vya HIV (viral load) na kiwango cha sukari kwenye damu, kupima Presha yako, na kukamilisha mahojiano. Kushiriki katika mahojiano haya ni kwa hiari.

What happens if I become pregnant during the study?

Je, ni nini itafanyika ikiwa nitakuwa mjamzito wakati wa utafiti?

Women who are part of study Group A and become pregnant while in the study will be asked to go back to the HIV clinic and attend their scheduled clinic visits. A pregnant woman in Group A will be encouraged to continue coming to her microfinance group, but the CO will not be able to deliver her drugs or attend to her clinical care needs in the community. She must go to the clinic to get her HIV drugs. Women who are part of study Group B who become pregnant during the study will be seen in the HIV clinic. We do not think there will be more risk to the pregnant woman or the unborn baby by participation in the study. However, this study will not directly help pregnant women or their babies.

Wanawake ambao ni mojawapo wa washiriki kwenye kundi A la utafiti na wanakuwa wajawazito wakati wa utafiti wataulizwa kurudi kwenye kliniki ya HIV na kuhudhuria kliniki zao jinsi ilivyopangwa. Mwanamke mjamzito katika Kundi A atahimizwa kuendelea kuja kwenye kikundi chake cha mikopo midogo, lakini daktari hataweza kumpelekea dawa zake au kuhudumia mahitaji yake ya kikliniki huko katika jamii. Lazima aende kliniki ili aweze kupokea dawa zake za HIV. Wanawake ambao ni mojawapo wa washiriki kwenye Kundi B ambao wanakuwa wajawazito wakati wa utafiti wataonekana katika kliniki ya HIV. Hatufikiri kwamba kutakuwa na hatari zaidi kwa mama mjamzito au mtoto ambaye hajazaliwa kushiriki katika utafiti. Hata hivyo, utafiti huu hautasaidia moja kwa moja wanawake wajawazito au watoto wao.

Risks of taking part in this study

Hatari ya kushiriki katika utafiti huu

Blood draws

Kutolewa kwa damu

Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, light headedness, and in extremely rare cases, fainting or infection. However, the study staff are well trained to perform blood draws and we do not expect any complications to you from the procedure.

Kutolewa kwa damu kunaweza kusababisha usumbufu, kuvuja damu, au alama kwenye sehemu ambapo sindano inadungiwa kwa mwili, uwepesi kichwani, na katika hali nadra sana, kuzirai au kupata maambukizo. Hata hivyo, wafanyikazi wa utafiti wamefuzu katika hiyo kazi ya kutoa damu na hatutarajii shida yoyote kwako kutokana na kitendo hiki.

Risk of losing confidentiality and increased stigma

Hatari ya kupoteza usiri na kuongezeka kwa unyanyapaa

For people in Group A, there is a risk of losing confidentiality (privacy) and increased stigma because of the community visits by the CO. This may cause other family members or neighbors to become curious. However, the study team will be as unnoticeable as possible while making community visits. Nobody outside of your group will be told the reason for the visits and only fellow study participants are allowed to be present during this part of the study. For people in Group B, there is also a risk of losing privacy. However, the clinic staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses to the survey will be coded with a study ID and will never include your name.

Kwa watu katika Kundi A, kuna uwezekano wa kupoteza usiri (faragha) na kuongezeka kwa unyanyapaa kwa sababu ya mitembeleo hii ya daktari katika jamii. Hii inaweza kusababisha wanafamilia wengine au majirani kudadisi zaidi. Hata hivyo, timu ya utafiti haitatambulika iwezekanavyo wakati wa kufanya mitembeleo hii katika jamii. Hakuna mtu yeyote nje ya kikundi chako atakayeambiwa sababu za mitembeleo hii na ni washiriki wenzako tu katika utafiti huu watakaoruhusiwa kuwepo wakati wa sehemu hii ya utafiti. Kwa watu katika Kundi B, pia kuna hatari ya kupoteza usiri. Hata hivyo, wafanyikazi wa kliniki watahakikisha kwamba rekodi zako zimehifadhiwa salama na habari zako zozote za kibinafsi hazitapewa mtu yeyote bila ruhusa. Habari zote unazotoa na majibu yako yote kwenye utafiti yatawekwa kutumia nambari fiche ya kitambulisho cha utafiti na haitajumuisha jina lako kamwe.

Benefits of taking part in the study

Faida za kushiriki katika utafiti

There is no direct benefit for participating in this study; however, the information learned from this study may help other people who are living with HIV for two reasons. One, it will help determine if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. Two, it will help determine if offering HIV care and other

health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Hakuna faida ya moja kwa moja kwa kushiriki katika utafiti huu; hata hivyo, habari zinazotokana na utafiti huu zinaweza kusaidia watu wengine ambao wanaishi na HIV kwa sababu mbili. Kwanza, itasaidia kuamua ikiwa kutoa huduma ya HIV na huduma zingine za afya katika jamii, badala ya kwenye kituo cha afya, itasaidia watu ambao wanaishi na HIV kuishi maisha yenye afya. Ya pili, itasaidia kuamua ikiwa kutoa huduma ya HIV na huduma zingine za afya kwa watu ambao ni washiriki wa vikundi vya mikopo midogo itasaidia watu ambao wanaishi na HIV kuishi maisha yenye afya.

Confidentiality

Usiri

We will try very hard to keep your records confidential (private). We cannot guarantee absolute privacy. Your medical information could be shared if required by the law. Only a coded number, not your name, will be used to identify your information on study materials. Your name will not be used in any reports that the study may publish. A group of people may look at our records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University IRB, the Purdue University IRB, the Johns Hopkins University IRB, the study staff, or the sponsor (NIH).

Tutajitahidi sana kuhifadhi rekodi zako kwa siri (faragha). Hatuwezi kuhakikisha usiri kabisa. Habari zako za matibabu zinaweza kupeanwa ikiwa inahitajika kulingana na sheria. Ni nambari tu fiche, sio jina lako, itatumika kutambua habari zako kwenye nakala za utafiti. Jina lako halitatumika katika ripoti zozote ambazo utafiti unaweza kuchapisha. Kikundi cha watu kinaweza kuangalia rekodi zetu ili kuhakikisha kuwa zimekamilika na ni za kweli. Kikundi kinaweza pia kuangalia rekodi zetu kwa uchambuzi wa habari (kuona ni nini maana ya habari ambazo watu walishiriki nasi). Vikundi vitakavyoangalia rekodi vinaweza kuwa wachunguzi wa utafiti na washiriki wao wa utafiti, Kamati ya Utafiti na Maadili ya Taasisi ya Moi (IREC), Bodi ya Ukaguzi ya Taasisi ya Chuo Kikuu cha Indiana (IRB), IRB ya Chuo Kikuu cha Brown, IRB ya Chuo Kikuu cha Purdue, IRB ya Chuo Kikuu cha Johns Hopkins, wafanyikazi wa utafiti, au mdhamini (NIH).

Data Sharing

Kushiriki Takwimu

We will not share the data from this study with anyone outside of our study staff team.

Hatutashiriki habari zozote kutoka kwa utafiti huu na mtu yeyote nje ya timu ya wafanyikazi katika utafiti.

Protecting your privacy during data collection

Kulinda usiri wako wakati wa utafiti

Participation in this study involves multiple visits from AMPATH staff who will include a clinical officer, pharmacy technician, peer navigator, and social worker. Staff will conduct visits during your regular scheduled microfinance group and will meet with you in a location that is private and away from the other group members. Because we want to ensure your privacy during these visits, we will ask anyone nearby, either family members or neighbors, to relocate until after we are finished.

Kushiriki katika utafiti huu kunahusisha mitembeleo mingi kutoka kwa wafanyikazi wa AMPATH ambao watajumuisha daktari wa kliniki daktari katika famasia, mhudumu ambaye pia ana virusi vya HIV, na mhudumu wa masuala ya kijamii. Wafanyikazi watatembelea wakati wa mikutano ya kikundi chako cha kawaida cha mikopo midogo na watakutana nawe katika eneo ambalo ni la faragha na mbali na wanachama wengine kwenye kikundi. Kwa sababu tunataka kuhakikisha usiri wako wakati wa mitembeleo hii, tutamwuliza mtu yeyote aliye karibu, awe wanafamilia au majirani, kukaa mbali hadi tutakapomaliza.

Costs

Gharama

For HIV, your medications and care services (physical examinations, viral load tests, peer support) will continue to be provided at no cost to you.

Kwa HIV, dawa zako na huduma (kukaguliwa kwa mwili, vipimo vya kiwango cha virusi vya HIV (viral load), msaada wa ushauri na mhudumu anayeishi na HIV) utaendelea kupeanwa bila malipo yoyote kwako.

For high blood pressure and diabetes, the lab tests at the beginning and end of the study will be free. However, you will pay for additional lab tests (if recommended by the clinician) during the course of the study. The cost for these tests are subsidized. You will also have to pay a small amount for your blood pressure and diabetes medications.

Kwa ugonjwa wa Presha na ugonjwa wa Kisukari, vipimo vya maabara ya hapo mwanzoni na mwisho wa utafiti vitakuwa vya bure. Hata hivyo, utalipia vipimo vingine (ikiwa itapendekezwa na daktari) kwa wakati wa utafiti. Gharama ya vipimo hivi vimepunguzwa. Utalazimika pia kulipa pesa kidogo kwa ajili ya dawa zako za ugonjwa wa Presha na ugonjwa wa kisukari.

You will not be giving up any of your legal rights by signing this consent form.

Hautakuwa unakiuka haki yako yoyote ya kisheria kwa kutia sahihi kwenye fomu hii ya idhini.

Payment/Compensation

Malipo / Fidia

We will collect information every three months related to your microfinance activities including your saving and loaning activities. Each time we collect microfinance information, you will receive KES 300.

How long will your part in the study last?

Je, kushiriki kwako katika utafiti itakuwa kwa muda gani?

If you enroll in this study, you will in the study for 18 months from the day you enroll.

Ukijiandikisha katika utafiti huu, utakuwa katika utafiti kwa miezi 18 tangu siku ya kujiandikisha.

What will happen if I miss or cannot attend one of my microfinance group meetings?

Je! Ni nini itafanyika ikiwa nitakosa au siwezi kuhudhuria mojawapo ya mikutano ya kikundi changu cha mikopo midogo?

If you do not attend a microfinance group meeting for any reason on a day that AMPATH staff are scheduled to conduct a visit, the staff will contact you to schedule a follow-up meeting for a time outside of your regularly scheduled group meeting.

Ikiwa hautahudhuria mkutano wa kikundi cha mikopo midogo kwa sababu yoyote katika siku ambayo wafanyikazi wa AMPATH wamepangiwa kuwatembelea, wafanyikazi watawasiliana na wewe ili kupanga mkutano wa ufuatiliaji kwa muda ambao hauambatani na ratiba ya mikutano yenu ya kila mara kwa kikundi.

Who is sponsoring this study?

Je, ni nani anayefadhili utafiti huu?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Utafiti huu unafadhiliwa na Taasisi za Kitaifa za Afya huko Merika (NIH). Hii inamaanisha kuwa timu ya utafiti inalipwa na mdhamini kwa kufanya utafiti. Watafiti kamwe, hata hivyo, hawana nia yoyote ya kifedha moja kwa moja na mdhamini au katika matokeo ya mwisho wa utafiti.

Your alternatives to joining the study

Njia zako mbadala za kujiunga na utafiti

Your participation in this study is voluntary. You may choose to discontinue your participation at any time without penalty. Refusing to participate will not impact any care you receive from AMPATH or any other provider.

Kushiriki kwako katika utafiti huu ni kwa hiari. Unaweza kuchagua kutamatisha kushiriki kwako wakati wowote bila adhabu. Kukataa kushiriki hakutaathiri huduma yoyote unayopokea kutoka AMPATH au kwa mhudumu mwengine yeyote.

Ending Consent

Kukomesha idhini

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Unaweza kukomesha idhini yako wakati wowote. Habari ambazo zimepatikana na kutumiwa kabla ya kukomesha idhini yako itaendelea kutumiwa katika utafiti. Ikiwa unataka kukomesha idhini yako, tafadhali tujulishe.

Who do I call if I have questions or problems related to the study?

Je! Niwasiliane na nani ikiwa nina maswali au shida zinazohusiana na utafiti?

- Call the principal investigator: Juddy Wachira at 070-524- 2450
- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

  Moi Teaching and Referral Hospital
  Institutional Research and Ethics Committee
  2nd floor. Door No. 219,
  P.O. Box. 3-30100
  Eldoret, Kenya
  Office line: 0787723677
  Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Je, saini yako kwenye fomu hii ya idhini inamaanisha nini?

Your signature on this form means:

Saini yako kwenye fomu hii inamaanisha:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
  Umejulishwa kuhusu kusudi la utafiti huu, taratibu, faida na hatari ambazo zinaweza kutokea.
- You have been given the chance to ask questions before you sign.
  Umepewa fursa ya kuuliza maswali kabla ya kutia saini.
- You have voluntarily agreed to be in this study.
  Umekubali kwa hiari kuwa katika utafiti huu.

_____	_____	_____
Print name of Adult Participant **Andika jina la mshiriki**	Signature of Adult Participant **Sahihi ya mshiriki**	Date **Tarehe**

_____	_____	_____
Print name of Person Obtaining Consent **Andika Jina la anayechukua idhini**	Signature of Person Obtaining Consent **Sahihi ya anayechukua**	Date

Appendix II: Adult Consent Form 2

(For standard of care patients who are asked to enroll in Aim 1)

Title of Research:	Harambee: Integrated Community-Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	23 February 2021

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.

What is the purpose of research study?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

Why we are asking you to participate?

1. You are being asked to participate in this study because:
2. You are at least 18 years old
3. You are an HIV patient
4. You have been taking antiretroviral (ART) medications for the past 6 months or longer
5. You receive care for HIV at an AMPATH HIV clinic
6. You have an AMPATH identification number
7. You do not have serious infections or illnesses that require immediate care or hospitalization
8. You are not a member of a community ART group (CARG)
9. You are not pregnant
10. You are not currently participating in a microfinance group

What will happen if you agree to participate in the study?

If you agree to participate in the study, the research team will ask you to complete a survey at the beginning (baseline) and at the end of the study (18 months). The survey will ask you questions about your household, access to food, access to HIV care, your medications, your community and your general health and well-being.

The research team will also collect information about you from your AMPATH and other medical records throughout the study. This information will include information about you like your age and gender, diagnoses for HIV, HIV progression (CD4 cell count, HIV viral load), hypertension and/or diabetes, medication history, the number of times you attend your clinic appointments and the dates of these visits and appointments.

Explanation of Procedures

The following steps will be followed if you agree to participate in the study:

Step 1: Baseline Assessment

To be eligible for this study, you must meet the criteria set by the study. A member of the research team will confirm this information with you.

