Integrating Community-Based HIV and Non-Communicable Disease Care with Microfinance Groups: A Formative Study in Western Kenya

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Abstract

Background: The Harambee Study is a cluster randomized trial in western Kenya that tests the effect, mechanisms, and cost-effectiveness of integrating community-based HIV and non-communicable disease (NCD) care with group microfinance (MF) on HIV treatment outcomes. This paper documents the formative work to: (1) identify, enumerate, and characterize existing community-based microfinance groups to refine the study's eligibility criteria, and (2) elicit support from multi-sectoral stakeholders in preparation for trial start.

Methods: This mixed methods formative research took place between November 2019 and February 2020 in western Kenya. Surveys were administered to 115 group leaders of community-based MF groups. Field notes and GPS coordinates of group meeting locations and HIV healthcare facilities were also taken. A further 28 in-person meetings and two workshops involving stakeholders from multiple sectors of the health system took place throughout the formative phase. Quantitative survey data was analyzed using STATA IC/13. Longitude and latitude coordinates were mapped to County boundaries using Esri ArcMap. Qualitative data obtained from the meetings and field notes were analyzed thematically.

Results: A total of 105 community-based microfinance groups were reached and 77 were eligible for the study. Of the eligible groups, we found differences in terms of definition of active membership, microfinance models, meeting location, and meeting frequency. Despite these differences, all the groups had an annual cycle period. Predominant themes emerging from the minutes and field notes revealed enthusiasm and support for the intervention among key stakeholders. Key stakeholders expressed a desire to have interventions integrated into the AMPATH care model for sustainability after the study period. Continuous engagement of various stakeholders, collaboration on various aspects of the study, identification of areas that could potentially lead to conflict, and overall increased transparency were identified as crucial to this integration.

Conclusions: For randomized controlled trials (RCTs) conducted in rural communities, formative research is essential for pre-determining eligibility, mapping implementation sites and eliciting buy-in from community leaders. Adaptations identified from formative work should be addressed prior to study start.

Trial registration: NCT04417127. Registered 4 June 2020 - Retrospectively registered, https://www.clinicaltrials.gov/ct2/show/NCT04417127

Key Messages Regarding Feasibility

- For this randomized controlled trail, the key uncertainties existing regarding its feasibility were to identify existing community-based microfinance groups that were eligible for our study and to understand the group dynamics as well as to elicit support among multi-sectoral stakeholders in preparation for trial start
- Of the105 community-based microfinance groups reached, 77 were eligible for the study. Among the eligible groups, we found differences in terms of definition of active membership, microfinance

models, meeting location, and meeting frequency. In addition, key stakeholders expressed a desire to have interventions integrated into the AMPATH care model for sustainability after the study period.

- The formative work confirmed some of the original study implementation strategies such as use of the HIV care protocols and the NCD care protocols as well as the implementation of an app-based bookkeeping system to help the groups manage their financial records better. However, it also suggested several important changes to the study design including the need to review its inclusion criteria at both the group and individual levels as well as the need for a study larger team and collaborations between the study and the AMPATH care program.

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. Retention in care remains a challenge in sub-Saharan Africa (1), where only 50% of PLHIV are virally suppressed (2). Lack of transport, food insecurity, lack of social support are some of the individual factors that contribute to poor viral suppression and retention in care (3). At the facility level, disproportionate provider-patient ratio, poor provider-patient dynamics, inefficient vertical care delivery, have also been shown to result to poor health outcome among PHLV (4, 5). Defining multilevel interventions that address these barriers to viral suppression is critical to achieving the 90-90-90 WHO goals (6). Rigorously tested differentiated HIV care packages are urgently needed to sustain viral suppression among PLHIV.

As PLHIV are living longer due to ART, the burden of non-communicable diseases (NCDs) among PLHIV is also increasing (7–10). This necessitates the integration of HIV/NCD care in order to collectively address the increasing number of HIV patients requiring NCD care (9, 11, 12). Previous studies in Kenya have successfully implemented an integrated community-based HIV, diabetes and hypertension program through adherence clubs (13, 14). However, the impact of this integrated care approach on clinical outcomes has not been well documented (13, 14). Innovate studies that assess the impact of integrated HIV/NCD care on patient health outcomes are urgently needed. This should be done considering the social and economic burden facing a considerable number of patients across the region.

We proposed a randomized control trial – *Harambee: Integrated Community-based HIV/NCD Care & Microfinance Groups in Kenya* (ClinicalTrials.gov Identifier: NCT04417127) – to demonstrate the effectiveness and sustainability of an innovative differentiated HIV and NCD care delivery model. The trial aims to collectively improve patient HIV treatment outcomes while addressing non-communicable chronic disease care needs within community-based microfinance groups (15). The specific aims of the *Harambee* study are to: (1) 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, (2) identify specific mechanisms through which microfinance and integrated community-based care impact viral suppression, and (3) assess the cost-effectiveness of microfinance and integrated community-based care delivery to maximize future policy and practice relevance of this promising intervention strategy.

This paper describes the methods used to conduct a formative evaluation in preparation for the start of the *Harambee* cluster randomized trial. Formative research is an essential component of rigorous implementation science in general; within the specific lens of HIV treatment and prevention interventions, “formative evaluation relates to assessment conducted prior to the intervention that is used in guiding the design of the evaluation in terms of content, audiences, messages, logistics, and related factors” (16). Thus, the aim of this paper is to document the formative work conducted prior to implementation of the *Harambee* trial, including (1) identifying, characterizing, and enumerating existing community-based microfinance groups that met the study’s eligibility criteria, and (2) creating awareness among multi-sectoral stakeholders in preparation for trial start.

