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Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial

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ABSTRACT

Introduction In Kenya, distance to health facilities, inefficient vertical care delivery and limited financial means are barriers to retention in HIV care. Furthermore, the increasing burden of non-communicable diseases (NCDs) among people living with HIV complicates chronic disease treatment and strains traditional care delivery models. Potential strategies for improving HIV/NCD treatment outcomes are differentiated care, community-based care and microfinance (MF).

Methods and analysis We will use a cluster randomised trial to evaluate integrated community-based (ICB) care incorporated into MF groups in medium and high HIV prevalence areas in western Kenya. We will conduct baseline assessments with n=900 HIV positive members of 40 existing MF groups. Group clusters will be randomised to receive either (1) ICB or (2) standard of care (SOC). The ICB intervention will include: (1) clinical care visits during MF group meetings inclusive of medical consultations, NCD management, distribution of antiretroviral therapy (ART) and NCD medications, and point-of-care laboratory testing; (2) peer support for ART adherence and (3) facility referrals as needed. MF groups randomised to SOC will receive regularly scheduled care at a health facility. Findings from the two trial arms will be compared with follow-up data from n=300 matched controls. The primary outcome will be VS at 18 months. Secondary outcomes will be retention in care, absolute mean change in systolic blood pressure and absolute mean change in HbA1c level at 18 months. We will use mediation analysis to evaluate mechanisms through which MF and ICB care impact outcomes and analyse 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.

Ethics and dissemination The Moi University Institutional Research and Ethics Committee approved this study (IREC#0003054). We will share data via the Brown University Digital Repository and disseminate findings via publication.

Trial registration number NCT04417127.

Strengths and limitations of this study

- First randomised controlled trial (RCT) to evaluate the impact of integrating HIV/non-communicable diseases care within group microfinance on viral suppression and retention in care.
- The cluster randomised design allows the effect of integrated community-based care to be differentiated from that of group microfinance and standard of care.
- The study will enrol patients regardless of viral suppression status, thereby reaching some of the highest-risk populations who are often excluded from other differentiated care models.
- The exclusion of HIV-negative participants limits the generalisability of study findings to groups that may otherwise benefit from community-based care and microfinance but protects the privacy and confidentiality of people living with HIV.

INTRODUCTION

Despite considerable advances in expanding access to antiretroviral therapy (ART) in sub-Saharan Africa (SSA) over the past decade, retention in HIV care remains suboptimal: only half of people living with HIV (PLHIV) in SSA are virally suppressed.[1–3] In western Kenya, the primary barriers to retention in HIV care are distance to health facilities, inefficient vertical care delivery and limited means for accessing transportation and food.[4–6] Access barriers are heightened in remote locations where travel is restricted and transportation fees are prohibitively high relative to income.[7] Such barriers lead to gaps in ART adherence and eventual unsuppressed viral load (VL), which allows for disease progression and greater risk of transmission.[8] The

growing burden of non-communicable diseases (NCDs) among PLHIV[9–12] further complicates chronic disease treatment (including ART adherence) for HIV care systems with limited resources.

Differentiated care aims to provide client-centred services that encourage ART adherence and engagement in care while maximising efficiency.[13–16] As health systems implement the WHO 2015 recommendations to 'treat all' with ART,[17] differentiated care models alleviate burden on already-strained health systems expanding to enrol new patients on ART, and bolster adherence for those already in care. In South Africa, community-based ART adherence clubs with quarterly group care for symptom checks and medication refills have increased retention and viral suppression (VS) while decongesting facilities.[18 19] In Kenya, medication adherence clubs[20 21] simultaneously provide HIV, diabetes and hypertensive medications to patients in the community, thereby addressing the increasing burden of NCDs among PLHIV in the community.[9–11] Though promising, the effectiveness of differentiated care models on clinical outcomes has not yet been evaluated in a randomised trial.

The true impact of differentiated and community-based care will hinge on the ability of these models to self-sustain. Microfinance (MF) has shown to be effective for improving economic outcomes for over 170 million poor people worldwide, and provides unparalleled opportunities for delivering health-related services to hard-to-reach populations.[22] MF can address barriers related to economic insecurity through increased income and savings. Delivering health services within MF groups addresses barriers of geographic accessibility and availability,[23] demonstrating improvements in care-seeking behaviours in multiple contexts.[23–26] However, delivering health services within the context of group-based MF has yet to be extended to HIV care.