If you agree to participate in the study today, we will confirm your HIV viral load from your AMPATH medical records and inform you of your HIV viral load once available. We will also perform a finger prick to test your blood sugar for diabetes. We may do another finger prick to confirm whether you have diabetes or not. We will tell you the result of the finger prick as soon as they are available. We will also measure your height, weight, temperature, waist circumference, and heart rate. To know if you have high blood pressure, we will measure your upper arm blood pressure as you sit quietly on a chair. If your blood pressure is high, we will measure your upper arm blood pressure again in 2 weeks and tell you the results as soon as they are available.

Lastly, you will also complete a survey that will ask you questions about your household, food security, access to HIV care, your medications, your community and your general health and well-being.

Step 2: Follow-up Assessment

At the end of the study (18 months), we will draw blood for HIV viral load testing. We will run the viral load tests at a laboratory that is designated by your AMPATH clinic and inform you of the results once available. If you were diagnosed with diabetes at the beginning of the study, a finger prick will be conducted to test your blood sugar levels. This result will be available immediately and you will be informed of the test result immediately. If you were diagnosed with high blood pressure, we will also take measurements of your height, weight, waist circumference, pulse rate and measure your upper arm blood pressure as you sit quietly on the chair. You will also be asked to complete a follow-up survey at the end of the study (18 months). The survey will ask you questions about your household, food security, access to HIV care, your medications, your community and your general health and well-being.

What happens if I decide to stop my treatment?

If you choose to stop receiving care in your usual AMPATH clinic or Ministry of Health clinic before the end of the study, or if you decide you cannot complete all of the scheduled care visits:

- As part of your routine care, you may be contacted by your clinic staff to understand why you decided to stop care
- Our research staff will reach out to you at the end of the study (18 months) for follow up assessment (HIV viral load testing, blood sugar level testing if needed, blood pressure measurement if needed, survey)

What happens if I become pregnant during the study?

You cannot join this study if you are currently pregnant. However, it is possible that some female patients might become pregnant during the study. Women who are part of study and become pregnant while in the study will be asked to go back to clinic and attend their scheduled clinic visits. She must go to the clinic to get her HIV drugs as usual. We do not think there will be more risk to the pregnant woman or the unborn baby by participation in the study. However, this study will not directly help pregnant women or their babies.

Risks of taking part in this study

Blood draws

Taking blood may cause some discomfort, bleeding, or bruising where the needle enters the body, light headedness, and in extremely rare cases, fainting or infection. However, the study staff are well trained to perform blood draws and we do not expect any complications to you from the procedure.

Risk of losing confidentiality and increased stigma

There is a risk of losing confidentiality (privacy). However, the clinic staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses to the survey will coded with a study ID and will never include your name.

Benefits of taking part in the study

We do not know if HIV care in the community keeps HIV-infected people as healthy as HIV-infected people who receive care at a health facility. It is possible that you may receive no benefit from being in this study. However, information learned from this study may help others who are infected with HIV live healthier lives.

Confidentiality

We will try very hard to keep your records confidential (private). We cannot guarantee absolute confidentiality. Your medical information could be shared if required by the law. Only a coded number, not your name, will be used to identify your information on study materials. Your name will not be used in any reports that the study may publish. A group of people may look at our research records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University Institutional Review Board (IRB), the Purdue University Institutional Review Board (IRB), the Johns Hopkins University Institutional Review Board (IRB), the study staff, or the sponsor (NIH).

Data Sharing

We will not share the data from this study with anyone outside of our study staff team.

Protecting your privacy during data collection

Participation in this study involves multiple visits from AMPATH staff who will include a clinical officer, pharmacy technician, peer navigator, and social worker. Staff will conduct visits during your regular scheduled microfinance group and will meet with you in a location that is private and away from the other group members. Because we want to ensure your privacy during these visits, we will ask anyone nearby, either family members or neighbors, to relocate until after we are finished.

Costs

For HIV, your viral load tests will continue to be provided at no cost to you.

For high blood pressure and diabetes, the lab tests at the beginning and end of the study will be free. However, you will pay for additional lab tests (if recommended by the clinician) during the course of the study. The cost for these tests are subsidized. You will also have to pay a small amount for your blood pressure and diabetes medications.

You will not be giving up any of your legal rights by signing this consent form.

Payment/Compensation

You will be asked to complete one survey 2 times during the study: once in the beginning and once at the end of the study (at 18 months). You will receive KES 300 each time you complete the survey.

How long will your part in the study last?

If you enroll in this study, you will be asked to participate now and in 18 months from now.

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Your alternatives to joining the study

Your participation in this study is voluntary. You may refuse to participate and there will be no penalty for refusing. Refusing to participate will not impact any care you receive from AMPATH, or any other provider. You may choose to discontinue your participation at any time without penalty.

Ending Consent

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Who do I call if I have questions or problems related to the study?

- Call the principal investigator: Juddy Wachira at 070-524- 2450
- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

Address: Moi Teaching and Referral Hospital
Institutional Research and Ethics Committee
2nd floor. Door No. 219,
P.O. Box. 3-30100
Eldoret, Kenya
Office line: 0787723677
Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date

_____	_____	_____
Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Appendix III. Survey assessment tool

Data Dictionary Codebook

Harambee Survey Assessment Tool (PID: 580)

07/29/2024 9:27pm

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: Meta-Data (metadata)			
1	[harambee_study_id]	1. Respondent's Harambee Study ID (Nambari ya kushiriki katika utafiti wa Harambee)	text, Identifier
2	[study_group_id]	Section Header: *Research assistant should record this information using the MF records, administrative worksheet and AMRS data. The RA can ask the respondent to verify the information. (Msaidizi wa utafiti anafaa kunukuu habari hii akitumia rekodi za kikundi cha mikopo midogo, nakala za uongozi katika chama pamoja na rekodi za AMRS. Msaidizi wa utafiti anaweza kuuliza mhojiwa kudhibitisha habari zozote.)* 2. Microfinance group Harambee Study ID (Kitambulisho cha kikundi cha mikopo midogo)	text, Required, Identifier
3	[interview_date]	3. Encounter/Interview date (Tarehe)	text (date_dmy)
4	[interviewer_name]	4. Interviewer name (Jina la anayehoji)	dropdown 1, HBR01 (Jael Onyango) 2, HBR02 (Diana Chemowo) 3, HBR03 (Joshua Juma) 4, HBR04 (Mercy Akinyi) 5, HBR05 (Beryl Wafula) 6, HTR01 (Dan Aburi) 7, HTR02 (Susan Mutahi) 8, HTR03 (Abraham Kiplasima) 9, HTR04 (Catherine Kafu) 10, HTR05 (Susan Mastamet) 11, HBR06 (Sheila Kirwa) 12, HBR07 (Susan Mutahi) 13, HTR06 (Beryl Wafula)
5	[interview_time]	5. Time interview started (Saa ya kuanza mahojiano)	text (time)
6	[metadata_complete]	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: Respondent Demographics (respondent_demographics)			
7	[gender]	Section Header: *Research assistant should read the following introductory text before starting the survey: (Msaidizi wa utafiti anapaswa kusoma maelezo yafuatayo ya utangulizi kabla ya kuanza mahojiano:) Hello, my name is _____. I am a research assistant for the Harambee study with AMPATH. I would like to ask you some questions to learn about your experience accessing healthcare and living in your community. I will ask you questions about your physical health, your mental health, and*	radio, Required 1, Male (Kiume) 2, Female (Kike)

		how you feel when you receive care. I will also ask you questions about your household and your community. Your answers will help me understand what types of services people who are living with HIV need to stay healthy. The questions will take about 20 minutes to complete. If you do not understand a question, you can ask me to clarify. You can skip any question that you do not want to answer. Please answer honestly. All of your answers will be kept private. (Habari, jina langu ni _____. Mimi ni msaidizi wa utafiti wa Harambee study katika AMPATH. Ningependa kukuuliza maswali kadhaa ili kujua kuhusu uzoefu (experience) wako katika kutafuta huduma pamoja na kuishi katika jamii yako. Nitakuuliza maswali kuhusu afya yako ya kimwili, afya yako ya kiakili, na jinsi unavyohisi unapoenda kupokea matibabu. Pia, nitakuuliza maswali kuhusu nyumba na jamii yako. Majibu yako yataniwezesha kuelewa ni aina zipi za huduma ambazo watu wanaoishi na virusi vya HIV wanahitaji ili kuwa na afya. Maswali haya yatachukua takriban dakika 20 kukamilisha. Ikiwa hauelewi swali, unaweza kuniuliza nieleze zaidi. Unaweza kuruka swali lolote ambalo hutaki kujibu. Tafadhali jibu kwa uaminifu. Majibu yako yote yatawekwa siri.) Do you have any question(s)? (Je, una swali lolote?) OK, let's begin. (Sawa, wacha tuanze.) Can you please tell me: (Je, unaweza kuniambia:) 1. Gender (Jinsia) (Note: Fieldworker Observation) (Kumbuka ni uchunguzi wa mtafiti)	
8	[date_of_birth]	2. Date of birth (Tarehe ya kuzaliwa)	text (date_dmy), Required
9	[marital_status]	3. What is your marital status (Hali yako ya ndoa ni ipi)	radio, Required 1 Never married (Sijawahi oa/oleka) 2 Married (Nimeoa au oleka) 3 Divorce/Separated (Taliki/Tengana) 4 Widowed (Mjane) 5 Other (Nyingine)
10	[marital_status_specify] Show the field ONLY if: [marital_status] = '5'	3a. Other marital status, specify (Hali Hali yako ya ndoa nyingine, eleza)	text
11	[schooling_achieved]	4. What is the highest level of schooling you achieved (Je, ni kiwango kipi cha elimu ambacho ulifanikiwa kufikia?)	radio, Required 1 None (Hakuna) 2 Primary (Shule ya msingi) 3 Secondary (Shule ya upili) 4 Tertiary (Zaidi ya shule ya upili)
12	[house_head]	5. Are you the head of the household (Je, wewe ndiye kiongozi wa nyumba yako) *If yes, END MODULE*	radio, Required 1 Yes (Ndio) 2 No (La)
13	[relation_to_head] Show the field ONLY if: [house_head] = '2'	6. Relation to household head (Una uhusiano upi na kiongozi wa nyumba)	radio 1 Spouse (Mchumba) 2 Child (Mtoto) 3 Other (Mwengine)

14	[relation_to_head_specify] Show the field ONLY if: [relation_to_head] = '3'	6a. Other relation to household head, specify (Uhusiano mwingine usiotajwa, eleza)	text
15	[respondent_demographics_complete]	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: Health Insurance (health_insurance)			
16	[healthcare_decisions]	Section Header: *I would like to ask you some questions about health insurance. Please answer honestly and to the best of your knowledge. All responses are confidential. (Ningependa kukuuliza maswali kadhaa kuhusu bima ya afya. Tafadhali jibu kwa uaminifu na kulingana na ufahamu wako. Majibu yote ni ya siri.)* 1. Who makes the main decisions regarding healthcare for your household? For example where to seek healthcare, when to seek healthcare, etc (Je, ni nani katika nyumba yako hufanya maamuzi kuhusu mambo ya afya kama vile mahali na wakati wa kutafuta huduma ya afya)	radio 1, Self (Wewe mwenyewe) 2, Partner/Spouse (Mpenzi/Mchumba/Mume/Mke wako) 3, Other (Nyingine)
17	[other_decision_maker] Show the field ONLY if: [healthcare_decisions] = '3'	1a. Who else apart from the ones listed above makes the decisions regarding healthcare for your household, specify (Je, ni nani mwingine hufanya maamuzi kuhusu mambo ya afya kama vile mahali na wakati wa kutafuta huduma ya afya ambaye hajatajwa, eleza)	text
18	[enrolled_in_nhif]	2. Have you ever been enrolled in NHIF (National Hospital Insurance Fund) (Je, umewahi kusiajiliwa kwa bima ya NHIF (Bima ya Afya ya Kitaifa)	radio 1, Yes (Ndio) 2, No (La)
19	[nhif_first_enrolled] Show the field ONLY if: [enrolled_in_nhif] = '1'	2a. Do you remember when you were first enrolled in NHIF (Je unakumbuka ni lini ulijiandikisha kwa NHIF)	radio 1, Yes (Ndio) 2, No (La) 98, Don't know (Sijui)
20	[when_enrolled_in_nhif] Show the field ONLY if: [nhif_first_enrolled] = '1'	2b. When were you enrolled in NHIF (Ni lini ulijiandikisha kwa NHIF)	text (date_dmy)
21	[nhif_super_cover] Show the field ONLY if: [nhif_first_enrolled] = '1'	2c. Do you currently have an NHIF cover (Je kwa sasa una bima ya Afya ya NHIF)	radio 1, Yes (Ndio) 2, No (La) 98, Don't know (Sijui)
22	[remember_nhif_use] Show the field ONLY if: [nhif_super_cover] = '1'	2d. Do you remember the number of times you have used NHIF in the past 12 months (Unakumbuka ni mara ngapi umetumia NHIF kwa miezi 12 iliyopita)	radio 1, Yes (Ndio) 2, No (La) 98, Don't know (Sijui)

23	[times_used_nhif_pst12 mnths] Show the field ONLY if: [remember_nhif_use] = '1'	2e. How many times have you used NHIF to cover health expenses of your household members in the past 12 months (Je, ni mara ngapi umetumia NHIF kulipia gharama ya matibabu ya watu wa nyumba yako kwa miezi 12 iliyopita)	text
24	[reason_no_nhif_cove r] Show the field ONLY if: [nhif_super_cover] = '2'	2f. Why don't you have NHIF coverage (Ni kwa nini hauna bima ya afya ya NHIF)	radio 1 Lack of finances (Ukosefu wa fedha) 2 Unsure how to access NHIF (Sina uhakika jinsi ya kupata bima ya NHIF) 3 See no benefit (Sioni faida yake) 4 Other (Nyingine)
25	[no_nhif_cover_specif y] Show the field ONLY if: [reason_no_nhif_cover] = '4'	2g. Other reason for no NHIF coverage, specify (Sababu nyingine ya kutokuwa na bima ya NHIF, eleza)	text
26	[other_cover]	3. Are you currently covered by any other health insurance apart from NHIF (Je, kwa sasa una bima yoyote nyingine ya afya kando na NHIF)	radio 1 Yes (Ndio) 2 No (La) 98 Don't know (Sijui)
27	[other_cover_specify] Show the field ONLY if: [other_cover] = '1'	3a. Please indicate the health insurance cover (Tafadhali taja jina la bima hiyo)	text
28	[health_insurance_comp lete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: OSLO Social Support Scale -3 (oslo_social_support_scale_3)			
29	[close_pple_yu_can_cou nt_on]	Section Header: *I would like to know about the type of social support that is available to you. Please tell me how much you agree or disagree with the following statements. Sasa, ningependa kujua kuhusu msaada wa kijamii unaopatikana kwako. Tafadhali nieleze jinsi gani unavyokubali au kutokubaliana na maelezo yafuatayo.* 1. How many people are so close to you that you can count on them if you have great personal problems (Je, ni watu wangapi wako na uhusiano wa karibu nawewe na unaweza wategemea ukiwa na shida yeyote ya kibinafsi)	radio 1 None (Hakuna) 2 1-2 (Mmoja hadi wawili) 3 3-5 Watatu hadi watano) 4 5+ (Zaidi ya watano)
30	[show_interest_in_what _you_do]	2. How much interest and concern do people show in what you do (Je watu huwa na kiasi gani cha haja na vitu ambavyo huwa unafanya)	radio 1 None (Hakuna) 2 Little (Kidogo) 3 Uncertain (Sina uhakika) 4 Some (Kiasi)

