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Bridging Income Generation with Group Integrated Care for Cardiovascular Risk Reduction: Rationale and Design of the BIGPIC Study

Rajesh Vedanthan, MD MPH¹, Jemima H. Kamano, MBChB, MMed^{2,3}, Hana Lee, PhD⁴, Benjamin Andama³, Gerald S. Bloomfield, MD MPH⁵, Allison K. DeLong, MS⁴, David Edelman, MD⁵, Eric A. Finkelstein, PhD MHA MA⁵, Joseph W. Hogan, ScD MS⁴, Carol R. Horowitz, MD MPH¹, Simon Manyara, BPharm⁶, Diana Menya, MBChB, Msc⁷, Violet Naanyu, PhD², Sonak D. Pastakia, PharmD MPH^{3,8}, Thomas W. Valente, PhD⁹, Cleophas C. Wanyonyi³, and Valentin Fuster, MD PhD¹

¹Icahn School of Medicine at Mount Sinai, New York, USA

²Moi University College of Health Sciences, School of Medicine, Eldoret, Kenya

³Academic Model Providing Access to Healthcare, Eldoret, Kenya

⁴Brown University, Providence, USA

⁵Duke University, Durham, USA

⁶Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany

⁷Moi University College of Health Sciences, School of Public Health, Eldoret, Kenya

⁸Purdue University, West Lafayette, USA

⁹University of Southern California, Los Angeles, USA

Abstract

Background—Cardiovascular disease (CVD) is the leading cause of mortality worldwide, with >80% of CVD deaths occurring in low and middle income countries (LMICs). Diabetes mellitus and pre-diabetes are risk factors for CVD, and CVD is the major cause of morbidity and mortality among individuals with DM. There is a critical period now during which reducing CVD risk among individuals with diabetes and pre-diabetes may have a major impact. Cost-effective, culturally appropriate, and context-specific approaches are required. Two promising strategies to improve health outcomes are group medical visits and microfinance.

Methods/Design—This study tests whether group medical visits integrated into microfinance groups are effective and cost-effective in reducing CVD risk among individuals with diabetes or at increased risk for diabetes in western Kenya. An initial phase of qualitative inquiry will assess

Corresponding author: Rajesh Vedanthan, MD, MPH, Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, Box 1030, Telephone: 212-659-9180, Fax: 212-849-2674, rajesh.vedanthan@mssm.edu.

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contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction. Subsequently, we will conduct a four-arm cluster randomized trial comparing: 1) usual clinical care, 2) usual clinical care plus microfinance groups only, 3) group medical visits only, and 4) group medical visits integrated into microfinance groups. The primary outcome measure will be one-year change in systolic blood pressure, and a key secondary outcome measure is one-year change in overall CVD risk as measured by the QRISK2 score. We will conduct mediation analysis to evaluate the influence of changes in social network characteristics on intervention outcomes, as well as moderation analysis to evaluate the influence of baseline social network characteristics on effectiveness of the interventions. Cost-effectiveness analysis will be conducted in terms of cost per unit change in systolic blood pressure, percent change in CVD risk score, and per disability-adjusted life year saved.

Discussion—This study will provide evidence regarding effectiveness and cost-effectiveness of interventions to reduce CVD risk. We aim to produce generalizable methods and results that can provide a model for adoption in low-resource settings worldwide.

Keywords

cardiovascular disease; diabetes; blood pressure; group medical visits; microfinance; social network analysis; randomized controlled trial; cost-effectiveness; qualitative analysis

Introduction

Cardiovascular disease (CVD) is recognized as the leading cause of mortality worldwide, with more than 80% of CVD deaths occurring in low and middle income countries (LMICs).¹ CVD is the second leading cause of death in sub-Saharan Africa and is the first among those over the age of 30.^{2,3} Concurrent with the epidemiologic burden is the economic burden of CVD in LMICs.⁴

Diabetes mellitus (DM) and pre-diabetes are risk factors for CVD,⁵ with CVD recognized as the major cause of morbidity and mortality among those with DM.⁶ With the number of individuals with DM in LMICs projected to nearly double in the next two decades,⁶ the burden of CVD is expected to increase substantially. Thus, there is now a critical period during which reducing CVD risk among individuals with DM and pre-diabetes may slow this trend.⁷ Elevated blood pressure (BP) is a major contributor to cardiovascular complications in people with diabetes and pre-diabetes. Moreover, elevated BP in the general population has become more prevalent in sub-Saharan Africa and is expected to contribute significantly to CVD risk in the region in the future.⁸ Therefore, BP control among these individuals is a powerful and cost-effective way to reduce CVD burden.⁹

Components of the Proposed Intervention to Reduce Cardiovascular Risk

Addressing financial barriers, medication supply, clinic attendance, patient-provider communication, and self-efficacy in low-resource settings are proven elements to successful CVD risk reduction.¹⁰ Cost-effective, culturally appropriate, and context-specific approaches are required. Two strategies that show promise include group medical visits and microfinance.