Methods

Setting

The Academic Model Providing Access To Healthcare (AMPATH) is a joint partnership between Moi University School of Medicine, Moi Teaching and Referral Hospital, and a consortium of North American academic medical centers universities led by Indiana University and including Brown and University of Toronto (17). Established as an HIV care system, AMPATH currently serves over 150,000 HIV-positive patients in 800 Ministry of Health [MoH] facilities across 10 counties in western Kenya with all HIV care and treatment being provided free of charge (18). Over the years, AMPATH, in cooperation with the Kenyan MoH, has taken a comprehensive, integrated, community-centered, and financially-sustainable health care delivery approach that is responsive to the needs of the entire population (17). For instance, in response to the substantial and growing burden of diabetes mellitus (DM) and hypertension, AMPATH formed a Chronic Disease Management (CDM) program (19, 20) and a reliable supply chain system for hypertension and diabetes medications (21). Furthermore, to address patient’s economic security needs, AMPATH created the Family Preservation Initiative (FPI) program which supports patients to earn a sustainable source of income through skills training, microcredit, agribusiness support, a fair-trade-certified crafts workshop and agricultural cooperatives (22). FPI has been able to form more than 1349 community-based microfinance groups (with over 27,249 people) as part of *Group Integrated Savings for Empowerment* (GISE). The FPI program works with trained Group Empowerment Service Providers (GESPs) at the community level to form, train and continually offer needed support to the community-based GISE groups. GISE group members mobilize and manage savings and provide interest-bearing loans to members without a requirement for collateral. All members of the group are encouraged to save some money at each meeting and contribute nominal fee to create a social fund to cover unanticipated emergencies or welfare issues of group members (23). Initially starting with HIV patients, GISE groups have expanded to include pregnant women (24), patients with DM and hypertension (19, 23) as well as community members living in AMPATH’s catchment areas. The expansion of the GISE groups offer a unique opportunity to provide critical HIV and NCD care to new, rural populations with minimal financial impact (25).

Harambee Study Design

The Harambee Study is a randomized controlled trial that will use a cluster randomized controlled design to perform a pragmatic evaluation of integrated community-based care incorporated into existing microfinance (MF) groups located within two study sites in western Kenya: Busia County and Trans Nzoia County. The study will include three distinct study arms; Study Arm A, Study Arm B and Study Arm C. (Figure 1)

Study Arm A participants will receive the integrated community-based care (ICB) intervention during regularly scheduled MF group meetings. The intervention will include; (1) integrated care visits by clinical teams which will entail vital signs screening, consultation with a clinical officer, medication distribution (ART and medications for other chronic and acute conditions), and point-of-care laboratory testing (creatinine, blood glucose, hemoglobin A1C, and viral load), (2) peer support during every monthly MF meeting and, (3) referrals to facilities for emergency or acute care needs that cannot be addressed in the community. *Study Arm B* participants will meet as usual in their MF groups and will continue to receive regular standard of care from an AMPATH facility. While *Study Arm C* participants will continue receiving regular standard of care from an AMPATH facility and will have had no exposure to AMPATH microfinance groups since enrolling in care.

Formative Study Design

For this formative study, we used a mixed methods approach to identify, characterize, and enumerate existing community-based microfinance groups that met the study's eligibility criteria as well as to describe the process of community entry. Data collection occurred between November 2019 and February 2020.

Data Collection

We used mixed data collection methods to characterize the community-based microfinance groups and to describe the community entry process. Quantitative data was collected using a survey while the qualitative data was collected in the form of field notes from meetings with key stakeholders, including MF group leaders.

Surveys: Based on information provided by the FPI team, we purposively sampled 36 GISE groups (13 in Busia; 23 in Trans Nzoia) in the first phase of the mapping exercise which took place in November 2019. Eligibility criteria included groups: (a) with over 70% of members living with HIV, (b) actively engaged in microfinance activities, (c) met at least once in the last six months, (d) whose members seek care at an AMPATH health facility and (e) not enrolled in any Community ART Group (CAG). A second phase of the mapping exercise took place between January and February 2020. During this phase, information from the AMPATH retention department and the Community Health Volunteers (CHVs) in the various community units within the AMPATH catchment areas was used to purposively sample an additional 79 (39 in Busia; 40 in Trans Nzoia) community-based HIV support groups that engage in microfinance activities.

We used GESPs and CHVs to obtain the names and contact information of group leads, specifically the chairperson, secretary and treasurer. We worked with GESPs and CHVs on basis of their knowledge, experience and good working relationship with GISEs and community-based HIV support groups respectively. The GESPs and CHVs introduced the study's research assistants to the group leaders and an interview date was set. Verbal consent was obtained and researcher-based questionnaires were administered to the group lead. The group chairperson was the preferred candidate to respond to the survey, but on occasions where they were unavailable, the questionnaire was administered to the group secretary or treasurer. The questionnaire was programmed into RedCap® with 16 questions, which focused on group characteristics, group activities and HIV care.

The surveys were conducted by trained research assistants at the group's meeting location for the purposes of retrieving the GPS coordinates of group meeting locations. To ensure privacy and confidentiality, the surveys were conducted in the group's meeting room with only the research assistant and the group lead present. Upon completion of the interview, the research assistants traveled to the health facility mentioned by the group lead as the facility where most group members seek HIV care services to collect the GPS coordinates of the facility. Only one facility per group was entered into RepCap®. The GPS coordinates were then used to examine the distance between group meeting location and health facilities where members seek HIV care services. Each survey took between 30-45 minutes.