			5 | A lot (Sana)
31	[get_help_from_neighbours]	3. How easy is it to get practical help from neighbors if you should need it (Je ni rahisi kiasi gani kupata usaidizi kutoka kwa majirani iwapo utahitaji usaidizi)	radio 1 | Very difficult (Ngumu sana) 2 | Difficult (Ngumu) 3 | Possible (Inawezekana) 4 | Easy (Rahisi) 5 | Very easy (Rahisi sana)
32	[oslo_social_support_scale_3_complete]	Section Header: *Form Status* Complete?	dropdown 0 | Incomplete 1 | Unverified 2 | Complete
Instrument: Adapted Medical Outcomes Study HIV Health Survey (MOS-HIV) (adapted_medical_outcomes_study_hiv_health_survey_m)			
33	[health_in_general]	Section Header: *Now I would like to ask you a few questions about your health recently. (Sasa ningependa kukuuliza maswali chache kuhusu afya yako hivi karibuni.)* 1. In general would you say your health is (Kwa ujumla, unaweza kusema afya yako ni)	radio 1 | Good (Nzuri) 2 | Neither good nor bad (Kadri) 3 | Poor (Mbaya)
34	[bodily_pain_in_past_30days]	2. How much bodily pain have you generally had during the past 30 days (Je, umekuwa na maumivu ya kimwili kiasi gani kwa siku 30 zilizopita)	radio 1 | None (Hakuna) 2 | Very mild (Kidogo sana) 3 | Mild (Kidogo) 4 | Moderate (Kiasi) 5 | Severe (Kali) 6 | Very Severe (Kali sana)
35	[paint_interfere_with_work]	3. During the past 30 days, how much did pain interfere with your normal work, including both work outside the home and housework (Katika siku 30 zilizopita, je, ni kwa kiasi gani maumivu iliingilia kati kwenye kazi zako za kawaida, ukijumlisha kazi za nje ya boma na zile za kinyumbani)	radio 1 | Not at all (Hapana kabisa) 2 | A little bit (Kidogo kiasi) 3 | Moderately (Kiasi) 4 | Quite a bit (Sana) 5 | Extremely (Pakubwa sana)
36	[adapted_medical_outcomes_study_hiv_health_survey_m_complete]	Section Header: *Form Status* Complete?	dropdown 0 | Incomplete 1 | Unverified 2 | Complete
Instrument: Patient Health Questionnaire-2 (patient_health_questionnaire2)			
37	[pleasure_in_doing_things]	Section Header: *Over the last 2 weeks, how often have you been bothered by the following problems (Kwa muda wa wiki mbili umekumbwa na haya matatizo)* 1a. Little interest or pleasure in doing things (Kukosa hamu au kutofurahia kufanya kazi)	radio (Matrix) 0 | Not at all (Hakuna Kabisa) 1 | 1-3 days in a week (Siku 1-3 kwa wiki) 2 | 4-5 days in a week (Siku 4-5 kwa wiki)

			3 | 6-7 days in a week (Siku 6-7 Kwa wiki)
38	[feeing_depressed]	1b. Feeling down, depressed or hopeless (Kujihisi mnyonge, kosononeka au kusosa matumaini)	radio (Matrix) 0 | Not at all (Hakuna Kabisa) 1 | 1-3 days in a week (Siku 1-3 kwa wiki) 2 | 4-5 days in a week (Siku 4-5 kwa wiki) 3 | 6-7 days in a week (Siku 6-7 Kwa wiki)
39	[worried_or_anxious]	Section Header: *2. Over the last 2 weeks, how often have you been bothered by any of the following problems (Kwa wiki mbili zilizopita umekumbwa na haya matatizo)* 2a. Feeling worried or anxious (Kujihisi kuwa na wasiwasi au shauku)	radio (Matrix) 0 | Not at all (Hakuna kabisa) 1 | Several days (Siku kadhaa) 2 | More than half the days (Zaidi ya nusu ya siku) 3 | Nearly every day (Karibu kila siku)
40	[unable_to_stop_worrying]	2b. Being unable to stop yourself from worrying (Kukosa uwezo wa kujizuia kuwa mwenye wasiwasi)	radio (Matrix) 0 | Not at all (Hakuna kabisa) 1 | Several days (Siku kadhaa) 2 | More than half the days (Zaidi ya nusu ya siku) 3 | Nearly every day (Karibu kila siku)
41	[patient_health_questionnaire2_complete]	Section Header: *Form Status* Complete?	dropdown 0 | Incomplete 1 | Unverified 2 | Complete
Instrument: Adapted ACTG Self Report Adherence Questionnaire (adapted_actg_self_report_adherence_questionnaire)			
42	[days_missed_dose_in_pst4dys]	Section Header: *Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember to take their pills. (Baadhi ya watu ambao wanaishi na virusi vya HIV huwa wana tembe nyingi za kumeza kwa nyakati tofauti kwa siku. Wengi hupata ugumu kila mara kukumbuka kuzimeza tembe zao.) I would like to ask you about the HIV medications that you took over the last four days. (Ningependa kukuuliza kuhusu dawa za HIV ambazo umechukua kwa siku nne zilizopita.)* 1. During the past 4 days, on how many days have you missed taking all your doses? Select only one response (Katika siku 4 zilizopita, ni siku ngapi umekosa kuchukua kipimo cha dawa zako zote inavyopaswa? Chagua jibu moja tu)	radio 1 | None (Hakuna) 2 | One day (Siku moja) 3 | Two days (Siku mbili) 4 | Three days (Siku tatu) 5 | Four days (Siku nne)
43	[follow_schedule_in_pst4dys]	2. Most HIV medications need to be taken on a schedule. How often did you follow your specific schedule over the last 4 days (Dawa nyingi za virusi vya HIV zahitaji kuchukuliwa kwa masaa inayohitajika (ratiba). Ni mara ngapi ulimeza dawa zako kwa masaa inyaohitajika kwa siku 4 zilizopita)	radio 1 | Never (Kamwe) 2 | Some of the time (Saa zingine) 3 | About half of the time (Karibu nusu ya kila mara) 4 | Most of the time (Mara nyingi) 5 | All of the time (Wakati wote)

44	[meds_have_special_instrns]	3. Do any of your anti-HIV medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids" (Je, dawa zako zozote za virusi vya HIV zina maagizo maalum, kama vile meza "pamoja na chakula" au "kwenye tumbo tupu" au "na maji mengi")	radio 1 Yes (Ndio) 2 No (La)
45	[follow_instrns_in_past4dys] Show the field ONLY if: [meds_have_special_instrns] = '1'	3a. If Yes, how often did you follow those special instructions over the last four days (Ikiwa Ndio, Je, ni mara ngapi ulifuata hayo maagizo maalum kwa siku nne zilizopita	radio 1 Never (Kamwe) 2 Some of the time (Saa zingine) 3 About half of the time (Karibu nusu ya kila mara) 4 Most of the time (Mara nyingi) 5 All of the time (Wakati wote)
46	[missed_any_dose_in_last_12mnths]	Section Header: *Now, I would like to ask you just a few more general questions about how you have been taking your medication. (Sasa ningependa kukuuliza maswali machache ya kijumla kuhusu jinsi umekuwa ukimeza madawa yako)* 4. Have you missed a dose of any of your medications in the last 12 months Je, kwa miezi kumi na mbili iliyopita, umakosa kumeza hata kipimo kimoja cha madawa yako	yesno 1 Yes 0 No Custom alignment: RH
47	[period_missed_meds] Show the field ONLY if: [missed_any_dose_in_last_12mnths] = '1'	4a. When was the last time you missed any of your medications (Je, ni lini mwisho ulikosa kumeza dawa yako yoyote)	dropdown 1 1. Within the past week (Mnamo wiki iliyopita) 2 2. 1 to less than 2 weeks ago (Wiki 1 lakini chini ya wiki 2 zilizopita) 3 3. 2 to less than 4 weeks ago (Wiki 2 lakini chini ya wiki 4 zilizopita) 4 4. 1 to less than 3 months ago (Mwezi moja lakini chini ya miezi 3 iliyopita) 5 5. More than 3 months ago (Zaidi ya miezi 3 iliyopita) 6 6. Never skip medications (Kamwe sijakosa dawa zangu)
48	[away_from_home] Show the field ONLY if: [period_missed_meds] <> '6'	Section Header: *5. People may miss taking their HIV medications for various reasons. How often have you missed taking your medications in the past 30 days, because you: (Select one response for each question) (Ni mara ngapi umekosa kumeza dawa zako kwa siku 30 zilizopita, kwa sababu wewe: (Chagua jibu moja kwa kila swali)* 1. Were away from home (Ulikuwa mbali na nyumbani)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
49	[busy_with_other_things] Show the field ONLY if: [period_missed_meds] <> '6'	2. Were busy with other things (Ulikuwa umeshughulika na vitu vingine)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
50	[simply_forgot]	3. Simply forgot (Ulikuwa umesahau tu)	radio (Matrix)

	Show the field ONLY if: [period_missed_meds] <> '6'		1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
51	[too_many_pills_to_take] Show the field ONLY if: [period_missed_meds] <> '6'	4. Had too many pills to take (Ulikuwa na tembe nyingi sana za kumeza)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
52	[avoid_side_effects] Show the field ONLY if: [period_missed_meds] <> '6'	5. Wanted to avoid side effects (Ulikuwa unataka kuepukana na athari mbaya)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
53	[didnt_want_other_to_notice] Show the field ONLY if: [period_missed_meds] <> '6'	6. Did not want others to notice you taking medication (Ulikuwa hutaki wengine wakuone ukimeza dawa)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
54	[change_in_daily_routine] Show the field ONLY if: [period_missed_meds] <> '6'	7. Had a change in daily routine (Ulikuwa na mabadiliko katika taratibu yako ya kila siku)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
55	[felt_drugs_were_toxic] Show the field ONLY if: [period_missed_meds] <> '6'	8. Felt like the drug was toxic/harmful (Ulikuwa unahisi kwamba dawa ilikuwa na sumu/hatari)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
56	[slept_throu_dose_time] Show the field ONLY if: [period_missed_meds] <> '6'	9. Fell asleep/slept through dose time (Ulikuwa umelala/ukalala hadi wakati wa kumeza dawa ukapita)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
57	[felt_sick_or_ill]	10. Felt sick or ill (Ulikuwa unajiskia mgonjwa)	radio (Matrix)

	Show the field ONLY if: [period_missed_meds] <> '6'		1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
58	[felt_depressed] Show the field ONLY if: [period_missed_meds] <> '6'	11. Felt depressed/overwhelmed (Ulikuwa unahisi kusongwa au kuzidiwa na mawazo)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
59	[prob_taking_meds_spec_time] Show the field ONLY if: [period_missed_meds] <> '6'	12. Had problems taking pills at specified times (Ulikuwa na tatizo la kumeza tembe kwa nyakati maalum)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
60	[ran_out_of_pills] Show the field ONLY if: [period_missed_meds] <> '6'	13. Ran out of pills (Ulikuwa umeishiwa na tembe zako)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
61	[felt_healthy] Show the field ONLY if: [period_missed_meds] <> '6'	14. Felt healthy (Ulikuwa unajiskia mzima)	radio (Matrix) 1 Never (Kamwe) 2 (1-2 times) Rarely (Nadra) 3 (3-5 times) Sometimes (Wakati mwingine) 4 (> 5 times) Often (Mara nyingi)
62	[adapted_actg_self_report_adherence_questionnaire_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Extent of Nonadherence (DOSE-Nonadherence) Questionnaire (extent_of_nonadherence_dosenonadherence_questionna)			
63	[tested_and_found_high_bp]	a) Have you been tested and found that you have high blood pressure (Je, umewahi pimwa na ukapatikana ya kwamba uko na ugonjwa wa pressure)	radio 1 Yes (Ndio) 2 No (La) Custom alignment: RH
64	[taking_meds_for_high_bp]	b) Are you currently taking medications for your high blood pressure	radio 1 Yes (Ndio)

	Show the field ONLY if: [tested_and_found_high_bp] = '1'	(Je, kwa sasa unameza dawa za ugonjwa wa pressure)	2 No (La) Custom alignment: RH
65	[missed_my_medicine] Show the field ONLY if: [taking_meds_for_high_bp] = '1'	Section Header: *1. In order for medication for hypertension (pressure) to work, people have to take it as prescribed. For one reason or another, many people can't or don't always take all of their medication as prescribed. We want to know how often you have missed your medication(s) for hypertension (pressure). (Ili dawa za ugonjwa wa pressure zifanye kazi, watu wanapaswa kuzimeza kama ilivyoagizwa. Kwa sababu moja au nyingine, watu wengi hawawezi au kwa mara nyingi hawazimezi dawa kama ilivyoagizwa. Tunataka kujua ni mara ngapi umekosa kumeza dawa zako za ugonjwa wa pressure.* Over the past seven days, I missed my medicine (Kwa siku saba zilizopita, nilikosa kumeza dawa yangu)	radio (Matrix) 1 (0) None of the time (Hakuna wakati) 2 (1-2) A little of the time (Wakati kidogo) 3 (3-4) Some of the time (Saa zingine) 4 (5-6) Most of the time (Mara nyingi) 5 (7) Every time (Kila wakati)
66	[skipped_a_dose] Show the field ONLY if: [taking_meds_for_high_bp] = '1'	Over the past seven days, I skipped a dose of my medicine (Kwa siku saba zilizopita, nilikosa kumeza kipimo cha dawa yangu kimaksudi)	radio (Matrix) 1 (0) None of the time (Hakuna wakati) 2 (1-2) A little of the time (Wakati kidogo) 3 (3-4) Some of the time (Saa zingine) 4 (5-6) Most of the time (Mara nyingi) 5 (7) Every time (Kila wakati)
67	[didnt_take_a_dose] Show the field ONLY if: [taking_meds_for_high_bp] = '1'	Over the past seven days, I did not take a dose of my medicine (Kwa siku saba zilizopita, Sikumeza kipimo chochote cha dawa yangu bila kusudia)	radio (Matrix) 1 (0) None of the time (Hakuna wakati) 2 (1-2) A little of the time (Wakati kidogo) 3 (3-4) Some of the time (Saa zingine) 4 (5-6) Most of the time (Mara nyingi) 5 (7) Every time (Kila wakati)
68	[tested_and_found_diabetes]	c) Have you been tested and found that you have diabetes (Je, umewahi kupimwa na kupatikana ya kwamba uko na ugonjwa wa kisukari)	radio 1 Yes (Ndio) 2 No (La) Custom alignment: RH
69	[taking_meds_for_diabetes] Show the field ONLY if: [tested_and_found_diabetes] = '1'	d) Are you currently taking medications for your diabetes (Je, kwa sasa unameza dawa za ugonjwa wa kisukari)	radio 1 Yes (Ndio) 2 No (La)
70	[missed_diabetes_meds] Show the field ONLY if: [taking_meds_for_diabetes] = '1'	Section Header: *2. In order for anti-diabetic medication(s) to work, people have to take it as prescribed. For one reason or another, many people can't or don't always take all of their medication as prescribed. We want to know how often you have missed your anti-diabetic medication(s). (Ili dawa za ugonjwa wa kisukari zifanye kazi, watu wanapaswa kuzimeza kama ilivyoagizwa. Kwa sababu moja au nyingine, watu wengi hawawezi au kwa mara nyingi hawazimezi dawa kama ilivyoagizwa. Tunataka kujua ni mara ngapi umekosa kumeza dawa zako za ugonjwa wa kisukari.)* Over the past 7 days, I missed my medicine (Kwa siku saba zilizopita, nilkosa kumeza dawa yangu)	radio (Matrix) 1 None of the time (Hakuna wakati) 2 A little of the time (Wakati kidogo) 3 Some of the time (Saa zingine) 4 Most of the time (Mara nyingi) 5 Every time (Kila wakati)
71	[skipped_dose_for_diabetes]	Over the past 7 days, I skipped a dose of my medicine (Kwa siku saba zilizopita, nilikosa kumeza	radio (Matrix)