AIMS

The objective of this study is to address the challenge of improving HIV and NCD outcomes among PLHIV in rural, low-resource settings. The central hypothesis is that integrating HIV and community-based NCD care with group-based MF will improve VS and retention among PLHIV in Kenya via two mechanisms: improved household economic status and easier access to care. Harambee (Kiswahili for 'pulling resources together') is based on strong feasibility and acceptability evidence of community-based care with group MF for NCDs in Kenya.[27 28] Thus, the aims of the Harambee study are:

1. Evaluate the extent to which integrated community-based HIV care with group MF affects versus and retention in care among PLHIV in rural western Kenya by randomising existing MF groups to receive either: (A) integrated community-based HIV and NCD care, or (B) standard of care (SOC). We will augment trial data with medical record and active follow-up data from matched controls who are not involved in MF and receiving standard care (C), comparing outcomes in groups A, B and C.
2. Identify the specific mechanisms through which MF and integrated community-based (ICB) care impact versus using a mixed-methods approach. We will conduct quantitative mediation analysis to examine two main mediating pathways (household economic conditions and easier access to care), as well as exploratory mechanisms (food security, social support, HIV-related stigma). We will use qualitative methods and multistakeholder panels to contextualise implementation of the intervention.
3. Estimate the cost-effectiveness of the intervention relative to SOC with and without MF in terms of (1) cost per HIV suppressed person-time, (2) cost per patient retained in HIV/NCD care and (3) cost per disability-adjusted life-year (DALY) saved.

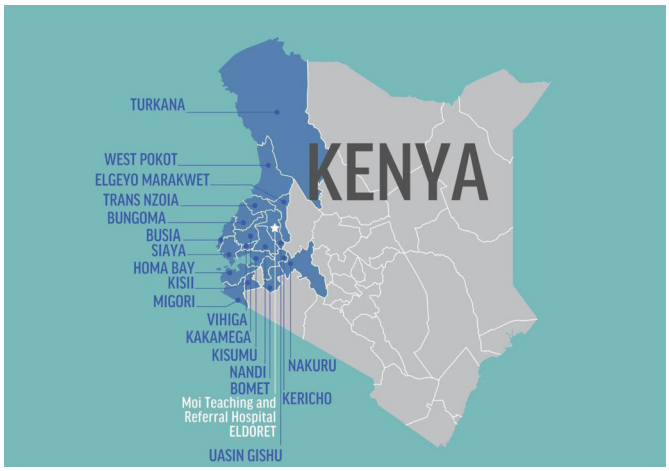

Figure 1 AMPATH catchment area. Harambee study activities will be conducted in Busia county and Trans Nzoia county.

METHODS AND ANALYSIS

Setting

The Academic Model Providing Access to Healthcare (AMPATH) programme is an academic global health partnership between Moi Teaching and Referral Hospital, Moi University, and a consortium of North American universities led by Indiana University.[29 30] Since 2001, AMPATH has grown to provide care to over 165 000 PLHIV across more than 800 clinical sites in western Kenya (figure 1). AMPATH's HIV clinical care protocols follow WHO[31] and Kenyan National AIDS and STI Control Programme guidelines,[32] and entail routine 12-month VL monitoring with more intensive monitoring for unsuppressed patients. Patient data are managed via AMPATH's electronic medical record system (AMRS). In response to the growing burden of diabetes and hypertension, AMPATH formed a Chronic Disease Management (CDM) programme in partnership with the Government of Kenya and local communities.[33] The CDM programme has a robust diabetes and hypertension

management protocol (online supplemental appendix 1) and uses medicines contained in the Kenyan national formulary.[34] AMPATH also runs the Group Integrated Savings for Empowerment (GISE) programme to support income-generating opportunities. The GISE programme follows the Village-Level Savings and Loan Associations model[35 36] to create community-led savings groups. MF group members mobilise and manage their own savings, provide interest-bearing loans to group members, and contribute to a social fund for use in cases of emergency and group welfare issues. More than 6484 HIV-positive AMPATH patients currently participate in GISE.