Field notes: Field notes were taken during the survey sessions to record any information that could not be captured in Redcap®. Notes of matters beyond the survey such as topography, challenges faced before and after the surveys, as well as opportunities spotted, were taken.

Meetings: A series of in-person meetings involving a stakeholders from multiple sectors of the health system took place throughout the formative study. (Table 1) Stakeholders included the AMPATH care program management, AMPATH Chronic Disease management, AMPATH care program county-based management teams; County-based MoH officers and other HIV donor funded programs working within the select counties. Initial predominantly face-to-face meetings provided an opportunity to introduce the study aims and scope. Follow-up meetings focused on updating the stakeholders on the progress of the social mapping including the successes and the challenges. Finally, the AMPATH care program team at the county level was invited to a workshop with discussions centered on: feedback from the survey, review of study documents and tools, and review of the intervention design. All meetings proceedings were documented in the form of official minutes.

Table 1
Formative research data collection methods

Method	Participants	No. conducted (No. of participants)
Surveys	Community-Based Microfinance Group Leaders (Chairperson/Secretary/Treasurer)	115 (115)
Meetings	AMPATH High-Level Management	1 (3)
	MoH County-Based High-Level Administrators	1 (5)
	AMPATH County-Based High- & Mid-Level Administrators	2 (34)
	AMPATH Chronic Disease Management Team	1 (5)
	NGO Administrators	1 (9)
	AMPATH Family Preservative Initiative (FPI)	1 (7)
Workshops	County-Based MoH and AMPATH High- &Mid-Level Administrators	2 (29)

Analysis

Descriptive statistics and quantitative survey data were analyzed using STATA IC/13 (College Station, TX: Stata Press). Longitude and latitude coordinates of the microfinance groups were mapped to County boundaries using Esri ArcMap. Qualitative data obtained from the meetings and field notes were analyzed thematically with the themes being derived directly from the data. Both the quantitative and qualitative data were triangulated to make strategic decisions about the study design and material content.

Results

Characterizing the community-based microfinance groups

We characterized the groups that we reached in order to identify groups that were eligible for our study and to understand the group dynamics.

Determining eligibility

We reached 105 community-based microfinance groups, 53 groups in Trans Nzoia County and 52 groups in Busia County. The majority (85%) of the groups had at least 70% of their members living with HIV.

Nearly all (98%) of the HIV-positive group members seek HIV care at AMPATH health facilities with very few (1%) groups having enrolled in the Community ART Groups care model at AMPATH.

Most (96%) of the groups engage in microfinance activities; however, a slightly lower number (87%) of the groups had met at least once in the last six months at the time of the survey. Also, only a few groups (9%) had previously participated in research. Table 2 presents a summary of group dynamics with a focus on items related to the inclusion criteria. Overall, 77 groups were eligible for the study: 44 groups in Busia County and 33 in Trans Nzoia County.

Table 2: Group Dynamics

	Trans Nzoia	Busia
Community-based groups	n=53	n=52
Engagement in microfinance activities, n (%)	49 (78)	52 (100)
≥70% of members living with HIV, n (%)	38 (60)	51 (98)
≥one member owns a smartphone, n (%)	30 (48)	35 (67)
Previous participation in research, n (%)	1 (2)	8 (15)
Participation in a CAG, n (%)	0 (0)	1 (2)
Eligible Groups, n (%)	**33 (62)**	**44 (85)**

During the first phase of the survey, we found low HIV status disclosure at the group level within GISEs. This was especially true for Trans Nzoia County where only 11 out of the 23 GISE groups reached had at least 70% of the members disclosing their HIV status to the group. Having started as an initiative to financially empower HIV-positive patients, we expected to find high levels of HIV disclosure within these GISE groups. However, the GESPs revealed that most of the original GISE groups either evolved into mixed groups (i.e. groups with both HIV-positive and HIV-negative individuals) or turned dormant. In these mixed groups, members living with HIV confide in GESPs/CHVs who act as a link between members and the health facility, but they do not disclose their HIV status to the group or any other members within the group. Non-disclosure at the group level was attributed to high levels of stigma and discrimination towards people living with HIV within the community. The majority of the group members reportedly chose to keep their HIV status private to protect their confidentiality as well as to ensure cohesion, as most members do not want to be associated with HIV. Therefore, in mixed groups, HIV disclosure at the group level could influence the sustainability of the groups. Overall groups reported a well-defined leadership structure at the group level.

Group dynamics

Upon establishing the 77 groups that were eligible for the study, it was important to understand these groups. We were interested in understanding how the groups define active membership, the kind of microfinance activities that they engage in, how often they engage in these activities, and the group meeting location in relation to the health facility where majority of the group members seek HIV care services.

Defining group membership. MF groups had an average of 22 members per group with approximately 17 active members. Individual groups define active membership differently; however, these definitions can be broadly categorized in three ways. First, an active member is one who attends all the group meetings, remits their savings, takes up loans and repays the loan in a timely manner. Second, an active member can be someone one who attends up to 50 percent of the group meetings and remits their savings or loan repayment in a timely manner. Third, active membership can also mean a member who remits their savings and loan repayment without necessarily attending any group meetings. However, as stated above, some groups had a special category of group members who were not defined as active/inactive members as their sole purpose in the group is to repay a loan that they had defaulted on. For the study, this information is critical towards informing the inclusion criteria for individual participation in the study. While the group inclusion criteria can be based on factors related to the activity of the group as an entity, individual members must also meet specific inclusion criteria in order to be enrolled in the study. If the inclusion criteria allow for variable definitions of individual participation in the group, there would be concerns regarding whether or not individual participants were being exposed to the same intervention across the arms of the study.