	Show the field ONLY if: [taking_meds_for_diabetes] = '1'	kipimo cha dawa yangu kimaksudi)	1 None of the time (Hakuna wakati) 2 A little of the time (Wakati kidogo) 3 Some of the time (Saa zingine) 4 Most of the time (Mara nyingi) 5 Every time (Kila wakati)
72	[didnt_take_diabetes_meds] Show the field ONLY if: [taking_meds_for_diabetes] = '1'	Over the past 7 days, I did not take a dose of my medicine (Kwa siku saba zilizopita, sikumeza kipimo chochote cha dawa yangu bila kusudia)	radio (Matrix) 1 None of the time (Hakuna wakati) 2 A little of the time (Wakati kidogo) 3 Some of the time (Saa zingine) 4 Most of the time (Mara nyingi) 5 Every time (Kila wakati)
73	[extent_of_nonadherence_dosenonadherence_questionna_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Barriers to Accessing Care (barriers_to_accessing_care)			
74	[hard_to_receive_care_pst6mths]	1. In the past 6 months, has it ever been hard for you to receive care for HIV (Kwa miezi 6 iliyopita, je, imewahi kuwa ngumu kwako kupokea matibabu ya HIV)	radio 1 Yes (Ndio) 2 No (La) 98 Don't Know (Sijui) 99 Refuse (Kataa) Custom alignment: RH
75	[challenges_past_6mnths] Show the field ONLY if: [hard_to_receive_care_pst6mths] = '1' or [hard_to_receive_care_pst6mths] = '98'	2. In the past six months, have you encountered challenges with getting care for other health problems (other than HIV)? (Kwa miezi sita iliyopita, umekumbana na changamoto za kiafya (ijapokuwa HIV))	radio 1 Yes (Ndio) 2 No (La) Custom alignment: RH
76	[challenge_receiving_care] Show the field ONLY if: [challenges_past_6mnths] = '1'	2a. What are some of these challenges (je, ni nini baadhi ya hizi changamoto)	checkbox 1 challenge_receiving_care___1 1. Transportat was too difficult or expensive (Usafiri ulikuwa mgumu sar au ghali) 2 challenge_receiving_care___2 2. I didn't h enough money to p for care (Sikuwa na pesa za kutosha za

			kulipia huduma)
		3	challenge_receiving_care___3	3. I forgot about my scheduled appointmer (Nilisahau kuhusu tare ya kliniki ilivyopangw
		4	challenge_receiving_care___4	4. My last experience was not pleasant (Sikufurahia experience yangu ya mwisho nilipokuwa natafuta matibabu)
		5	challenge_receiving_care___5	5. Other (Nyingine)
77	[other_challenge_to_getting_to_facility] Show the field ONLY if: [challenge_receiving_care(5)] = '1'	If there is other challenge of getting to the facility, specify	text
78	[demands_that_hinder_care] Show the field ONLY if: [hard_to_receive_care_pst6mths] = '1' or [hard_to_receive_care_pst6mths] = '98'	3. In the past 6 months, has work and/or family demands made it difficult for you to receive care (Kwa miezi sita iliyopita, je mahitaji ya kikazi ama ya kifamilia yamefanya iwe ngumu kwako kupokea matibabu ya virusi vya HIV)	radio 1 Yes (Ndio) 2 No (La) Custom alignment: RH
79	[demands_hindering_care] Show the field ONLY if: [demands_that_hinder_care] = '1'	3a. What are some of these demands? (je, ni nini baadhi ya haya mahitaji?)	checkbox 1 demands_hindering_care___1 1. My famil needed money that I would have spent on receiving care (Familia yangu walihitaji pesa ambazo ningetumia kupokea matibabu) 2 demands_hindering_care___2 2. I had to work during the

			time I was supposed to go for care (Nililazimik kufanye kazi wakati ambao nilifaa kuendea matibabu)
		3	demands_hindering_care___3	3. I had a family obligation e.g., event, funeral (Nilikuwa na majukumu ya kifamilia k.v. sherehe, matanga)
		4	demands_hindering_care___4	4. My famil would find out that I had HIV if I went for care (Familia yangu ingegundu kuwa ninaishi na virusi vya HIV endapo ningeende matibabu)
		5	demands_hindering_care___5	5. Other (Nyingine)
80	[other_work_family_demands] Show the field ONLY if: [demands_hindering_care(5)] = '1'	3b. Other family/work demands that hinder care, specify	text
81	[clinic_issues_got_in_the_way] Show the field ONLY if: [hard_to_receive_care_pst6mths] = '1' or [hard_to_receive_care_pst6mths] = '98'	4. In the past 6 months, were there issues that got in the way of you receiving care (Kwa miezi sita iliyopita, kumekuwa na maswala ambayo yalikuzuia kupokea huduma)	radio 1 Yes (Ndio) 2 No (La) Custom alignment: RH
82	[list_of_clinic_issues] Show the field ONLY if:	4a. What were these issues (Je ni nini baadhi ya haya maswala)	checkbox 1 list_of_clinic_issues___1 1. Lack of the medications I

	[clinic_issues_got_in_the_way] = '1'		needed (Ukosefu wa ma dawa nilizohitaji) 2 | list_of_clinic_issues___2 | 2. The doctors or providers were not there (Madaktari au wahudumu wa afya hawakuwepo) 3 | list_of_clinic_issues___3 | 3. The staff was not nice (Wahudumu hawakuwa wazuri) 4 | list_of_clinic_issues___4 | 4. The care was not good (Huduma haikuwa nzuri) 5 | list_of_clinic_issues___5 | 5. The community would find out that I had HIV if I went for care (Jamii ingegundua kuwa ninaishi na virusi vya HIV endapo ningeendea matibabu) 6 | list_of_clinic_issues___6 | 6. Other (Nyingine)
83	[other_clinical_issues] Show the field ONLY if: [list_of_clinic_issues(6)] ='1'	4b. What other clinical issues got in the way, specify	text
84	[medical_issues_in_the_way] Show the field ONLY if: [hard_to_receive_care_pst6mths] = '1' or [hard_to_receive_care_pst6mths] = '98'	5. In the past 6 months, have you personally experienced any medical issues that got in the way of you receiving care (Kwa miezi 6 zilizopita mekuwa na sababu zozote za kiafya ambazo zilikuzuia kupokea huduma)	radio 1 | Yes (Ndio) 2 | No (La) Custom alignment: RH
85	[medical_reasons] Show the field ONLY if: [medical_issues_in_the_way] = '1'	5a. What were these medical reasons (Je ni nini baadhi ya sababu hizi za kiafya)	checkbox 1 | medical_reasons___1 | 1. I felt too sick to go to the clinic (Nilihisi

			mgonjwa sana kwenda kliniki)
			2 medical_reasons___2 2. My medicine was not working (Dawa zangu hazikuwa zikifanya vizuri)
			3 medical_reasons___3 3. I was experiencing side effects from the medicine (Nilikuwa nikipata athari kutokana na dawa zenyewe)
			4 medical_reasons___4 4. I felt well and didn't need care (Nilihisi vizuri na sikuhitaji huduma)
			5 medical_reasons___5 5. I didn't want to keep taking medicine (Sikutaka kuendelea kutumia dawa)
			6 medical_reasons___6 6. I was taking too many pills a day (Nilikuwa nameza tembe nyingi kwa siku
			7 medical_reasons___7 7. Other (Nyingine)
86	[other_medical_issues] Show the field ONLY if: [medical_reasons(7)]='1'	5b. What other medical issues got in the way, specify	text
87	[other_reasons_pst_6mths] Show the field ONLY if: [hard_to_receive_care_pst6mths] = '1' or [hard_to_receive_care_pst6mths] = '98'	6. Please describe what other reasons got in the way of you receiving care in the past 6 months (Tafadhali eleza sababu gani zinginezo zilizokuzuia kupokea huduma katika miezi 6 iliyopita)	text
88	[barriers_to_accessing_care_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Patient Satisfaction Survey (patient_satisfaction_survey)			

89	[courtesy_and_respect]	Section Header: *Now I would like to hear about your experience receiving care at AMPATH health facilities. Please answer honestly and to the best of your knowledge. All responses are confidential. (Sasa, ningependa kusikia jinsi umekuwa ukipokea huduma katika kliniki za AMPATH. Tafadhali jibu kwa uaminifu na kulingana na ufahamu wako. Majibu yote ni ya siri.)* 1. When you go to receive HIV care, how often do staff at the health facility treat you with courtesy and respect	radio (Matrix) 1 All the time (Kila wakati) 2 A lot of the time (Mara nyingi) 3 Some of the time (Wakati mwingine) 4 None of the time (Hakuna hata wakati)
90	[listen_carefully]	2. When you go to receive HIV care, how often do doctors or health providers listen carefully to you	radio (Matrix) 1 All the time (Kila wakati) 2 A lot of the time (Mara nyingi) 3 Some of the time (Wakati mwingine) 4 None of the time (Hakuna hata wakati)
91	[ask_for_your_opinion]	3. When you go to receive HIV care, how often do doctors or health providers ask for your opinion regarding your healthcare	radio (Matrix) 1 All the time (Kila wakati) 2 A lot of the time (Mara nyingi) 3 Some of the time (Wakati mwingine) 4 None of the time (Hakuna hata wakati)
92	[satisfied_with_time_given]	4. When you go to receive HIV care, how often are you satisfied with the amount of time your doctor/provider spends with you	radio (Matrix) 1 All the time (Kila wakati) 2 A lot of the time (Mara nyingi) 3 Some of the time (Wakati mwingine) 4 None of the time (Hakuna hata wakati)
93	[private_and_confidential]	Section Header: *Please tell me how much you agree or disagree with the following statements. (Tafadhali niambie ni kwa kiasi gani unakubaliana au haukubaliani na mambo yafuatayo.)* 5. The providers can be trusted to keep my medical information private and confidential	radio (Matrix) 1 Agree (Nakubali) 2 Neither agree nor disagree (Sikubali wala sikatai) 3 Disagree (Sikubali)
94	[treat_people_same_way]	6. Health workers treat people with HIV the same way as they treat people with other illnesses	radio (Matrix) 1 Agree (Nakubali) 2 Neither agree nor disagree (Sikubali wala sikatai) 3 Disagree (Sikubali)
95	[satisfation_with_the_care]	7. Overall, how satisfied are you with the HIV care you receive (Kwa ujumla, unaridhika kiasi gani na huduma ya HIV unayopokea)	radio 1 Very satisfied (Nimeridhika sana) 2 Satisfied (Nimeridhika) 3 Not satisfied (Sijaridhika) Custom alignment: RH
96	[patient_satisfaction_survey_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete

Instrument: **Felt Stigma Questionnaire** (felt_stigma_questionnaire)			
97	[hiv_was_a_punishment]	Section Header: *Now I would like to hear about your experience living with HIV. Please feel free to share your experience. All of your responses are confidential. (Sasa ningependa kusikia kuhusu uzoefu wako wa kuishi na virusi vya HIV. Tafadhali shiriki kwa kiasi kikubwa au kidogo jinsi unavyopenda. Majibu yako yote ni ya siri.) In the past thirty days, how often have the following statements applied to you: (Katika siku thelathini zilizopita, ni mara ngapi taarifa zifuatazo zimekuhusu:)* 1. In the past thirty days, how often have you felt that having HIV was a punishment for things I had done in the past.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
98	[avoided_coz_if_hiv_status]	2. In the past thirty days, how often have you felt that people were avoiding me because of my HIV status.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
99	[lose_friends_coz_of_hiv]	3. In the past thirty days, how often have you feared that I would lose my friends if they learnt about my having HIV.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
100	[treated_differentl_coz_hiv]	4. In the past thirty days, how often have you felt like people that I know were treating me differently because of my HIV status.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
101	[looked_down_coz_of_hiv]	5. In the past thirty days, how often have you felt like people looked down on me because I have HIV.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
102	[no_relations_coz_of_hiv]	6. In the past thirty days, how often have you avoided sexually interacting with my wife/husband/girlfriend/boyfriend because most people don't want a relationship with someone with HIV.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
103	[avoided_situations]	7. In the past thirty days, how often have you avoided a situation because I worried of people knowing I have HIV.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
104	[embarrassed_coz_of_hiv]	8. In the past thirty days, how often were you embarrassed about having HIV.	radio (Matrix)