The present study will be conducted in two counties: Busia and Trans Nzoia. Each county has rural health facilities staffed by physicians, advanced practice practitioners and nurses, while community health workers provide health promotion and disease prevention education in the community. There is a long-standing relationship between AMPATH's HIV, CDM and GISE programmes and the local county healthcare providers and communities.

In Kenya's rural areas, prevalence of hypertension and diabetes mellitus among adults ages 15–64 years is estimated to be 24.7% (95% CI 22.3% to 27.2%)[37] and 1.9% (95% CI 1.3% to 2.5%),[38] respectively. In the counties targeted for study implementation, HIV prevalence in adults is 9.9% in Busia and 4.0% in Trans Nzoia, compared with 4.9% nationally.[39] In both counties, over 90% of adults living with HIV are virally suppressed (VL ≤400 copies/mL).[40]

Conceptual framework

Our research is guided by the Andersen behavioural model of health utilisation and elements of the socioecological model which emphasise the multilevel determinants of retention, ART adherence and VS (figure 2).[41 42] The interwoven relationship between individual characteristics and household and healthcare environments work together to impact health outcomes, including retention in HIV care and VS.[43] It is possible that the intervention will improve retention in care and VS through direct care delivery or through other mediating pathways such as improved household economic conditions, easier access to care, increased social support and reduced HIV-related stigma. Our study will examine the effect of improving the household socioeconomic environment via MF, and the interacting aspects of individual and healthcare environments with community-based care in MF groups.

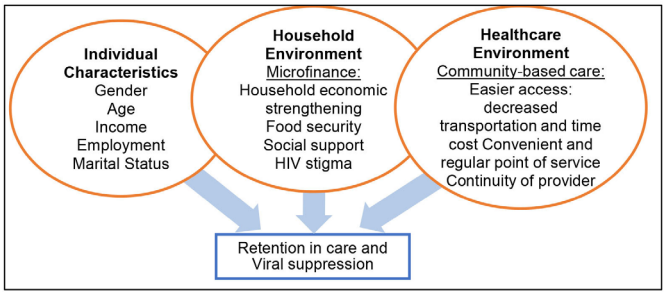

Figure 2 Conceptual framework.

Community mobilisation and baseline assessments

Research personnel and AMPATH outreach staff will conduct initial community mobilisation meetings with MF group leaders. Leaders will in turn inform their members about the study and randomisation process.

MF group members who meet all eligibility criteria (described below) and agree to participate will complete baseline assessments during the first MF group meeting following study start. At baseline, participants will complete informed consent procedures, provide a blood draw for HIV VL testing and complete survey assessments. Surveys will assess the following constructs: household economic status (Demographic & Health Survey, DHS, Wealth Index),[44] food security (Household Food Insecurity Access Scale),[45] barriers to accessing HIV care,[46] social support (Oslo Social Support Scale),[47] internalised HIV stigma,[48] quality of life (adapted MOS-HIV),[49 50] and the Patient Health Questionnaire-2 (PHQ-2),[51] medication adherence (adapted AIDS Clinical Trial Group adherence[52] and Voils DOSE-Nonadherence[53] questionnaire), and patient-reported satisfaction with care.[54] Biological specimens will be processed in AMPATH's research and clinically certified labs. Participants will also consent to have their AMRS data accessed for secondary outcome analysis.

We will recruit as many MF group members as possible and provide the intervention when more than half of the group members consent to participate. We will compare the distribution of cluster-specific rates of consent between treatment arms and, if necessary, adjust for cluster-specific consent rates during statistical analysis. Group members who do not wish to participate will not be excluded from any MF activities.

Cluster randomised trial

We will conduct a two-arm cluster randomised trial, with a matched group of SOC only participants, comparing MF+ICB to MF+SOC to SOC (figure 3).

Randomisation will occur at the level of MF group clusters and be stratified by county to achieve balance across geography and level of pre-existing MF participation. Group cluster randomisation will occur after all consenting participants complete baseline assessments using a computer-generated sequence to randomise MF groups to receive either ICB care or standard care. Randomisation will be conducted centrally by biostatisticians at Brown University.