Group financial activities. The eligible groups have been in existence for a period ranging from 6 months to 18 years at the time of the survey. All the groups have an annual cycle period during which they engage in various activities with microfinance being the dominant one. The groups have diverse microfinance models. The common microfinance model across the two counties is the table-banking concept where members of a group contribute an agreed minimum amount of money termed as savings during their regular meeting. The funds are pooled for members to take interest-bearing loans based on demand. This goes on for a period of 8-10 months when the lending stops and outstanding loans are repaid in readiness for share out. Share out, which is paying back of savings together with the interest gained from loaning, is done during the 12th month. At the end of the cycle period the savings are paid back, and interest earned is distributed to all members and is proportional to the amounts saved. It is also during this meeting that decisions are made about group membership during the next cycle. (Figure 2) Some groups in Busia County do not share out the savings during their share-out. Instead, they use these funds to make group investments and then share out the income generated over the cycle. While a few other groups across the two counties engage in the merry-go-round concept, where members of the group contribute a fixed amount for a fixed duration and each member is paid the entirety of the collected money on a rotating schedule.

Membership for the next cycle is largely informed by a member's financial record including their ability to save and repay their loan on time. Loan repayment was mentioned as a key contributor to group conflict and disintegration. Different groups handle loan defaulters differently; some groups discontinue defaulters' membership, while others take legal action against them, and yet others retain them in the group for the purposes of recovering the money. Understanding group cycles and how loan defaulters are handled is important for informing the study about retention of study participants during the intervention period. Furthermore, it will be critical for the study to understand the group dynamics and how the composition of group members, the duration of time that the group has been together, and the way that

defaulters are handled may have an eventual impact on not only their financial success as a group but in the ways in which people living with HIV participate in the group influences their engagement with HIV care and treatment over time.

Meeting Frequency and Location. Less than half (40%) of the groups reported monthly meetings; with a considerable number reporting inconsistency in group meetings during certain time periods. Overall, inconsistencies were reported for the month of January in both sites. Further inconsistencies were reported for the months of April/May and September/October which are the planting and harvesting seasons in Trans Nzoia, and the months of May, June and July which is the low fishing season in Busia. This they attributed to lack of funds among members due to loss of income and channeling of finances towards school fees and farming.

The groups reported meeting in different venues. The common meeting location is the group members' homesteads with majority of such groups having rotational meetings from one member's home to another and a few meeting routinely in one member's home. Other groups reported meeting at health facilities and this had three dimensions. One, groups that meet at a local health facility that does not provide HIV care services did so as a measure of protecting individual members HIV status and ultimately avoiding stigma. This was especially true for predominately HIV-positive groups in Trans Nzoia County. Two, some groups meet at a local facility that provides HIV care services even though group members do not necessarily receive their HIV care services in that health facility. Three, groups that meet at a mid-volume or high-volume HIV care facility where the members receive their HIV care. For such groups, they work with the health facility to align their group meetings with their HIV care appointment dates. Mid-volume HIV care facilities are those whose patient population is between 500 and 999 patients, while high-volume HIV care facilities are those whose patient population is more than 1000.

Mapping Group Meeting Location in Relation to HIV Care Health Facilities

Busia County has 45 AMPATH HIV clinics. Groups identified seven facilities as the key facilities where their members seek HIV care services with Port Victoria Sub-County Health Facility being reported as the facility where about a third (32%) of the groups have their members seeking HIV care. All seven facilities mentioned were either mid-volume or high-volume HIV care facilities. The GPS data revealed that groups in Busia country are concentrated around the HIV care facilities. (Figure 3) The mean distance from the groups meeting location to the health facility where group members seek HIV care is 2.84 miles and ranges from 18.32 to 0 miles as illustrated in Table 3.

Table 3: Distance from group meeting location to HIV care Health Facility

Distance (Miles)	Mean	SD	Min	Max
Busia County	2.84	3.15	0	18.32
Trans Nzoia County	3.25	3.32	0	15.52

Among the 55 AMPATH HIV clinics in Trans Nzoia County, 12 were identified as the facilities were group members seek their HIV care with Kitale County Referral Hospital being reported as the health facility were half (50%) of the groups had their members seeking HIV care. This was largely out of fear of being spotted at HIV health facility located near them by people known to them. This has a cost and time implication on these patients as they are required to have regular contact with their HIV care providers. As illustrated in Figure 3, groups meeting locations are widely spread out with majority of the groups meeting in locations situated far from the HIV care facilities. The mean distance from the groups meeting location to the health facility where group members seek HIV care is 3.25 miles and ranges from 15.52 to 0 miles. (Table 3) Overall, we found that majority of the group members across the counties seek HIV care services at high-volume (53%) or mid-volume (32%) AMPATH health facilities. Mapping the groups meeting locations in relation to the health facilities where group members seek HIV care is vital in informing the study on the county-based health facility to station the study's clinical team. Clinical teams will be based at the health facility where majority of the group members seek HIV care.

Smartphone ownership

Of the eligible groups surveyed, 64% had at least one member who owned a smartphone. Having access to smartphone technology would enable the groups to use apps and mobile banking services for tracking their group finances. In addition, given the challenges associated with COVID-19, having members connected by smartphone would enable continuation of many group activities during social distancing measures. Assessment of smartphone ownership is key to informing decisions on mechanisms of group microfinance data collection during the intervention.