			1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
105	[keep_status_a_secret]	9. In the past thirty days, how often have you felt that keeping my HIV status a secret was important.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
106	[home_life_disrupted]	10. In the past thirty days, how often have you felt like my home life has been disrupted because of my HIV status.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
107	[job_adversely_impacted]	11. In the past thirty days, how often have you felt like my business/job has been adversely impacted because of my HIV status.	radio (Matrix) 1 Never (Kamwe) 2 Sometimes (Wakati mwingine) 3 Often (Mara nyingi) 4 Always (Kila mara)
108	[felt_stigma_questionnaire_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Household Food Insecurity Access Scale (HFIAS) (household_food_insecurity_access_scale_hfias)			
109	[worry_of_no_food_in_pst4wks]	Section Header: *First, I would like to ask you some questions to see if you have experienced any new challenges accessing food for yourself and your family members. Please answer honestly and to the best of your knowledge. All responses are confidential. (Kwanza, ningependa kukuuliza baadhi ya maswali kuona ikiwa umepitia changamoto yoyote geni ya kujipatia lishe pamoja na jamii yako. Tafadhali jibu kwa ukweli wako wote na ufahamu wako. Majibu yote yatakuwa ya siri.)* 1. In the past 4 weeks, did you worry that your household would not have enough food (Kwa wiki nne zilizopita, je ulikuwa na wasiwasi kuwa nyumba yako itakosa lishe ya kutosha)	radio 1 Yes (Ndio) 2 No (La)
110	[how_often_do_you_worry] Show the field ONLY if: [worry_of_no_food_in_pst4wks] = '1'	1a. How often did this happen (Jambo hili limefanyika mara ngapi)	dropdown 1 1. Rarely (once or twice in the past 4 weeks) (Nadra (mara moja au mbili kwa wiki nne zilizopita) 2 2. Sometimes (three to ten times in the past 4 weeks) (Wakati mwingine (mara tatu hadi kumi kwa wiki nne zilizopita) 3 3. Often (more than ten times in the past 4 weeks (Mara mingi (zaidi ya

			mara kumi kwa wiki nne zilizopita)
111	[didnt_eat_coz_of_no_resources]	2. In the past 4 weeks, were you or any household member not able to eat because of a lack of resources (Kwa wiki nne zilizopita , je, wewe ama mtu yeyote katika jamii yako hamukuweza kupata lishe kwa sababu ya ukosefu wa pesa)	radio 1 Yes (Ndio) 2 No (La)
112	[how_often_do_you_not_eat] Show the field ONLY if: [didnt_eat_coz_of_no_resources] = '1'	2a. How often did this happen (Jambo hili limefanyika mara ngapi)	dropdown 1 1. Rarely (once or twice in the past 4 weeks) (Nadra (mara moja au mbili kwa wiki nne zilizopita) 2 2. Sometimes (three to ten times in the past 4 weeks) (Wakati mwingine (mara tatu hadi kumi kwa wiki nne zilizopita) 3 3.Often (more than ten times in the past 4 weeks) (Mara mingi (zaidi ya mara kumi kwa wiki nne zilizopita)
113	[eat_smaller_portions_of_food]	3. In the past 4 weeks, did you or any household member have to eat smaller portions of food than you felt you needed because there was not enough food (Kwa wiki nne zilizopita, je wewe ama mtu yeyote katika jamii yako mmelazimika kukula kipimo kidogo cha chakula kuliko kiwango mnachohitaji kwa sababu chakula haikutosha)	radio 1 Yes (Ndio) 2 No (La)
114	[how_often_do_eat_smaller_portions] Show the field ONLY if: [eat_smaller_portions_of_food] = '1'	3a. How often did this happen (Jambo hili limefanyika mara ngapi)	dropdown 1 1. Rarely (once or twice in the past 4 weeks) (Nadra (mara moja au mbili kwa wiki nne zilizopita) 2 2. Sometimes (three to ten times in the past 4 weeks) (Wakati mwingine (mara tatu hadi kumi kwa wiki nne zilizopita) 3 3.Often (more than ten times in the past 4 weeks) (Mara mingi (zaidi ya mara kumi kwa wiki nne zilizopita)
115	[household_food_insecurity_access_scale_hfias_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Household Economic Status (household_economic_status)			
116	[electricity]	Section Header: *Before we conclude, I would like to know about some of the items you have in your household. Which of the following items does your household own. (Kabla ya kutimisha, ningependa kujua kuhusu baadhi ya vitu ambavyo unavyo katika nyumba yako. Je, ni yapi kati ya vitu vifuatavyo ambavyo nyumba yako inamiliki)* 1. Electricity (Umeme)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
117	[radio]	2. Radio (Redio)	radio (Matrix)

			1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
118	[television]	3. Television (Runinga/televisheni)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
119	[mobile_phone]	4. Mobile telephone (Simu ya rununu)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
120	[non_mobile_phone]	5. Non-mobile telephone (Simu isiyo ya rununu)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
121	[refrigerator]	6. Refrigerator (Jokofu)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
122	[solar_panel]	7. Solar panel (Jopo la jua)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
123	[table]	8. Table (Meza)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
124	[chair]	9. Chair (Kiti)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)

125	[sofa]	10. Sofa (Kiketi cha sofa)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
126	[bed]	11. Bed (Kitanda)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
127	[cupboard]	12. Cupboard (Kabati)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
128	[clock]	13. Clock (Saa ya ukuta)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
129	[microwave]	14. Microwave oven (Tanuri ya microwave)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
130	[dvd_player]	15. DVD player (Kifaa cha kuchezea DVD)	radio (Matrix) 1 Yes (Ndio) 2 No (No) 98 I don't know (Sijui) 99 Refuse (Kataa)
131	[livestock]	Section Header: *16. How many of each of the following livestock animals does your household own (Je, ni ngapi ya kila aina ya mifugo ifuatayo ambayo nyumba yako inamiliki)* a. Cattle (Ngombe) *Number owned*	text
132	[sheep]	b. Sheep (Kondoo) *Number owned*	text
133	[goat]	c. Goat (Mbuzi) *Number owned*	text
134	[chicken]	d. Chicken (Kuku) *Number owned*	text
135	[donkey]	e. Donkey (Punda) *Number owned*	text

136	[own_other_livestock]	f. Do you own other livestock	yesno 1 Yes 0 No Custom alignment: RH
137	[other_livestock_name_1] Show the field ONLY if: [own_other_livestock] = '1'	f. Name of other (1) livestock owned (Jina ya mifugo mingine)	text
138	[number_of_other_livestock_1] Show the field ONLY if: [own_other_livestock] = '1'	g. Number of other (1) livestock owned (Nambari ya mifugo mengine)	text
139	[other_livestock_name_2] Show the field ONLY if: [own_other_livestock] = '1'	h. Name of other (2) livestock owned (Jina ya mifugo mingine)	text
140	[number_of_other_livestock_2] Show the field ONLY if: [own_other_livestock] = '1'	i. Number of other (2) livestock owned (Nambari ya mifugo mengine)	text
141	[other_livestock_name_3] Show the field ONLY if: [own_other_livestock] = '1'	j. Name of other (3) livestock owned (Jina ya mifugo mingine)	text
142	[number_of_other_livestock_3] Show the field ONLY if: [own_other_livestock] = '1'	k. Number of other (3) livestock owned (Nambari ya mifugo mengine)	text
143	[use_of_livestock]	17. What are the livestock used for (Ikiwa jumla ya mifugo inayomilikiwa ni zaidi ya sufuri Je, mifugo hii hutumika kwa namna gani)	radio 1 Household consumption (Lishe ya nyumba) 2 Income generation (Uzalishaji mapato) 3 Both (Zote mbili) 4 N/A (Haihusiki)
144	[own_or_rent_farm_land]	18. Do you rent or own any farm land (Je unakodisha au unamiliki shamba lolote)	yesno 1 Yes 0 No Custom alignment: RH
145	[know_acres_owned_by_hh]	18a. Do you know the number of acres of agricultural land owned by household	radio

	Show the field ONLY if: [own_or_rent_farm_land] = '1'	(Unajua kiasi ya shamba unayomiliki)	1 Yes 2 No 3 Don't know Custom alignment: RH
146	[acres_of_land_owned] Show the field ONLY if: [know_acres_owned_by_hh] = '1'	18b. If yes, how many acres of agricultural land does your household own (Ikiwa ndio, ni hecta ngapi ya shamba ya kilimo ambayo nyumba yako inamiliki)	text
147	[use_of_rented_or_owned_land] Show the field ONLY if: [own_or_rent_farm_land] = '1'	19. What is the land used for (Je shamba hili latumika kivipi)	checkbox 1 use_of_rented_or_owned_land___1 Rent 2 use_of_rented_or_owned_land___2 Plant for house consu 3 use_of_rented_or_owned_land___3 Plant for inc gener 4 use_of_rented_or_owned_land___4 Anima farmi 5 use_of_rented_or_owned_land___5 Land sitting 6 use_of_rented_or_owned_land___6 Other
148	[other_use_for_land] Show the field ONLY if: [use_of_rented_or_owned_land(6)]= '1'	19a. If other use for land, specify	text
149	[household_economic_status_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete

			1 Unverified 2 Complete
Instrument: Employment and Income Status (employment_and_income_status)			
150	[primary_employment]	Section Header: *Finally, I would like to ask you about your current employment and income status. (Kwa kumalizia ningependa kukuuliza kuhusu hali yako ya sasa ya kuajiriwa na mapato yako ya sasa hivi.)* 1. Which of the following options best describes your primary employment? You are a (Je ni gani baadhi ya majibu yafuatayo inaeleza vyema ajira yako ya msingi? Wewe ni) Primary employment is defined as the employment that brings the largest contribution to your household income. (Ajira ya msingi ni ajira mayo inachangia pakuu kwa mapato ya nyumbani kwako)	dropdown 1 1. Farmer (Mkulima) 2 2. Daily laborer/piece work earner in agricultural or health sector (Mfanyikazi wa kila siku katika sector ya ukulima ama afya) 3 3. Wage earner in non-agriculture large business (factory operation) (Mfanyi kibarua katika biashara kubwa isiyo ya kilimo (uendeshaji wa kiwanda)) 4 4. Small business owner (duka, kiosk, trade in farm produce) (Mfanya biashara ndogo (Duka, Kiosk, Kuuza bidhaa ya shamba)) 5 5. Artisan (e.g. welder, blacksmith, craftsman, carpenter) (Juakali (k.v. fundi wa chuma, seremala, fundi)) 6 6. Salaried employee (Mfanyikazi anayelipwa mshahara) 7 7.Unemployed/not working (Hujaajiriwa/Hauna kazi) 8 8. Student (Mwanafunzi) 9 9.Retiree (Umestaafu) 10 10.Other (Nyingine) 11 11. Don't know (Sijui) 12 12. Refused to answer (Kataa kujibu)
151	[other_pri_employment] Show the field ONLY if: [primary_employment] = '10'	1a. Please indicate other primary employment not listed above (Tafadhali eleza ni ajira ya msingi ipi unayofanya ambayo haijatajwa hapo awali)	text
152	[est_monthly_income] Show the field ONLY if: [primary_employment] = '1' or [primary_employment] = '2' or [primary_employment] = '3' or [primary_employment] = '4' or [primary_employment] = '5' or [primary_employment] = '6' or [primary_employment] = '7' or [primary_employment] = '8' or [primary_employment] = '9'	2. What is your estimated monthly income in Kenyan shillings (KES) (Je mapato yako ya kila mwezi ukikadiria katika fedha za Kenya ni shilling ngapi)	dropdown 1 1. < 1,000 2 2. 1,000 - 2,999 3 3. 3,000 - 4,999 4 4. 5,000 - 9,999 5 5. >10,000 6 6. N/A - receive non-monetary gifts (Haihusiki- kupokea zawadi ambazo sio pesa) 98 7. Don't know (Sijui) 99 8. Refused to answer (Kataa kujibu)

153	[time_interview_ended_arm_c]	Section Header: *FOR ARM C PARTICIPANTS ONLY We are now finished with this survey. Thank you for taking the time to speak with me today. All of your responses will remain private and the information you shared will help us during this study. Do you have any questions? Thank you very much. (Sasa, tumetamatisha mahojiano haya. Asante kwa kuchukua muda wako kuzungumza nami leo. Majibu yako yote yatabaki kuwa ya siri na habari ulizoshiriki zitatusaidia katika utafiti huu. Je, unayo maswali yoyote? Asante sana.* 3. Time interview ended for Arm C	text (time)
154	[employment_and_income_status_complete]	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: HTN/DM Screening Form (htndm_screening_form)			**[collapsed]**
Instrument: GISHE Individual Record Form (gishe_individual_record_form)			**[collapsed]**

Appendix IV. Microfinance data collection instruments

Data Dictionary Codebook

Harambee Survey Assessment Tool (PID: 580)

07/29/2024 9:27pm

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: Meta-Data (metadata)			**[collapsed]**
Instrument: Respondent Demographics (respondent_demographics)			**[collapsed]**
Instrument: Health Insurance (health_insurance)			**[collapsed]**
Instrument: OSLO Social Support Scale -3 (oslo_social_support_scale_3)			**[collapsed]**
Instrument: Adapted Medical Outcomes Study HIV Health Survey (MOS-HIV) (adapted_medical_outcomes_study_hiv_health_survey_m)			**[collapsed]**
Instrument: Patient Health Questionnaire-2 (patient_health_questionnaire2)			**[collapsed]**
Instrument: Adapted ACTG Self Report Adherence Questionnaire (adapted_actg_self_report_adherence_questionnaire)			**[collapsed]**
Instrument: Extent of Nonadherence (DOSE-Nonadherence) Questionnaire (extent_of_nonadherence_dosenonadherence_questionna)			**[collapsed]**
Instrument: Barriers to Accessing Care (barriers_to_accessing_care)			**[collapsed]**
Instrument: Patient Satisfaction Survey (patient_satisfaction_survey)			**[collapsed]**
Instrument: Felt Stigma Questionnaire (felt_stigma_questionnaire)			**[collapsed]**
Instrument: Household Food Insecurity Access Scale (HFIAS) (household_food_insecurity_access_scale_hfias)			**[collapsed]**
Instrument: Household Economic Status (household_economic_status)			**[collapsed]**
Instrument: Employment and Income Status (employment_and_income_status)			**[collapsed]**
Instrument: HTN/DM Screening Form (htndm_screening_form)			**[collapsed]**
Instrument: GISHE Individual Record Form (gishe_individual_record_form)			
182	[nature_of_encounter_visit]	1. Nature of encounter	radio 1 Initial visit 2 Recurrent visit Custom alignment: RH
183	[gishe_id_number]	Section Header: *INDIVIDUAL MEMBER DATA (DATA YA MWANACHAMA) (to be completed for each individual member of the group) (Kila mwanachama ajaziwe data yake)* 2. GISHE/Chamaa/MF Group ID Number (Nambari ya Kikundi)	text
184	[phone_number]	3. Current Phone number (Nambari ya simu)	text (number, Min: 0)
185	[date_first_join_group]	4. When did this individual first join a GISHE/Chamaa/MF group	text (date_dmy)