Study participants

This trial will enrol 1200 participants. Forty existing MF groups with 900 participants will be randomised to receive either the ICB intervention (MF+ICB) or SOC (MF+SOC). We will compare results from the two trial arms to AMRS and active follow-up data from 300 matched patients who are receiving SOC without MF (SOC).

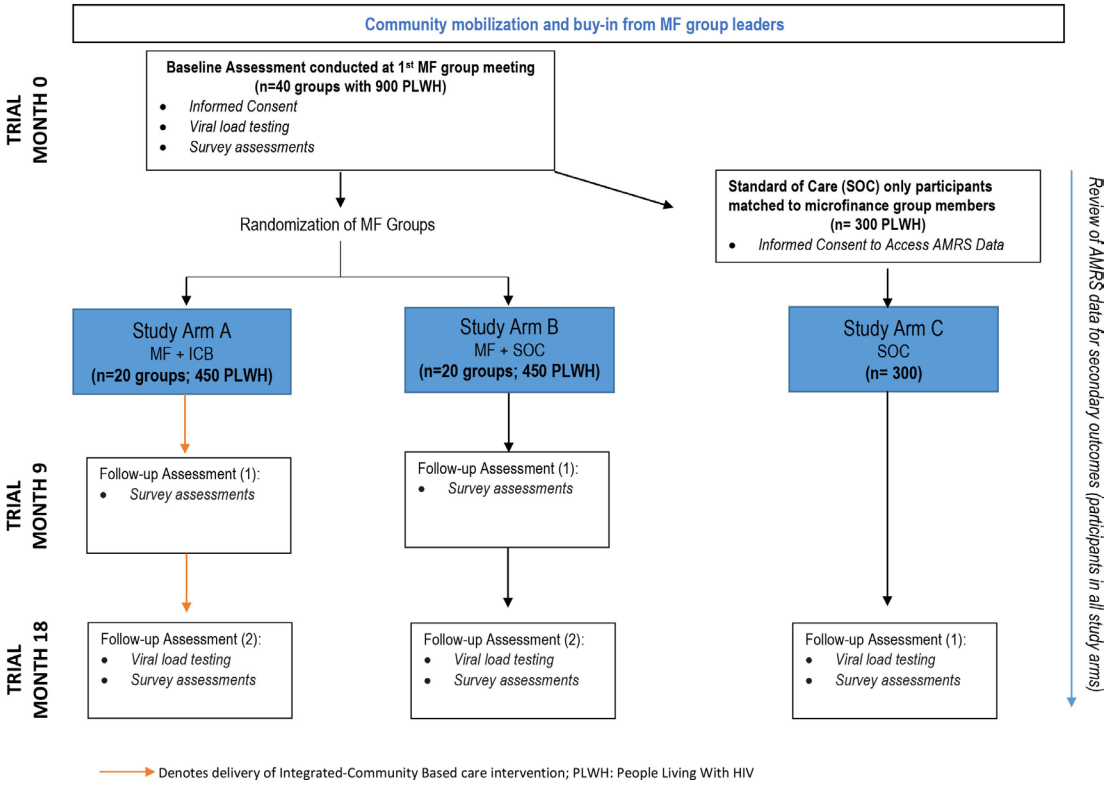

Figure 3 Cluster randomised trial design. ICB, integrated community-based care; MF, microfinance.

A MF group will be eligible for study participation if it meets the following criteria: is an active AMPATH GISE group that was formed at least 6 months prior to study baseline and is consistently meeting and engaging in saving and lending; and is an AMPATH GISE group with a majority of group members who are AMPATH HIV patients who have disclosed their HIV status. Non-AMPATH MF groups and AMPATH Community ART Groups (CARGs) will not be eligible for study inclusion.

Members of eligible MF groups will be invited to participate if they meet the following criteria: at least 18 years of age at study baseline; HIV-positive; have ever received HIV-related care through AMPATH after 2010; initiated ART at least 6 months prior to study baseline; are consistently attending GISE group meetings within the last 6 months and actively engaging in saving and lending; have an AMPATH Medical Record System (AMRS) ID; and are willing and able to provide informed consent. MF group members who participate in an AMPATH CARG or the Bridging Income Generation with Group Integrated Care (BIGPIC) study[28] will not be eligible for study inclusion. During the enrolment visit, research assistants will review eligibility criteria and study procedures and provide sufficient time for MF group members to ask questions. Individuals will provide voluntary written informed consent for study participation (online supplemental appendix 2). Study participation will not be restricted to stable (ie, virally suppressed) patients.