Community entry

Overall, we held 28 face-to-face stakeholder meetings and 2 stakeholder workshops. (Table 1) Minutes from these meetings and workshops together with field notes from the survey revealed three two major themes; (1) perception of the intervention, and (2) integration of the intervention into the AMPATH care model.

Perception of intervention

Group leaders, GESPs, CHVs and the key stakeholders in the health system expressed enthusiasm and support for the intervention. At the facility level, the intervention was perceived as having the potential to significantly improve patient's retention in care and viral load suppression as it addresses barriers related to distance, congestion at the clinic and provider-patient relationship dynamics. Furthermore, this intervention provides for community viral load testing, an innovation that the AMPATH care team expressed desire to learn more about and possibly adopt in the future so as to fully achieve a community differentiated care model. The current AMPATH differentiated care model requires patients to visit the health facility annually or semi-annually for purposes of viral load testing.

At the community level, the intervention was perceived as additional support to HIV patients. Group leaders GESPs, and CHVs reported that there are rising cases of non-communicable diseases in the community thus the idea of a community-based integrated care model was highly welcomed. Furthermore, the frequent group visits by health care providers is perceived as an opportunity to closely monitor HIV patients and to offer groups education on HIV management to dispel prevailing myths and misconceptions.

Group leads gave suggestions on maximizing the potential of this intervention. On the health care component, they suggested inclusion of cancer screening and especially cervical cancer within this community-based integrated care model. While on the microfinance component, they reported not feeling adequately equipped to make best use of their group savings despite having received some form of training on microfinance management. They therefore suggested that the intervention provides training and mentorship on various aspects: predominantly group investment, investment diversification and handling defaulters. This information is crucial in the development of financial literacy training materials that are reflective and more responsive to the needs of the target groups. These financial literacy sessions which will be conducted throughout the 18-month intervention period, will be designed to fill in the notable gap in group knowledge, skills and efficacy related to managing and controlling finances. This will not only enhance the groups' capacity for saving and/or investing but also their retention in the study, especially for the control arm participants.

Integration of the intervention into the AMPATH care model

Key stakeholders expressed a desire to have this intervention integrated into the AMPATH care model for ease of transition after the study period. This, they said, can only be realized through continuous engagement of various stakeholders at the county and headquarters levels, collaboration on various aspects of the study, identification of areas that could potentially lead to conflict, and overall increased transparency.

Opportunities to collaborate: Collaboration was viewed as an avenue for fostering ownership, ultimately influencing the success of the intervention. The study was urged to use existing structures such as the National HIV and NCD protocols, AMPATH motorcycle riders used for transporting blood samples in Trans Nzoia County, AMPATH pharmaceutical technologists within the two sites and AMPATH's laboratory to avoid creating a parallel program. The study was further urged to employ a clinical team with experience working within the AMPATH care program. This team together with all other study employees working at the county level will report to the AMPATH county administrators and project manager.

Potential Challenges: Stakeholders flagged areas that could potentially pose challenges to the intervention. First, facility in charges, program officers and county administrators expressed concerns over the microfinance component in community-based HIV care groups. This, they perceived, has had a negative influence on patient's HIV care in the past with patients who default on repaying their loans in such groups dropping out of HIV care in fear of being tracked at the health facility by group members. Secondly, there were fears among county administrators and county Medical Officers that the study

might encroach on existing studies and/or partner projects. However, meetings with these groups revealed that partner projects were targeting a different category of HIV patients while the Chronic Disease Management (CDM) studies were focusing on health system strengthening through empowering local health facilities to provide CDM. Thirdly, stakeholders were not confident with clinicians' ability to draw blood for VL testing as it had been proposed in the study protocol. This they attributed to clinician's lack of experience in this area. They recommended having phlebotomists as part of the study's clinical team. Finally, there were concerns about the study's inclusion/exclusion criteria with stakeholders urging the study to follow National HIV Guidelines on Community-based ART Groups. These guidelines state that virally unsuppressed patients and pregnant women should be exempted from the community-based ART groups. They further urged the study team to widen its scope to include PMTCT mothers as well as children and adolescents living with HIV and their caregivers. They attributed this to the fact that caregivers and children living with HIV are normally given the same return-to-clinic date thus having a caregiver receive HIV care at the community level and then bring the child to the health facility undermines the efforts of community-based HIV care.

Discussion

The formative study brought to light a range of issues, many of which directly influence the planning and implementation of the planned intervention. (Table 4) The formative work confirmed some of the original study implementation strategies such as use of the HIV care protocols and the NCD care protocols, but also suggested several important changes to the study design.

The formative work made it clear that the study needed to review its inclusion criteria at both the group and individual levels. At a group level, the original intent of the study was to enroll predominately HIV-positive GISE groups. However, the formative study revealed that most of these groups have either evolved into mixed groups or turned dormant with very few GISE groups meeting the study inclusion criteria. The study therefore opened up to community-based HIV groups that engage in any type of microfinance activities. These groups further revealed diverse definitions of active membership at an individual level in the group. This information led to a standardized definition by the study team. Furthermore, meetings with the various stakeholders made it apparent that at an individual level, the study must adhere to clinical guidelines for handling unsuppressed patients. This led to the development of a protocol on referring participants who are virally unsuppressed at baseline and those who become unsuppressed in the course of the study to the clinic for follow-up testing and additional adherence counseling, as they would have in clinic-based care.