	Show the field ONLY if: [nature_of_encounter_visit] = '1'	(Je, mara ya kwanza mwanakikundi huyu kujiunga na kikundi ilikuwa lini)	
186	[total_share_contributed] Show the field ONLY if: [nature_of_encounter_visit] = '1'	5. Total amount of shares contributed in this current GISHE/Chamaa/MF group (Jumla ya hisa (pesa) alizochanga katika kikundi hiki cha sasa)	text (integer, Min: 0, Max: 100000)
187	[outstanding_loan_bal] Show the field ONLY if: [nature_of_encounter_visit] = '1'	6. Total outstanding loan balance in this current GISHE/Chamaa/MF group (Jumla ya pesa za mkopo alizonazo katika kikundi hiki cha sasa)	text (integer, Min: 0, Max: 100000)
188	[no_of_meetings_attended] Show the field ONLY if: [nature_of_encounter_visit] = '2'	Section Header: *RECCURENT DATA* 7. Number of meetings attended during last period (Nambari ya mikutano uliyohudhuria kwa musimu uliopita)	text (number, Min: 0, Max: 60)
189	[total_shares_purchased] Show the field ONLY if: [nature_of_encounter_visit] = '2'	8. Total number of shares purchased during the last period (Jumla ya hisa zilizonunuliwa msimu uliopita)	text (integer, Min: 0, Max: 100000)
190	[loans_disbursed] Show the field ONLY if: [nature_of_encounter_visit] = '2'	9. Total amount of loans disbursed during the last period (Jumla ya mikopo iliyochukuliwa msimu uliopita)	text (integer, Min: 0, Max: 100000)
191	[loan_bal_outstanding] Show the field ONLY if: [nature_of_encounter_visit] = '2'	10. Total loan balance outstanding on current date (Jumla ya mikopo ambazo hazijalipwa hadi sasa)	text (integer, Min: 0, Max: 100000)
192	[purpose_for_loan] Show the field ONLY if: [nature_of_encounter_visit] = '2' and [loans_disbursed] <> ''	11. For what purpose did this member use the borrowed funds during the last period (Je, mwanachama alitumia pesa alizokopa msimu uliopita kufanya nini)	checkbox 1, purpose_for_loan___1, To pay off other debts 2, purpose_for_loan___2, To buy farm inputs such as seeds, ox plough 3, purpose_for_loan___3, To pay school fees

			for children
			4 purpose_for_loan___4 To pay for medical expenses (health insurance, medical fees, medications)
			5 purpose_for_loan___5 To trade and invest in small business
			6 purpose_for_loan___6 To repair shelter or homestead
			7 purpose_for_loan___7 To buy clothing for self and family
			8 purpose_for_loan___8 Other
193	[other_use_of_loan] Show the field ONLY if: [purpose_for_loan(8)] ='1'	11a. If other use of loan specify	text
194	[use_social_fund] Show the field ONLY if: [nature_of_encounter_visit] = '2'	12. Did this individual use the social fund during this period (Je, mwanachama alitumia pesa za mfuko wa jamii katika msimu uliopita)	radio 1 Yes- Granted, no payment 2 Yes- Borrowed with repayment 3 No Custom alignment: RH
195	[funds_repaid_during_period] Show the field ONLY if: [use_social_fund] = '2'	12a. If yes, borrowed with repayment, were the funds repaid during this period (Kama ni ndio-kuomba na malipo, je pesa zililipwa kwa msimu huo)	yesno 1 Yes 0 No Custom alignment: RH
196	[social_fund_without_repayment] Show the field ONLY if: [use_social_fund] = '1'	12b. If yes- granted with no repayment, what was the reason for using the social fund (Kama ni ndio, je pesa za mfuko wa jamii zilitumika kufanya nini)	dropdown 1 1.Bereavement/Funeral 2 2. Hospital/Medical fees 3 3. School fees 4 4. Celebration (birthday, baby shower) 5 5. Natural disaster (drought, flood, fire)

			6 | 6. Other
197	[other_reason_for_social_fund] Show the field ONLY if: [social_fund_without_repayment] = '6'	12c. If other reason, specify (Kama ni nyingine, taja)	text
198	[defaulted_since_last_encounter] Show the field ONLY if: [nature_of_encounter_visit] = '2'	13. Has this individual defaulted during the last encounter (Je mwanachama huyu amakosa kulipa mkopo wake tangu mara ya mwisho mlipokutana)	yesno 1 | Yes 0 | No Custom alignment: RH
199	[reasons_defaulted] Show the field ONLY if: [defaulted_since_last_encounter] = '1'	13a. If defaulter, give reasons for defaulting (Kama ni ndio, je ni jambo lipi lilimsababisha kutolipa mkopo)	checkbox 1 | reasons_defaulted___1 | No longer attending meetings 2 | reasons_defaulted___2 | No longer able to contribute/sha 3 | reasons_defaulted___3 | Emergency (Family, health, death) 4 | reasons_defaulted___4 | Defaulted on loan 5 | reasons_defaulted___5 | Other
200	[other_reason_defaulted] Show the field ONLY if: [reasons_defaulted(5)] = '1'	13b. If other reason for defaulted, specify (Kama ni nyingine, taja)	text Custom alignment: RH
201	[time_interview_ended]	Section Header: *We are now finished with this survey. Thank you for taking the time to speak with me today. All of your responses will remain private and the information you shared will help us during this study. Do you have any questions? Thank you very much. (Sasa, tumetamatisha mahojiano haya. Asante kwa kuchukua muda wako kuzungumza nami leo. Majibu yako yote yatabaki kuwa ya siri na habari ulizoshiriki zitatusaidia katika utafiti huu. Je, unayo maswali yoyote? Asante sana.* 14. Time interviewed ended (Wakati mahojiano yalikamilika)	text (time)
202	[gishe_individual_record_form_complete]	Section Header: *Form Status* Complete?	dropdown 0 | Incomplete 1 | Unverified 2 | Complete

Data Dictionary Codebook

GISHE Group Record Form (PID: 575)

07/29/2024 9:31pm

Instruments	Events

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: GISHE Group Record Form (gishe_group_record_form)			
1	[harambee_study_group_id]	1.Harambee study group ID (Nambari ya utambulisho wa Kikundi)	text
2	[collection_date]	2. Date of data collection (Tarehe ya kukusanya ujumbe)	text (date_dmy), Required
3	[study_county]	3. County of study	radio 1, Busia 2, Trans Nzoia Custom alignment: RH
4	[mf_group_name_in_busia] Show the field ONLY if: [study_county] ='1'	4. Microfinance group name in Busia county	dropdown 1, Jipe Moyo Support Group 2, Wapendanao Support Group 3, Sisi Pekee Yetu (Hatuko Pekee Yetu) 4, Safina Support Group 5, Mabinju Support Group 6, Tujitolee Support Group 7, Heri Mimi Support Group 8, Magombe Abakanya Support Group 9, Abemanya Afya Support Group 10, Mundika Support Group 11, Mubwayo Support Group 12, Faith Support Group 13, Survivor 2 14, Habari Njema Support Group 15, Survivor 3 Support Group 16, Roho Moja ni Moja Support Group 17, Njia Moja Kazi Moja Support Group

			18 Tumaini Support Group 19 Bukalama Support Group 20 Alakara Support Group 21 Amua Support Group 22 Amerikwai Post-Test Support Group 23 Amua Support Group Mukhobola 24 Kakurikit Esenyi Support Group 25 Kisandu Support Group 26 Murende Support Group 27 Lwanya Support Group 28 Munongo Werusia Support Group 29 Afya ni Bora Support Group 30 Linda Maisha Support Group 31 Amuka Ujitegemee Support Group 32 Mudoma Support Group 33 Abakhaywa Support Group 34 Tumaini Budwong'i Support Group 35 Ageng'a Star Support Group 36 Esiri Muefwe Siri Mueng'we Support Group 37 Tumekubali Support Group 38 Motomoto Support Group 39 Muramba Support Group 40 Other
5	[other_group_name_busia] Show the field ONLY if: [mf_group_name_in_busia] = '40'	4.1. Other group name in Busia County	text
6	[study_group_name_in_tn] Show the field ONLY if: [study_county] = '2'	4a. Microfinance group name, in Trans Nzoia county	dropdown 1 Amua Support Group 2 Busiere Support Group 3 Faith Support Group

			4 | Healing Support Group 5 | Imahutu Support Group 6 | Ingakha Support Group 7 | Jihimize Support Group 8 | Jipange Support Group 9 | Jitahidi Support Group 10 | Lungai Support Group 11 | Maandalio Support Group 12 | Maisha Bora Support Group 13 | Misege Support Group 14 | Mkuyuni Support Group 15 | Msamaria Support Group 16 | Neema Support Group 17 | Rays Of Hope Support Group 18 | Sango Support Group 19 | Umoja Support Group 20 | Other
7	[other_group_name_tnz] Show the field ONLY if: [study_group_name_in_tn] = '20'	4a.1. Other group name in Trans Nzoia County	text
8	[nature_of_encounter]	5. Nature of encounter	radio 1 | Initial visit 2 | Recurrent visit Custom alignment: RH
9	[name_of_info_provider] Show the field ONLY if: [nature_of_encounter] = '1'	6. Name of person providing information (Jina la mtu anayepeana ujumbe)	text, Required
10	[role_of_info_provider] Show the field ONLY if: [nature_of_encounter] = '1'	7. Role of person providing information (Jukumu la mtu anayepeana ujumbe)	radio 1 | Secretary/Record Keeper (Katibu/Mlinda rekodi) 2 | Treasurer/Box Keeper (Mweka hazina/Mlinda kisanduku) 3 | Chairperson (Mwenyekiti)

			4 Money Counter (Mhesabu Hela) 6 Vice Chair (Naibu wa Mwenyekiti) 5 Other (Nyingine)
11	[other_role] Show the field ONLY if: [role_of_info_provider] = '5'	7a. If other role, specify: (Kama ni nyingine, bainisha):	text
12	[current_cycle_number] Show the field ONLY if: [nature_of_encounter] = '1' or [nature_of_encounter] = '2'	8. What is the current cycle number of the group (Je. kikundi hiki imegawa pesa mara ngapi tangu ianza)	text (number, Min: 0, Max: 14)
13	[current_cycle_start_date] Show the field ONLY if: [nature_of_encounter] = '1' or [nature_of_encounter] = '2'	9. When did the current cycle start (Je, huu mzunguko wa sasa ulianza lini)	text (date_dmy), Required
14	[total_group_no_cyc_start] Show the field ONLY if: [nature_of_encounter] = '1' or [nature_of_encounter] = '2'	10. Total number of members in the group at the start of this current cycle (Nambari ya wanachama katika kikundi hiki mwanzo wa mzunguko huu wa sasa)	text (integer, Max: 40)
15	[group_active_total] Show the field ONLY if: [nature_of_encounter] = '1' or [nature_of_encounter] = '2'	11. Total number of active group members in this current cycle (Nambari ya wanachama wanao shiriki kikamilifu katika mzunguko wa sasa) (Note: active members are regularly attending GISHE meetings and pay shares/social funds) (Kumbuka: Wanachama wanao shiriki kikamilifu ni wale ambao huhudhuria mikutano ya Chamaa mara kwa mara na hulipa fedha za hisa/kusaidia katika janga)	text (integer, Max: 40)
16	[date_of_last_encounter] Show the field ONLY if: [nature_of_encounter] = '2'	Section Header: *The following questions refer to the data collection period starting from the last encounter when the form was collected to the present. (Maswali yafuatayo yanahusiana na wakati wa ukusanyaji wa ujumbe (deta) kuanzia mara ya mwishofomu ilipojazwa hadi sasa)* 12. Date of last encounter when form was collected (Tarehe ambayo fomu ilijazwa mara ya mwisho)	text (date_mdy)

17	[number_of_meetings] Show the field ONLY if: [nature_of_encounter] = '2'	13. How many meetings took place during the data collection period (Je, ni mikutano mingapi zilifanywa wakati wa ukusanyaji wa ujumbe)	text (number, Min: 0, Max: 15)
18	[meet_as_a_group] Show the field ONLY if: [nature_of_encounter] = '1'	Section Header: *GROUP PROCESS (Mchakato wa kikundi)* 14. How often do you meet as a group (Je, huwa munakutanamara ngapi lama kikundi)	radio 1, Weekly (Kila Wiki) 2, Bi-monthly (Baada ya wiki mbili) 3, Monthly (Kila Mwezi) 4, Quarterly (Baada ya miezi tatu) 5, Other (Nyingine)
19	[meet_as_a_group_specify] Show the field ONLY if: [meet_as_a_group] = '5'	14a. How often do you meet as a group, other specify: (Je, huwa munakutanamara ngapi lama kikundi, nyingine, bainisha):	text
20	[registration_fee] Show the field ONLY if: [nature_of_encounter] = '1'	13. Registration fee amount (Fedha ya kujiandikisha katika kikundi)	text (integer, Min: 0, Max: 20000)
21	[social_fund_value] Show the field ONLY if: [nature_of_encounter] = '1'	14. Single social fund value (Fedha ya kusaidia katika janga)	text (integer, Min: 0, Max: 20000)
22	[single_share_value] Show the field ONLY if: [nature_of_encounter] = '1'	15. Single share value (Thamani ya hisa moja)	text (integer, Min: 0, Max: 20000)
23	[gishe_group_record_form_complete]	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete

Appendix V: Adult Consent Form 3

(For microfinance group members or AMPATH staff who are asked to participate in Aim 2 in-depth interviews)

Title of Research:	Harambee: Integrated Community-Based HIV/NCD Care and Microfinance Groups in Kenya
Principal Investigators:	Juddy Wachira; Becky Genberg; Omar Galarraga
IREC Approval #:	0003054
Sponsor:	National Institute of Mental Health (NIMH)
Version Date:	23 February 2021

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part in the study at all. If you choose to join the study, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you right away if we learn any new information that might affect whether you wish to continue to be in the study.

What is the purpose of research study?

The purpose of this research study is to learn if offering HIV care and other health services in the community, instead of at a health facility, will help people who are living with HIV to live healthier lives. This research study also wants to learn if offering HIV care and other health services to people who are members of microfinance groups will help people who are living with HIV to live healthier lives.

What will happen if you agree to participate in the study?

If you agree to participate in this study, you will be interviewed by a trained member of our research team. This interview will last approximately one hour and will take place in a private, quiet, and convenient location, off-site of AMPATH. The interview will include a discussion of factors that you believe are important to understand integration of HIV and primary care into microfinance groups. If you agree to participate, the interviewer will record the interview using a digital recording device. The interviewer may also take notes during the interview.

What type of questions will be asked during the interview?

The purpose of the interview is to learn *how* microfinance groups help patients with HIV live healthier lives. The purpose of the interview is also to learn *how* delivering HIV care in the community help patients with HIV live healthier lives.

Risks of taking part in this study

There are no physical risks associated with participating in this study. You may experience psychological discomfort when sensitive topics are discussed. There is a minimal risk of losing confidentiality (privacy). However, the research staff will be sure that your records are kept safe and your personal information is not given to anybody without permission. All of the information you provide and all of your responses during the interview will be coded with a study ID and will never include your name.

Benefits of taking part in the study

We do not know if HIV care in the community keeps HIV-infected people as healthy as HIV-infected people who receive care at a health facility. It is possible that you may receive no benefit from being in this study. Information learned from this study may help others who are infected with HIV live healthier lives.

Confidentiality

Your name or other information that may identify you will not be associated with your answers during this interview, the recording, transcription, or any other notes made by the interviewer. We will transcribe the interview from the recording and destroy the audio file. The transcribed documents will be stored in secure locations and digital files will be protected with passwords. Only members of the study team will have access to the data. No one at AMPATH, including your physician, AMPATH employees, or other patients, will know your answers to the questions in this interview.

We will try very hard to keep your information confidential (private). We cannot guarantee absolute confidentiality. Your information could be shared if required by the law. A group of people may look at our research records to make sure they are complete and true. A group may also look at our records for data analysis (to see what the information people shared with us means). The groups looking at the records could be study investigators and their research partners, the Moi Institutional Research and Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB), the Brown University Institutional Review Board (IRB), the Purdue University Institutional Review Board (IRB), the Johns Hopkins University Institutional Review Board (IRB), the study staff, or the sponsor (NIH).