Intervention and control

Microfinance (MF) with Integrated Community-Based (ICB) Care

ICB care will be delivered in intervention groups at monthly MF 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 intervention will include the following components: (1) integrated care visits by a clinical team occurring monthly during trial months 1–6, and then quarterly for trial months 7–18, which include clinical evaluation, consultation with a clinical officer, medication distribution (ART and other chronic and acute medications), and point-of-care laboratory testing (creatinine, blood glucose, haemoglobin A1C (HbA1c) and VL as it becomes available); (2) peer support for promoting ART adherence during every MF meeting and (3) referrals to facilities for emergency or acute care needs that are not feasible to address in the community.

Care teams will review AMRS to coordinate care delivery with participants' needs at the time of study visits. All patients will have had VL monitoring as part of standard care. Initial intervention group visits (trial months 1–6) will focus on non-HIV-related needs and screening for NCDs. Facilities will be informed that participants will be receiving HIV care outside of clinic for the duration of the study, unless emergency or acute care is required. We will follow AMPATH's established care protocols for handling new opportunistic infections, suspected viral resistance, malignancy screening and diagnosis. These protocols are available via AMPATH's Clinical Protocols

and Standard Operating Procedures directory: https://wiki.ampath.or.ke/display/ACPS.

At each MF group meeting, participants will undergo routine triage and screening and receive health education in a group setting. Each participant will meet with a clinical officer in a privacy tent to review symptoms, ask questions and receive referrals as needed. Participants will receive prescriptions for ART and other medications which will be dispensed by a pharmaceutical technician. Peer navigators and social workers will be available to provide counselling or facilitate referrals.

Microfinance (MF) with Standard of Care (SOC)

An attention-matched control design is inherent in this study. MF groups randomised to receive SOC will meet as usual in their MF groups and continue to receive regular care from an AMPATH-supported rural health facility.

Standard of care

This will be the current SOC delivered by the AMPATH HIV and CDM programmes, in accordance with standard operating procedures for HIV care, diabetes, and hypertension. SOC participants are not involved in MF and will continue to receive regular care from an AMPATH-supported health facility. SOC patients will be invited to enrol as they attend regular HIV care visits and provide voluntary written informed consent for study participation (online supplemental appendix 2).

Data collection

We will conduct assessments for primary and secondary outcomes in all three trial arms at 18 months. This will include VL testing and administration of survey assessments. For intermediary outcomes analysis (aim 2), we will conduct one additional data collection round at 9 months in the two trial arms. For participants who do not attend MF meetings during assessment time points, we will use their contact information to schedule follow-up data collection outside of regular MF meetings.

Clinical data will be collected in the field during intervention visits by clinical officers using mobile tablets with secure data encryption and cloud-based data capture. These tablets are the same devices being used by clinicians delivering care within AMPATH facilities. All clinical encounter forms are currently supported in the field and uploaded to the main AMRS server. Data collected as part of care delivered during the intervention will become part of the patient's electronic medical record. AMRS data will be reviewed for secondary outcomes on an ongoing basis for all study participants.

Outcomes

The primary outcome measure will be VS at 18 months. Secondary outcome measures will be (1) retention in care at 18 months, defined as the proportion of scheduled visits attended during the study period; (2) 18-month absolute mean change in systolic blood pressure (SBP) and (3) 18-month absolute mean change in HbA1c level. Mean changes in SBP and HbA1c level have shown to be associated with longer-term cardiovascular benefit,[27 55–58] even when traditional control thresholds are not met.