The study had proposed to have a clinical team comprising of the clinical officers, pharmaceutical technologists, social workers and peer mentors, on a full-time basis. The formative work revealed the need for a larger team and collaborations between the study and the AMPATH care program. The study will employ clinical officers, phlebotomists and FPI officers on a full-time basis. As part of collaboration with the AMPATH care program, the study will use the program's pharmaceutical technologists and county-based riders for transportation of blood samples.

The majority of these groups were lacking adequate financial management skills with groups highlighting areas in which they need support. This information is important for the development of financial literacy materials that will be used to empower the groups through continuous training and mentorship by the FPI officers on the team. Additionally, the majority of the groups having access to smartphone technology validated our plan to implement an app-based bookkeeping system to help the groups manage their records better. They will equally receive training on using the app.

Some of the issues brought to light by the formative evaluation study were beyond the scope of the proposed intervention, and thus will not be considered. These were issues raised by stakeholders in their quest to have the study provide a holistic integrated model. These include the suggested inclusion of procedures such as cancer screening as well as the inclusion of more categories of HIV patients such as PMTCT mothers, and children and adolescents living with HIV.

Table 4
Implications of formative evaluation on planned intervention

Concept	Original Study Criterion	Barrier identified During Formative Evaluation	Opportunity Identified During Formative Evaluation	Criterion Adaptation
Inclusion criteria (Group-level)	Predominantly HIV-positive GISE Groups	GISE groups have either evolved into mixed groups or turned dormant	____	Opening up the intervention to community-based HIV groups that engage in microfinance activities
Inclusion criteria (Individual-level)	HIV-positive adults	National HIV guidelines outline patient's eligibility for participation in Community-based ART groups	____	(1) HIV-positive. However should: -be virally suppressed -not be pregnant -not be a member of a CAG -have no active opportunistic infection/other serious comorbidity such as cancer. (2) Development of a protocol on handling virally unsuppressed participants
Definition of active membership at the group level	Have participated in at least one microfinance group meeting in the prior 12 months at study baseline	Groups define active membership differently	____	Have participated in at least one microfinance group meeting in the prior 6 months at study baseline

GISE: Group Integrated Savings for Empowerment [interchangeably also called microfinance groups]; CAG: Community ART Group; CHVs: Community Health Volunteers

Concept	Original Study Criterion	Barrier identified During Formative Evaluation	Opportunity Identified During Formative Evaluation	Criterion Adaptation
Clinical Team	Team to comprise of: clinical officers, pharmaceutical technologists, social workers and peer mentors, on a full-time basis.	Low confidence in clinicians' ability to adequately conduct some procedures such as drawing blood for viral load testing.	(1) Study to rely on existing structures such as the county-based riders program and CHVs.	(1) Study to employ phlebotomists. (2) Study to work with the county-based riders on sample collection and delivery.

GISE: Group Integrated Savings for Empowerment [interchangeably also called microfinance groups]; CAG: Community ART Group; CHVs: Community Health Volunteers

Conclusion

This formative evaluation work demonstrates a perceived need for the proposed intervention. Nevertheless, the data uncovered specific issues with the proposed intervention that called for design adaptations to improve study acceptance and feasibility. Overall, the research highlights the need for refinement of the study inclusion criteria, the importance of allowing some flexibility across the sites to address local variability and the significance of taking a participatory approach as it facilitates collaboration and commitment among key stakeholders. For future community-based interventions, we recommend that researchers undertake extensive formative research to determine the on-going appropriateness of any proposed interventions and to inform amendments to those interventions in the final planning and early implementation stages.

Abbreviations

AMPATH: Academic Model Providing Access To Healthcare

ART: Antiretroviral therapy

CAG: Community ART Group

CDM: Chronic Disease Management

CHV: Community Health Volunteer

DM: Diabetes Mellitus

FPI: Family Preservation Initiative

GESP: Group Empowerment Service Provider

GISE: Group Integrated Savings for Empowerment

ICB: Integrated community-based care

MF: Microfinance

NCD: Non-communicable disease

PLHIV: People living with HIV

PMTCT: Prevention of mother-to-child transmission

Declarations

Ethics approval and consent to participate

This study has been approved by the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC Approval # 0003054) and Brown University (IAA #18-90). For the formative research described in this paper, verbal informed consent was obtained from each leader of identified microfinance groups. Solely aggregate, group level data were collected and entered into REDCap for analysis. The formative research presented in this paper was conducted in preparation for the *Harambee* cluster randomized trial, which is registered in ClinicalTrials.gov (NCT04417127; Registered June 2020 at https://clinicaltrials.gov/ct2/show/NCT04417127) and will be conducted in compliance with the Declaration of Helsinki and Good Clinical Practice (GCP).

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

CF, JW, BLG and OG lead study conception and research design. CF and JW oversaw data collection in the field. JAO and DA collected data. VO provided statistical expertise and analyzed the GIS data. CF and MWB lead manuscript preparation and all authors read and approved the final version.