Data Sharing

We will not share the data from this study with anyone outside of our study staff team.

Costs

There will be no cost to you to participate in this interview.

Payment/Compensation

If you choose to participate in an interview, you will receive KES 300 as a thank you for your time. You will also receive refreshments during the interview.

What will happen if you miss or cannot attend your scheduled interview?

If you do not attend your scheduled interview for any reason, the study staff will contact you to schedule a follow-up interview.

Who is sponsoring this study?

This research is funded by the National Institutes of Health in the United States. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

Your alternatives to joining the study

Your participation in this study is voluntary. You may refuse to participate and there will be no penalty for refusing. Refusing to participate will not impact any care you receive from AMPATH, or any other provider. You may choose to discontinue your participation at any time without penalty.

Ending Consent

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you wish to end your consent, please let us know.

Who do you call if you have questions or problems related to the study?

- Call the principal investigator: Juddy Wachira at 070-524- 2450

- Call or contact the **Moi University Institutional Research and Ethics Committee (IREC)** if you have questions about your rights as a study participant. Contact IREC if you feel you have not been treated fairly or if you have other concerns. The IREC contact information is:

  Address: Moi Teaching and Referral Hospital
  Institutional Research and Ethics Committee
  2nd floor. Door No. 219,
  P.O. Box. 3-30100
  Eldoret, Kenya
  Office line: 0787723677
  Email: irecmtrh@gmail.com or contact@irec.or.ke

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

_____	_____	_____
Print name of Adult Participant	Signature of Adult Participant	Date

_____	_____	_____
Print name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Appendix VI: KEY INFORMANT INTERVIEW GUIDE – PARTICIPANTS

Introduction: *Review the study procedures and details with participant, including audio recording, confidentiality, and rights to refuse participation. Obtain informed consent*.

Because you are a patient of an AMPATH clinic, we want to learn about your experience receiving HIV and primary care through AMPATH. (If the participant is also in a microfinance group, you can also say that you want to learn about their experience as a microfinance group member.) We also want to hear about some of the challenges you face in getting care and about what would help you to receive the care your need on a regular basis.

Please remember that anything you say during this interview will be not be shared with anyone at AMPATH or in the community.

I. Socio-demographic:

a) Age in years
a) Gender
b) Most recent visit to AMPATH clinic and reason for visit
c) Time has been a member of a microfinance group (for trial participants)

II. ART adherence barriers and facilitators

The intent of this portion of the agenda is to explore participant's self-reported barriers/facilitators to accessing HIV care, including household economic conditions, food security, geography/distance, social support, and HIV-related stigma.

1. **Lead question**: What was your biggest concern when you found out you were HIV positive and started ART?

2. Follow-up question: Do you take your ART medication as indicated? What are some reasons why you do not or have not taken your ART medication as indicated, meaning as often or as much as told by medical personnel?

3. Follow-up question: When you WANT to stay adherent ART, what gets in the way?
    a. Medication/regimen: How does the medication experience (side effects, schedule, dosing) affect your ability to take ART as prescribed?
    b. Patient factors:
        i. Probe: developmental hallmarks such as family responsibility
        ii. Probe: specific challenges relating to mental health
    c. Peer, partner, family factors
        i. Probe: Support (or lack of support) from family, friends, clinicians, others
        ii. Probe: Does HIV stigma affect your decision to take ART? How? (explore covert ART use and concerns over inadvertent disclosure)
    d. Clinician factors
        i. Probe: positive and negative provider attitudes for clinical needs of people living with HIV
        ii. Probe: differences (if any) in experience between clinical care environments (e.g., different clinics, different regions)
    e. Structural factors: What about living in your community makes it easy or hard for you to take ART as prescribed?
        i. Probe: Transport, food security, housing, migration

f. **Lead question**: What helps you to STAY adherent to ART? "Adherent" means taking medication as often and/or as much as told by medical personnel.

III. Acceptability of receiving NCD/HIV integrated care in the community via microfinance groups

The intent of this portion is to introduce the idea of delivering NCD/HIV integrated care in the community via microfinance groups and to explore the acceptability ICB as a strategy for supporting better ART adherence in people living with HIV.

1. **Lead question**: We want to understand what you think about using microfinance groups to help people improve adherence to ART. By adherence we mean taking ART as prescribed. Do you think you and other people who are living with HIV would like to receive NCD/HIV care in the community when they attend a microfinance group meeting?

2. **Lead**: Can you tell us about how to design this type of health care service so that it supports adherence to ART among people who are living with HIV?
    a. How should the NCD/HIV care be DELIVERED to people in the community (e.g., to individuals privately, to a group of people trying to adhere)?
    b. How OFTEN should NCD/HIV service be delivered in the community (e.g., at every microfinance group meeting, at the payout meetings, monthly, quarterly?)

3. Follow-up question: To make sure you and other people who are living with HIV have all the support they need to adhere to ART, should NCD/HIV care be delivered on its own or in combination with other programs (such as motivational support, education on why adherence is important and how to adhere, or group/peer support groups for adherence)?

Closing: *Thank participant for their time. Remind participant about the confidentiality of the interview. Ask if they have any questions about anything that was discussed.*

EXAMPLE: Thank you for your time and for sharing your thoughts with us. We want to remind you that your comments will remain confidential. Do you have additional questions or comments?

Appendix VII: KEY INFORMANT INTERVIEW GUIDE – PROVIDERS

Introduction: *Review the study procedures and details with participant, including audio recording, confidentiality, and rights to refuse participation. Obtain informed assent/consent*.

AMPATH oversees over 1,300 microfinance groups, with 48 of these groups composed of only members living with HIV. AMPATH has begun to deliver chronic disease care, mainly for hypertension and diabetes, in a community-based group setting to those participating in microfinance groups. Our aim is to investigate whether it is feasible to adapt this model of group-based care delivery to address the needs of people living with HIV in microfinance groups.

We want to gather your thoughts on community-based care models, the strengths and challenges of integrating care, and the considerations that must be made when delivering HIV care outside of the health facility. We are particularly interested in your experience delivery NCD/HIV care to via microfinance groups through your role as a (insert job title).

A. Socio-demographic:

a) Age in years
a) Gender
b) Health provider cadre
c) Length of time working at AMPATH

B. Warm-up:

1. Tell me about yourself and your role within the AMPATH program
   Probes: Can you describe a normal working day for you?

Perception about patient involvement in community-based groups

2. What is your perception about community-based groups?
   Probes:
   - Perception about social support groups?
   - Perception about microfinance groups? E.g chamaz, merry-go-rounds

3. Do you know of any patient(s) in your clinic in any kind of community-based financial group(s)?
   If **NO** move to next question
   If **YES** continue with probes
   Probes:
   - Provide a small description about the group(s)
   - What is the role of the group(s)?
   - How are patients in these groups different from patients who are not in any group?

4. What do you think about patient's participation in community-based financial group(s) (including GISE, chama cha mama toto, joywo)?
   Probes:
   - What are the advantages of patients participating in community-based financial groups? (explore positive aspects on social, economic and health outcomes)
   - What are the disadvantages of patients participating in community-based financial groups? (explore negative aspects on social, economic and health outcomes)

Perception about care delivery beyond the health facility

5. What is your perception about delivering care to patient(s) outside the health facility?
   Probes:
   - What kind of care would you deliver?
   - For what kind of diseases?
   - How would you deliver this care?
   - Where would you prefer to deliver this care?
   - What are the advantages of delivering care to patients outside the health facility?
   - What are the disadvantages of delivering care to patients outside the health facility?

Integrating HIV care into community-based groups

6. What do you think about the idea of delivering HIV care to microfinance groups in the community as opposed to providing care at the health facility?
   Probes:
   - Why do you feel this way?

7. What do you think are the advantages of delivering HIV care to microfinance groups at the community level as opposed to providing care at the health facility?
   Probes:
   - Advantages to the patient (patient health outcomes, efficiency of care, quality of care)
   - Advantages to the provider at the facility level (efficiency of delivery, quality of care)
   - Advantages to the provider at the community level (efficiency of delivery, quality of care)

8. What do you think are some the challenges with delivering HIV care to microfinance groups at the community level as opposed to offering care at the health facility?
   Probes:
   - Challenges to the patient (patient health outcomes, efficiency of care, quality of care)
   - Challenges to the provider at the facility level (efficiency of delivery, quality of care)
   - Challenges to the provider at the community level (efficiency of delivery, quality of care)

9. How is delivering HIV care in microfinance groups different from providing care for other chronic diseases?

10. What do you think would make delivering HIV care to microfinance groups successful at the community level?
    Probes:
    - What kind of services should be delivered?
    - Who should deliver the services within the groups?
    - What would be the qualification of the providers who deliver care at the community level? (academic and personality traits, relationship to community)
    - What would be the composition of microfinance care groups? (Gender, Number, Disease/Health status)

- How often would the patients need to be seen at the facility?
- What could be done to ensure patient data collected at the community is captured by the AMPATH program?
- What could be done to make delivering HIV care to microfinance groups sustainable?

Perceived patient perspective

11. What concerns do you think patients may have about integrating HIV care into microfinance groups?
    Probes:
    - What do you think they may like about this integrated care model?
    - What do you think they may dislike about this integrated care model?

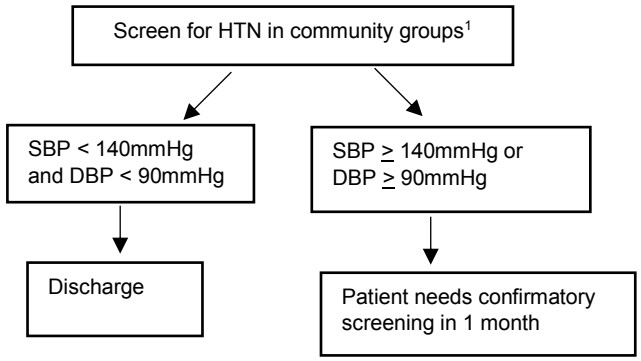
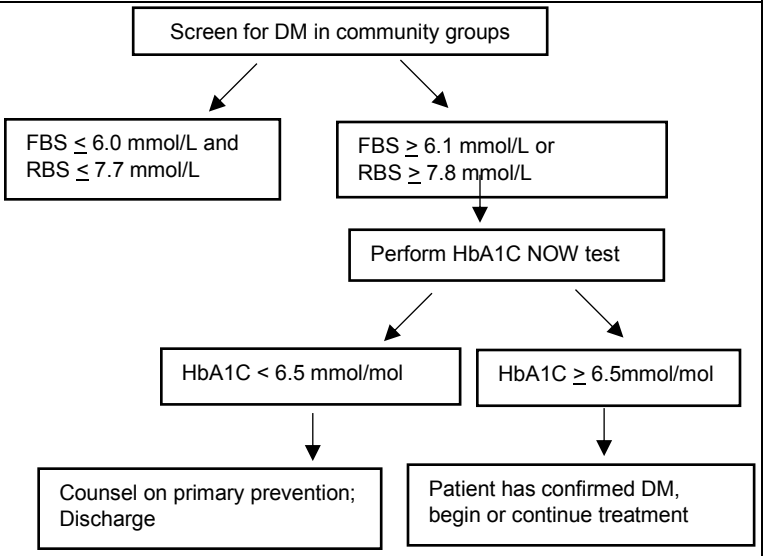
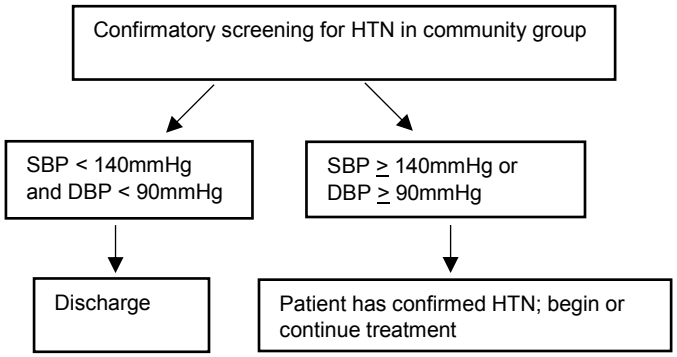
Additional comments

12. Is there anything else that is important for me to understand about community-based care delivery from your perspective? How about microfinance groups? How about the integration of HIV care into microfinance groups?

Closing: *Thank participant for their time. Remind participant about the confidentiality of the interview. Ask if they have any questions about anything that was discussed.*

EXAMPLE: Thank you for your time and for sharing your thoughts with us. We want to remind you that your comments will remain confidential. Do you have additional questions or comments?

Appendix VIII: NCD screening protocol at study baseline (implemented in all microfinance groups (Study Arms A and B))

<table>
<tr><th></th><th>Hypertension (HTN)</th><th>Diabetes (DM)</th></tr>
<tr><td>Screening (study baseline)</td><td> 
</td><td> 
</td></tr>
<tr><td>Screening (confirmatory after 1 month)</td><td> 
</td><td>1-month confirmatory screening not required</td></tr>
</table>

SBP: systolic blood pressure; DBP: diastolic blood pressure; FBS: fasting blood sugar; RBS: random blood sugar; HbA1C: hemoglobin A1C.
Screening for hypertension and diabetes was conducted in the community for all microfinance group members randomized to standard, facility-based (usual) care and to microfinance group members randomized to the integrated, community-based care intervention.

Addendum to the overall project protocol

This addendum summarizes changes that were made to the overall project protocol after the start of Aim 1 data collection on November 25, 2020.

1. The eligibility criteria in the original project protocol required that a group had to be an active, AMPATH-affiliated Group Integrated Savings for Health Empowerment (GISHE) group in order to enroll in the study. This criterion was revised during the recruitment period such that any active, community-based microfinance group (GISHE and non-GISHE) were eligible to enroll in the trial as long as a majority of their members received HIV-related care at an AMPATH facility. This change was made to maximize sample size given that many GISHE groups had transitioned to community ART groups at the time of study recruitment.

2. The original protocol stated that, among microfinance groups randomized to the intervention arm, integrated community-based care visits would occur monthly during months 1-6 of the trial and then quarterly for the remaining months (i.e., months 7-18 of the trial).

   Starting in October of 2021, integrated care visits were no longer delivered monthly during months 1-6 of the trial, and instead were delivered less frequently during months 1-6. Specifically, microfinance group enrollment and follow-up occurred in four phases, such that:
   - Phase I intervention groups in Busia and Trans Nzoia County received monthly visits during months 1-6 of the trial, and quarterly visits thereafter (in accordance with the original protocol).
   - Phase II intervention groups in Trans Nzoia County received monthly visits during months 1-6 of the trial, and quarterly visits thereafter.
   - Phase II, Phase III and Phase IV intervention groups in Busia County received monthly visits during the first three study visits (i.e., months 0 - 2 of the trial), and quarterly visits thereafter (i.e., from months 3 – 18).

   This change to the intervention delivery schedule was made to reduce administrative burden on clinical officers and study staff traveling to remote community meeting locations. Quarterly (rather than monthly) visits were still in keeping with AMPATH care protocols which most commonly recommend quarterly ART distribution for clinically stable HIV patients.