Analytical approach

As participants will not be randomised to the SOC arm, we will match individuals from the SOC and the two intervention arms on gender and age using coarsened exact matching.[59 60] After all data are collected, we will check statistical balance of pre-exposure covariates. If substantial differences are seen, we will use causal inference methods to account for those differences (eg, g-computation or doubly robust methods). We have successfully used these and other quasi-experimental methods in Kenya and elsewhere[61 62] to analyse the impact of economic-based interventions on health outcomes.[63–66]

The primary analysis of interest is comparing VS at 18 months between the MF+ICB and MF+SOC arms. As a secondary hypothesis, we will test MF+ICB vs SOC alone and MF+SOC vs SOC alone. We will use a generalised mixed effects model to test the primary and the secondary hypotheses.[67] For the primary outcome, the model we will use is:

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

where, Y_{ij} is VS at 18 months for participant i in cluster j, I_j is the indicator if cluster j is randomised to the MF+ICB arm, S_j is an indicator if cluster j comes from the SOC individuals, VB_{ij} is the baseline VL for participant i in cluster j, and c_j is the random effect associated with cluster j. The estimator β_1 estimates the difference between the MF+SOC and MF+ICB arms and positive values indicate higher VS in the MF+ICB arm. To test the primary hypothesis, we will perform a hypothesis test for H0: $\beta_1=0$. 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 secondary outcomes, we will modify the above model to reflect that retention in care is a proportion and that the absolute mean change in SBP and HbA1c level is a continuous outcome. Dropout from the study will be handled using inverse probability weighting.[68 69] The design, analysis and interpretation of trial results will follow the Consolidated Standards of Reporting Trials (CONSORT) statement on cluster randomised trials.[70] All data will be deidentified prior to analysis.

Power calculation

Forty existing MF group clusters with 900 PLHIV will be randomised in a 1:1 ratio to either MF +ICB or MF +SOC. For the power calculations, the SD of the group size was set to 5, type-1 error rate to 0.05, and the intraclass correlation coefficient to 0.05. Based on studies of the effect of financial interventions we expect at least 15% increase in VS between MF+ICB and MF+SOC, MF+SOC and SOC only, and MF+ICB and SOC only groups.[18 71] The power calculations used VS in MF+SOC ranging from 20% to 50% and accounted for 15% drop-out.[28] For all the different scenarios considered, the power to detect a 15% increase in VS was greater than 80% for testing all three hypotheses.

Mediation analysis

We will conduct quantitative and qualitative mediation analyses to examine the mechanisms by which MF and community-based care operate on VS and retention in HIV care.

Quantitative mediation analysis

We will use causal mediation analysis to evaluate the importance of causal pathways between MF with ICB care and VS and retention.[72] We will use survey assessments[44–46 48–50 54 73] collected at baseline, 9-month and 18-month follow-up visits. The primary analysis will focus on two mediators: household economic conditions[44 45] and access to care.[46] We will estimate the mediation effect of each mediator separately using the difference method and account for multiple comparisons using a Bonferroni correction. The generalised 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.[74] Secondary analyses will estimate the mediation effect of food security, social support and HIV-related stigma.

Qualitative mediation analysis

We will conduct qualitative in-depth interviews (IDIs) with 40 MF group participants (n=20 from each trial arm). Participants who participated in at least 2 MF group meetings during the trial will be purposively sampled after completing the 18-month assessment. Semistructured interviews will take place in a private and quiet location 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, social support and HIV-related stigma; (3) How participation in MF and/or community-based care impacts retention in care and ART adherence; (4) Satisfaction with HIV care delivery in the community or facility and (5) Suggested improvements for care delivery models.

Text from the IDIs with trial participants 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. Participant's coded data will be compared with identify mechanisms through which MF and community-based care impacted retention in HIV care and ART adherence, and the additive impact of the community-based care delivery in the intervention group.

We will additionally conduct IDIs with 10 staff who delivered the intervention (eg, clinical officers, pharmacy technicians, social workers) to assess domains related to job satisfaction, challenges to delivering community-based HIV/NCD care and context-specific issues with delivering care in this setting. We will analyse qualitative data from clinical staff to identify implementation challenges that would help explain the main study findings and allow for translation of the ICB care model to AMPATH's broader catchment area.

We will triangulate findings from the mediation analyses with trial results to explain the potential mechanisms of action and provide contextual evidence for scaling up and translating the ICB care intervention in future settings.