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Figures

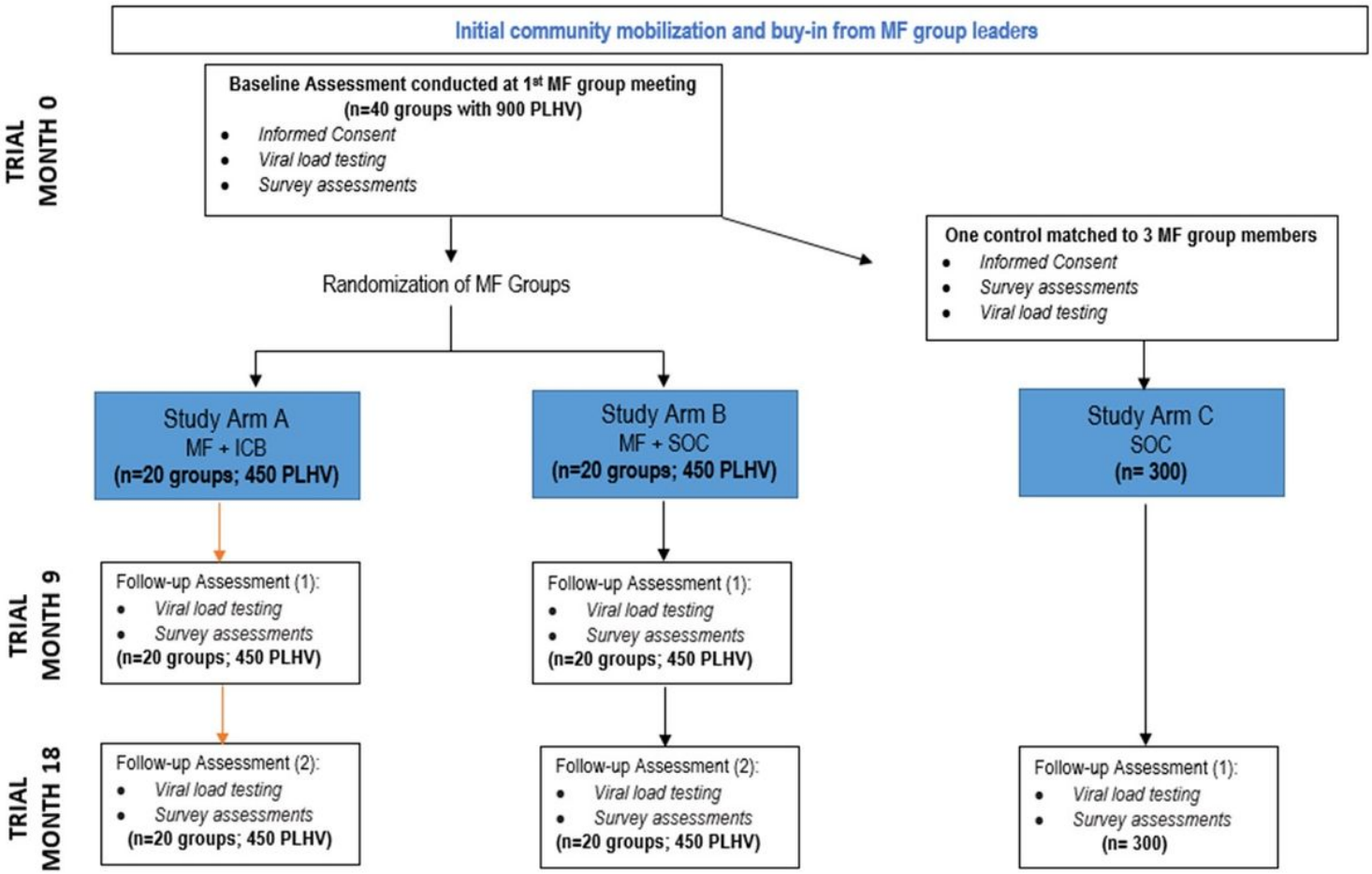

Figure 1

Schema for the Harambee Cluster Randomized Trial

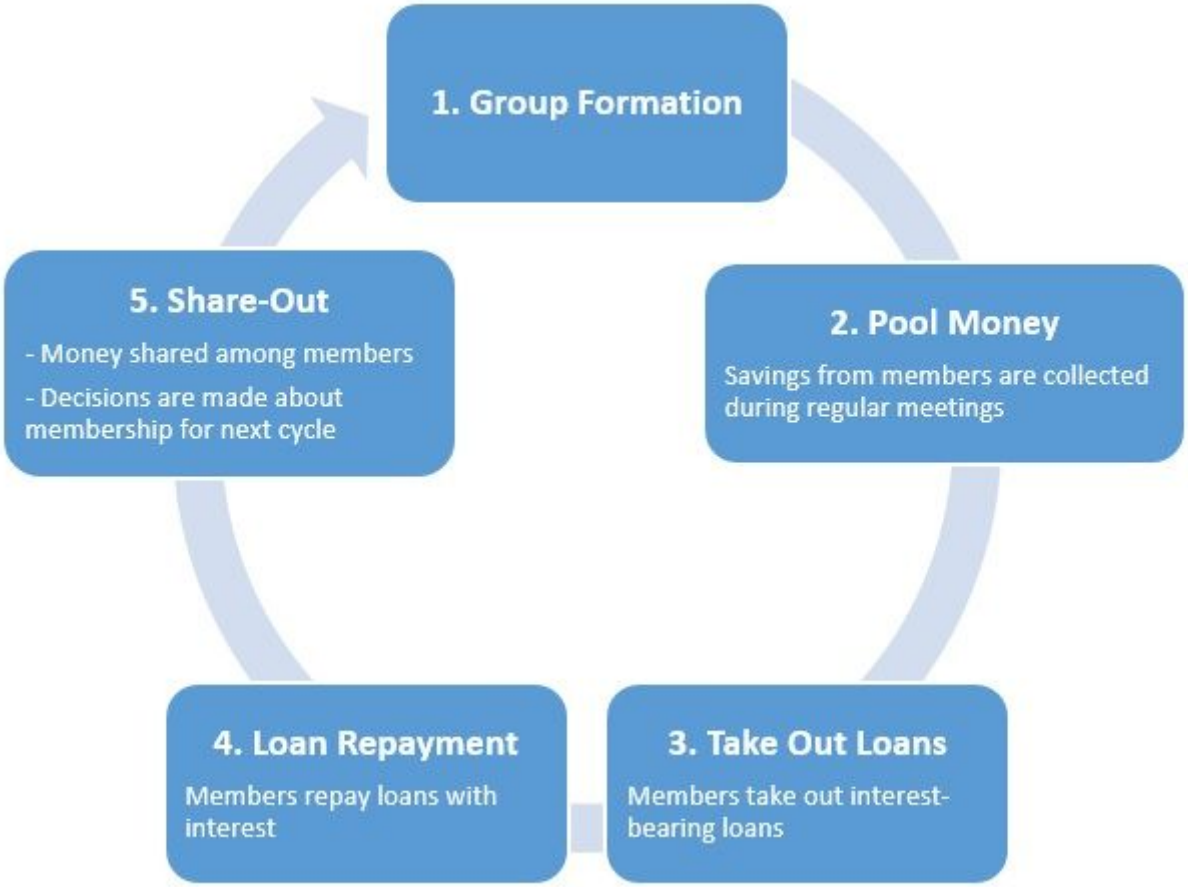

Figure 2

Table Banking Microfinance Model