3. The original project protocol stated that integrated community-based care would be delivered to intervention groups at monthly microfinance group meetings by a clinical team comprised of the same cadre of workers who deliver care in AMPATH-supported facilities (clinical officer, pharmacy technician, peer navigator, social worker).

   The protocol was revised after the start of enrollment (in November 2020) and prior to the start of the first integrated care visit in the community (in May 2021) such that solely a clinical officer attended each integrated care visit. This change was made to minimize the amount of attention drawn to intervention recipients during study visits in the community (e.g., to help minimize the potential for HIV-related stigma), to have community-care visits more closely mimic the personnel present during facility-based HIV visits, and to minimize administrative costs. The change was also made based on recommendations from AMPATH leadership and Ministry of Health personnel working in the respective study counties; these personnel suggested having minimal care personnel travel to the community as a way to minimize administrative costs and increase the likelihood the established HIV care and CDM programs would be able to take over the intervention model after study completion.

The clinical officer who delivered community-based care worked closely with facility-based personnel, including a pharmaceutical technician (helped with packaging of drugs), retention worker (assisted with tracking down lost-to-care participants), other facility-based clinical officers (received participants who were referred back to facility for emergencies, released participants who were eligible for community-based care), health records officers (facilitated access to patients records for data entry and/or retrieval as needed). For all microfinance groups, a phlebotomist attended the 18-month study visit in the community to collect blood samples to assess the study's primary outcome.

4. The original project protocol assumed that attending routinely scheduled microfinance group meetings would serve as a sufficient, built-in incentive for remaining engaged in the study and attending study visits. However, the study received Moi University Institutional Research and Ethics Committee (IREC) approval on April 20, 2021 to provide an inconvenience fee of 300 KES (~$2.5) for each survey assessment that enrolled study participants completed during the randomized trial. The study received IREC approval on April 20, 2021 to provide an inconvenience fee of 300 KES as well as lunch/refreshments to study participants and key stakeholders who participated in the Aim 2 in-depth interviews. The provision of inconvenience fees aimed to maximize retention and increase equity in human subjects research.

5. The original project protocol stated that the *primary* endpoint was achievement of HIV viral suppression (HIV-RNA <400 copies/mL) at 18 months. The definition of the primary endpoint was changed such that patients whose 18-month viral load assessment was before January 1, 2023 were considered virologically suppressed if their viral load was <400 copies/mL, and patients whose 18-month viral load assessment was on or after January 1, 2023 were considered suppressed if their viral load was <200 copies/mL. This change to the primary endpoint definition was made to reflect changes to Kenya's national recommendations for HIV monitoring cutoffs that took effect in August 2022 during the active follow-up period.

6. The original project protocol stated that blood draws for viral load assessments (primary outcome) would be ascertained for all participants during their 18-month study visit. This protocol was revised such that if a participant had a viral load result available in their medical records within the 3 months prior to their 18-month assessment date, then this result was used to assess their 18-month viral load. This change was made to reduce burden on participants by preventing them from having to provide multiple blood samples within less than 6 months of one another, and to conserve administrative resources and phlebotomist effort.

7. The original project protocol stated that the secondary endpoints of (1) absolute mean change in systolic blood pressure and (2) absolute mean change in HbA1c level from 0 to 18 months would be assessed among all enrolled trial participants. This was revised such that the secondary endpoints of (1) absolute mean change in systolic blood pressure and (2) absolute mean change in HbA1c level were only assessed among members of randomized microfinance groups, and were not assessed among matched standard of care patients. This change was made primarily to reduce administrative and logistical burden on the research team. After beginning the matching process, many of the eligible, matched standard of care patients were patients of health facilities that were distinct from those where the majority of microfinance group members received care. For several matched patients, they were the only Harambee participant who was a patient of that health facility. Thus, the human

and capital (e.g., fuel) resources needed to travel to the distinct health facilities to ascertain secondary outcome data for each matched patient were prohibitively high.

8. In order to enroll 300 patients receiving standard facility-based care and not engaged in a microfinance group (SOC), the original protocol stated that enrolled microfinance group participants should be matched 3:1 to eligible SOC patients on county, gender, age (+/- 5 years), and health facility. The matching protocol was revised on February 8, 2022 such enrolled microfinance group participants were matched 3:1 to eligible SOC patients on gender and age (+/- 5 years of microfinance participant). This change was made because most SOC patients who were invited to enroll in Busia County after February 8, 2022 were ineligible for study participation due to membership in either a microfinance group or a community ART Group. This change resulted in approximately 90 enrolled microfinance group members in Busia County being matched to 30 SOC patients in Trans Nzoia County on (1) age (within +/- 5 years of the GISHE participant's age) and (2) gender.

9. The original project protocol stated that group randomization would occur using a computer-generated sequence to randomize microfinance groups to receive either integrated community-based care (ICB) or standard of care, and that the randomization process would be conducted centrally by biostatisticians at Brown University.

   The cluster randomization approach was revised to use a transparent, community-engaged approach to increase transparency and cultivate trust between research personnel and study participants, clinical personnel, and local community leaders. Below is a summary of the steps that were implemented for at each community-engaged randomization ceremony. Six randomization ceremonies were conducted among the 57 microfinance groups following enrollment:
   - 2 randomization ceremonies each with 10 microfinance groups were conducted in Phase I groups
   - 2 randomization ceremonies each with 11 and 8 microfinance groups were conducted in Phase II groups
   - 1 randomization ceremony with 15 microfinance groups was conducted in Phase III groups
   - 1 randomization ceremony with 3 microfinance groups was conducted in Phase IV groups

   The below steps describe the community-engaged randomization process.

   Participants
   1. Group leaders (Chairperson, Secretary & Treasurer)
   2. AMPATHPlus Senior Technical Officers (STO)
   3. AMPATHPlus Program Officers (PO) (Sub-counties represented)
   4. Facility-in-Charge (Respective health facilities)
   5. (S)CASCOs (MoH county and sub counties represented)
   6. Retention Officers (Respective Health Facilities)
   7. Research Team (Research Coordinator/Assistant, FPI Officer, CO, Data Assistant, Project Manager)

   Prior to exercise
   1. Project manager worked with the Research Coordinator/Assistant to identify eligible groups based on recruitment data as well as follow-up data to ensure groups still meet the eligibility criteria.

2. Groups were selected based on, (1) sub-counties with the majority of groups, (2) number of consented group members. 10 groups were selected in Busia County and another 10 groups were selected in Trans Nzoia County
3. An appropriate time, date and venue for the exercise was set. The venue was chosen based on the facility where majority of consented participants seek HIV care. Research Coordinator/Assistant worked with the health facilities to secure a venue.
4. The project manager invited the MoH and the AMPATHPlus teams while the Research Coordinator/Assistant invited the group leaders
5. All parties acknowledged having received the invitation and confirmed attendance

Randomization exercise

1. STO/PO opened the meeting and introductions were done.
2. Project manager did a recap of the study aims and study procedures with an emphasize on the fact that this is research and therefore we do not know whether one arm is better than the other. She also capitalized on the similarities between study Arms A and B which included all groups having access to the services of the FPI officer, Screening for NCDs at baseline, Receiving a bucket and handwashing soap from the study.
3. Project manager explained what randomization is and how it was going to be conducted.
4. Project manager asked the group leaders to choose which side of the coin represents Study Arm A and which one represents study Arm B.
5. Chairpersons from each group were invited to the stand around the table, they were asked to select one representative to flip the coin who then went ahead to flip the coin to determine which label i.e. ("1" or "2") falls under study arm A or B.
6. 5 raffle tickets were labeled "1" & another 5 were labeled "2".
    a. Raffle numbers "1" and "2" will correspond to Study Arm A or B depending on the outcome of the flipped coin.
7. In each county, 10 group leaders from each of the 10 GISHE groups took turns selecting a raffle ticket.
8. The group leads then held onto their tickets until all the leads had picked their ticket.
9. Once all the leads had a ticket, the leads opened their tickets together and show them to the community attendees.
10. The raffle tickets were randomized into the respective Study Arms based on the label as aforementioned in 6a
11. Group leads were congratulated and given a chance to ask questions/seek any clarifications

Post Randomization

1. Project Manager communicated the randomization outcomes to the larger research team.
2. Group representative (group leads) present during the randomization communicated the randomization outcomes to their respective groups.
3. Align the Return to Care (RTC) dates for all the Study Arm A members.

10. The original Aim 1 analysis plan for the primary outcome (virologic suppression) that is summarized in section 7.2 of this protocol and in the published protocol (Genberg BL et al. Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial. BMJ Open. 2021 May 18;11(5):e042662. doi: 10.1136/bmjopen-2020-042662.) was revised. Details of the revised analysis plan, and reasons for the revision(s), are described in the following paragraphs.

Revised Analysis plan

Primary objective: Compare rates of viral suppression between the MF+ICB and MF+UC arms.

Secondary objective 1: Compare rates of viral suppression between the MF+ICB and UC arms.

Secondary objective 2: Compare rates of viral suppression between the MF+UC and UC arms.

Primary outcome definition: Achievement of HIV-1 RNA viral load suppression at 18-months. Participants whose 18-month viral load assessment occurred before January 1, 2023 were considered virologically suppressed if their viral load was <400 copies/mL. To adhere to changes to Kenya's national recommendations for HIV monitoring cutoffs that occurred during the trial, patients whose 18-month viral load assessment was on or after January 1, 2023 were considered suppressed if their viral load was <200 copies/mL.

Analysis set: The analysis set for all objectives is the intent-to-treat set and included all randomized participants for arms MF+ICB and MF+UC and all participants that in the UC arm that provided informed consent.

Analysis plan for the primary objective: The analysis of the primary objective was conducted using a doubly robust generalized estimating equation with a logit link function accounting for potentially differential dropout as described in Prague M et al.[7] The generalized estimating equation model included the intervention arm, used an independence working correlation matrix and the variance was estimated using a sandwich variance estimator for clustered data. The intervention effect was estimated using the log odds ratio coefficient of intervention in the generalized estimating equation. The primary hypothesis test of the intervention effect was conducted using a Wald test and 95% Wald-based confidence intervals were calculated.

Handling of dropout: Implementation of the method proposed in Prague M et al.[7] relies on specifying a model for the dropout probability and two outcome models (one for each treatment arm). For the method to be a valid way to handle dropout, either the model for the dropout probability or both outcome models need to be correctly specified. The model used for the dropout probability was a logistic regression model with linear main effects of county, treatment arm, log(viral load at baseline+1)), schooling achieved, age, and gender. The model used for the outcome model in the MF+ICB was a logistic regression model with linear main effects of county, log(viral load at baseline+1)), schooling achieved, age, and gender and the model used for the outcome model in the MF+UC was a logistic regression model with linear main effects of county, log(viral load at baseline+1)), schooling achieved, monthly income, age, and gender. Monthly income was only used in one of the models due to instability of the model fitting when it was added to the other models. The dropout weights were well behaved with the largest weight being 1.42; therefore, we did not experience any extreme weights and hence made no adjustments to account for them.

Handling of missing data: Multiple imputation was used to account for missing data on baseline covariates and Rubin's rule for variance estimation was used for variance estimation.

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[7] Prague M, Wang R, Stephens A, Tchetgen Tchetgen E, DeGruttola V. Accounting for interactions and complex inter-subject dependency in estimating treatment effect in cluster-randomized trials with missing outcomes. *Biometrics*. Published online 2016. doi:10.1111/biom.12519

Stability analysis: We performed stability analysis to determine how sensitive the results were to different specifications of the model used in the implementation of the doubly robust generalized estimating equation. This was done by modeling continuous covariates using second order polynomials and including interactions between the covariates. The results were similar to what is presented in the main manuscript.

Analysis plan for secondary objectives: The analyses of both secondary objectives were conducted using a doubly robust generalized estimating equation with a logit link function accounting for potentially differential dropout and confounding[8]. The generalized estimating equation models included the intervention arm, used an independence working correlation matrix and the variance was estimated using a sandwich variance estimator for clustered data. The intervention effects were estimated using the log odds ratio coefficient of intervention in the generalized estimating equation. The primary hypothesis tests of the intervention effects were conducted using a Wald test and 95% Wald-based confidence intervals were calculated.

Handling of confounding and dropout: Implementation of the method relies on specifying a model for the dropout probability and two outcome models (one for each treatment arm) and these procedures account for both dropout and confounding (under the assumption of no unmeasured confounding and a non-informative dropout). All three models were logistic regression models with linear main effects of county, log(viral load at baseline+1)), schooling achieved, age, and gender and the model for dropout probability also included the treatment arm.

Handling of missing data: Multiple imputation was used to account for missing data on baseline covariates and Rubin's rule for variance estimation was used for variance estimation.

Rational for revisions to original analysis plan:

We modified the primary outcome definition without looking at the data and to be in compliance with national guidelines that changed during the study's follow-up period. As a sensitivity analysis we reran the analysis with the current definition of viral suppression (i.e., <200 copies/mL) used for all participants, and the results were very similar to what the primary analysis shows.

The original analysis plan used a generalized linear model as the primary analysis method. The change in the analysis plan was made without looking at within arm data, but was made after the high rate of viral suppression was known (i.e., overall outcome prevalence was known but no between arm comparisons had been done). The reason for the change was: We have partially clustered data as the individuals in Arms MF+ICB and MF+UC are in clusters while participants in the UC arm are not. The mixed effects model requires correct specification of the distribution assumptions of random effects while the GEE does not. As verifying the distribution assumptions on people in a single cluster is impossible, we thought a GEE would provide a better approach. A recent manuscript[9] compared methods for analyzing partially clustered data and concluded "Analysis of partially clustered trials using GEEs with an independence working correlation structure may be preferred to avoid the limitations of mixed models and exchangeable GEEs" further supporting the change (this was published after the decision was made to change the analysis method).

[8] Prague M, Wang R, Stephens A, Tchetgen Tchetgen E, DeGruttola V. Accounting for interactions and complex inter-subject dependency in estimating treatment effect in cluster-randomized trials with missing outcomes. Biometrics. Published online 2016. doi:10.1111/biom.12519

[9] Lange, K. M., Sullivan, T. R., Kasza, J., & Yelland, L. N. (2024). Performance of mixed effects models and generalized estimating equations for continuous outcomes in partially clustered trials including both independent and paired data. Statistics in Medicine.

11. The original definition of the Aim 1 secondary outcome (retention in care) that is summarized in section 3.4 of this protocol and in the published protocol (Genberg BL et al. Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial. BMJ Open. 2021 May 18;11(5):e042662. doi: 10.1136/bmjopen-2020-042662.) was revised. Specifically, the secondary endpoint was revised to be measured as a binary variable (rather than as a proportion). The revised endpoint defined a participant as always retained in HIV care if they attended at least one HIV care visit in each quarter a visit was scheduled, where attending a visit was defined as attending a visit within +/- 28 days of their scheduled visit date. This revision was made to prevent potential measurement bias between the study arms given that some community care recipients had more frequent care visits during the first 6 months of the trial as compared to facility (standard) care participants.