Cost-effectiveness analysis

We will compare the two trial arms and matched controls using three closely linked analyses: (1) cost per HIV suppressed person-time, (2) cost per patient retained in HIV/NCD care and (3) cost per DALY saved.

For each intervention arm, we will estimate costs from the provider, patient, and government perspective using validated cost-tracking methods that capture all costs required for intervention delivery, as well as cost offsets that may result from improved health. First, we will take the perspective of AMPATH as a care provider. Total costs will represent the sum of fixed and variable costs. Per-patient variable costs will be calculated by multiplying the number of units of each good or service used by the unit cost. ART costs will be obtained from AMPATH/PEPFAR suppliers in Kenya. Unit costs for non-ART drugs will be estimated from invoices and key informant interviews. Clinical care unit costs will be estimated by multiplying the time of the clinical interaction (from time motion logs) by staff salaries. Fixed costs will be allocated to participants proportionally and include those incurred by the project not directly attributable to participants (eg, maintenance, utilities, testing equipment). Capital costs will be discounted at a rate of 7% per year to account for depreciation. Second, we will consider costs from the patient's point of view, which will include time and transport costs to the place where care is administered. Third, we will perform a potential cost-saving estimation from a government perspective where financial outlays are compared into the future to gauge the extent to which the proposed intervention can be financially self-sustained.

Once costs and effectiveness are calculated for each intervention arm, we will generate incremental cost-effectiveness ratios (ICERs) from each costing perspective.[75] We will examine whether ICERs are affected by changes in model parameters by performing one-way (and n-way) sensitivity analyses in which we examine the effect of changing one (or n) of the model parameters, holding all other parameters constant. 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.[76] We will additionally estimate return on investment using a cost–utility approach that we have successfully used for HIV testing[77] and can be adopted for HIV treatment retention interventions.[78]

LIMITATIONS

There are potential limitations to our study design. First, we expect to encounter difficulties prospectively following SOC participants over 18 months of the trial, due to logistical constraints of contacting these patients in the community. To pre-emptively address these difficulties, each SOC observation will be associated with a list of four ordered backup participants that will be used in instances when the original SOC participant cannot be located. Backup participants will be selected using AMRS such that they have the same age and gender as the original SOC participant. If exact matching for ordered backups is not possible, we will ensure gender is identical for all backups and then select each backup whose age is closest to the original SOC participant. Second, we may have some differential dropout and missing data because blinding of study participants and personnel is not possible due to the nature of the community-based intervention. Thus, our investigative team includes seasoned statisticians who are experienced in applying inverse probability weighting methods to address missing data, which will help ensure that analytical objectives are met. Finally, other differentiated care models are already being implemented by lay health workers across SSA exclusively among stable patients.[13] However, we expect that the Harambee ICB model will be able to provide care for unsuppressed patients because of the involvement of a clinical physician rather than reliance on ommunity health workers and/or peer navigators.

Despite these limitations, the Harambee study offers an innovate, culturally relevant, and potentially cost-effective approach to address the growing burden of NCDs among PLHIV in SSA. Evidence from this study will inform the delivery of ICB care to improve outcomes among PLHIV in similar settings.

TRIAL STATUS

For the cluster randomised trial portion of the study (aim 1), participant enrolment and baseline data collection began in November 2020 and is currently ongoing. Qualitative data collection and cost-effectiveness analyses have not yet begun. We anticipate that results from the trial will be available in 2023.

ETHICS AND DISSEMINATION

This protocol (V.1.0) has been approved the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC Approval # 0003054) and Brown University (IAA#18–90). Any changes made to this protocol will be reviewed and approved by the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee prior to implementation. The trial will be conducted in compliance with this study protocol and IREC-approved Data and Safety Monitoring Plan, as well as the Declaration of Helsinki and Good Clinical Practice. Results from this study will be reported in accordance with the CONSORT statement for cluster randomised trials.[70]

A manuscript with the results of the cluster randomised trial study will be published in a peer-reviewed journal. Separate manuscripts will be written for each of the secondary aims, and these will also be submitted for publication in peer-reviewed journals.

On completion of the trial, and after publication of the primary manuscript, data requests can be submitted to investigators at Brown University School of Public Health, USA.

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