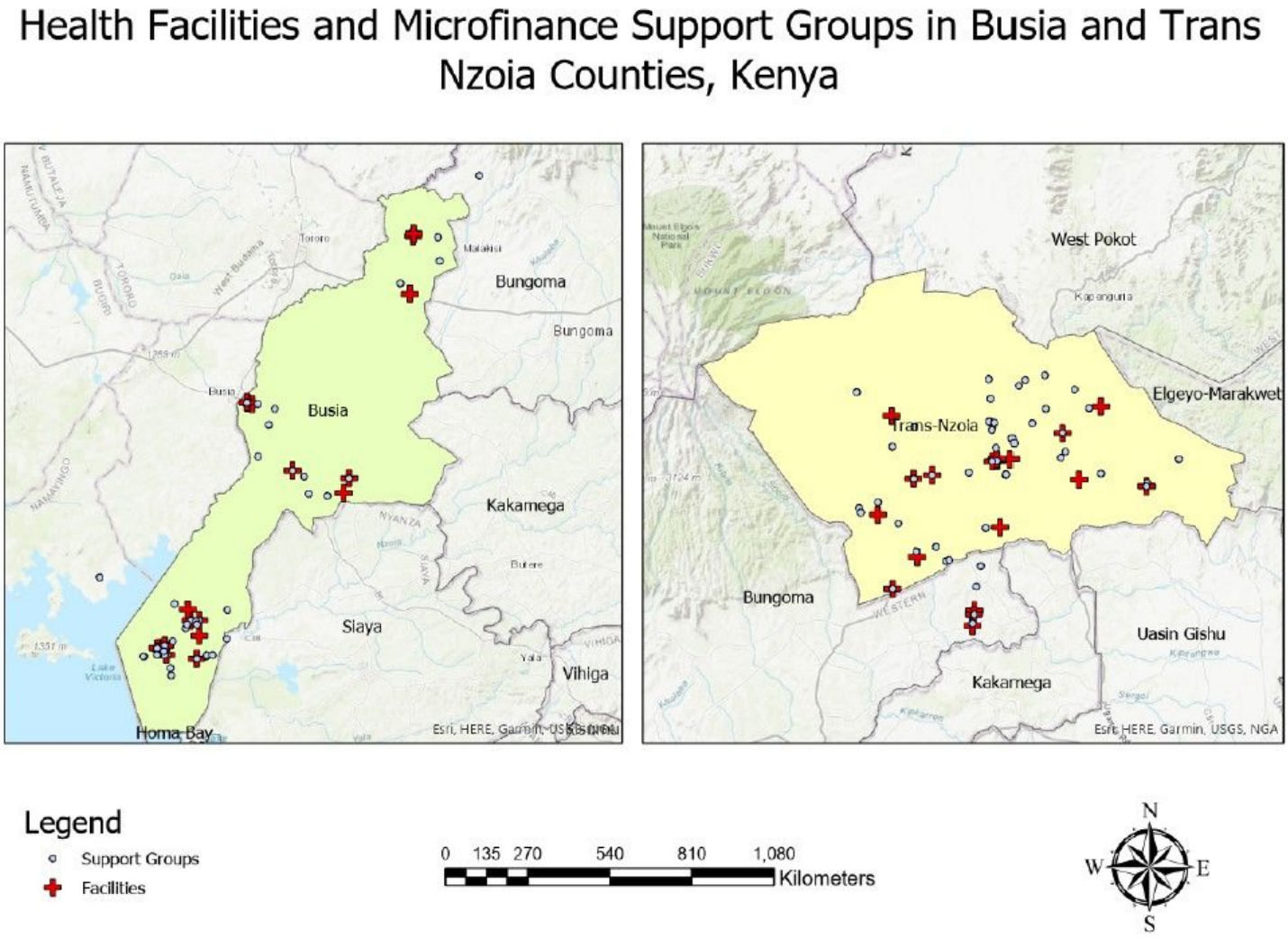

Figure 3

Locations of microfinance group meetings and health facilities where group members receive HIV care

Supplementary Files

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