The group medical visit (GMV), which is a clinical encounter between one or more clinicians and a group of patients, can increase the efficiency of care delivery, improve quality of care, enhance social support, and encourage self-efficacy.^{11,12} In high-income countries and high-resource settings, GMVs have improved outcomes in maternal and child health,¹³⁻¹⁵ DM, hypertension, and chronic disease management.^{11,16,17} However, this strategy is only recently being evaluated among vulnerable populations, and thus far only in high-income countries.^{18,19}

Poverty is both a cause and an effect of adverse health outcomes,^{20,21} and has been associated with health inequities.²² Microfinance encompasses a broad array of financial products, including payments, credit, and insurance, tailored to meet the particular needs of low-income individuals.²³ Microfinance initiatives have been shown to improve health outcomes,^{24,25} with the impact enhanced when coupled with health initiatives,²⁶ in the areas of infectious diseases,²⁷ women's health,^{28,29} child health,³⁰ and health insurance.³¹ However, the impact of microfinance on CVD risk reduction has not been well studied.

Aims

The purpose of this research study is to use a transdisciplinary implementation research approach to address the challenge of reducing CVD risk in low-resource settings. The central hypothesis is that GMVs integrated into microfinance groups will be effective and cost-effective in reducing CVD risk among individuals with diabetes and at increased risk for diabetes in western Kenya, hereafter referred to as our study population, and that the key modifiable CVD risk factor to be addressed is BP. We also hypothesize that group medical visits and microfinance may each reduce CVD risk, but that the integration of group medical visits and microfinance will yield the largest gains. Thus, the aims of the Bridging Income Generation with Group Integrated Care (BIGPIC) study are:

1. Identify the contextual factors, facilitators, and barriers that may impact integration of GMVs and microfinance for CVD risk reduction, using qualitative research methods. With this information, we will develop a contextually and culturally appropriate integrated GMV-microfinance model to reduce CVD risk.
2. Evaluate the effectiveness of GMVs and microfinance by comparing CVD risk reduction outcomes among our study population, in a four-arm cluster randomized trial comparing: 1) usual clinical care (UC), 2) usual clinical care plus microfinance groups only (MF), 3) GMVs only (GMV), and 4) GMVs integrated into microfinance groups (GMV-MF). The primary outcome measure will be one-year change in systolic blood pressure (SBP). A key secondary outcome measure is one-year change in overall CVD risk as measured by the QRISK2 score. We will also evaluate the influence of changes in social network characteristics on intermediate factors and intervention outcomes through mediation analysis, as well as the influence of baseline social network characteristics on effectiveness of interventions through moderation analysis.

3. Evaluate the incremental cost-effectiveness of each intervention arm, in terms of cost per unit change in SBP, percent change in CVD risk score, and per disability-adjusted life year saved.

Methods

Setting

The Academic Model Providing Access to Healthcare Partnership (AMPATH) was initiated in western Kenya in 2001 and has established an HIV care system that serves over 160,000 patients.³² In response to the substantial and growing burden of diabetes and hypertension, and in an effort to optimize delivery of care for chronic disease, AMPATH formed a Chronic Disease Management (CDM) program and established collaborative partnerships with the Government of Kenya and local communities.³³ The CDM program has developed a robust DM and hypertension management protocol (Appendix A) derived from the International Diabetes Federation,⁹ World Health Organization (WHO),³⁴ and Joint National Commission 7 and 8^{35,36} guidelines for DM and hypertension management, using medicines contained in the Kenyan national formulary.³⁷ AMPATH has also created a Safety Net Program to improve the economic security of clients without encouraging dependency, by promoting income-generating activities. The program has been able to successfully organize microfinance groups, initially starting with HIV patients and pregnant women,³⁸ and recently expanding to patients with DM and hypertension. Based on the model of Village-Level Savings and Loan Associations,³⁹ AMPATH's microfinance program is a client-driven model that involves the creation of community savings groups. Microfinance group members mobilize and manage their own savings, provide interest-bearing loans to group members, offer a limited form of financial insurance, and contribute to a social fund that is used in cases of emergency or welfare issues of group members.⁴⁰

This research project will be conducted within the AMPATH catchment area, in four Counties in western Kenya: Busia, Kisumu, Trans Nzoia, and Uasin Gishu (Figure 1). Each County has rural health facilities (sub-county hospitals, health centers and dispensaries; total 24) staffed by physicians, clinical officers (mid-level practitioners), and nurses, while community health workers (CHWs) provide health promotion and disease prevention education in the villages. There has been a longstanding positive relationship among AMPATH, healthcare providers, and the communities they serve. Both the CDM and Safety Net programs have an established presence in all these communities.

Conceptual Framework

Both microfinance and GMVs can improve health outcomes through many mechanisms (Figure 2). We hypothesize that both interventions can cause changes in social network characteristics,^{41,42} leading to improved intermediate factors (diet, physical activity, medication adherence, and retention in care), ultimately yielding CVD risk reduction (arrow 1). It is also possible that both interventions can impact the intermediate factors and health outcomes independent of social network characteristics (arrow 2). Likewise, changes in social network characteristics may mediate the relationship between the interventions and CVD risk reduction independent of the intermediate factors (arrow 3). In addition, the

interventions may be related to the health outcomes by other independent pathways (arrow 4). Finally, baseline differences in social network characteristics may moderate the impact of microfinance and GMVs on CVD risk reduction.

Microfinance can increase savings and income, leading to an increased ability to pay for healthier foods, medicines, diagnostic services, specialty consultation, and health insurance, which can improve diet, medication adherence and retention to care.⁴³ Microfinance can also lead to improved financial literacy, self-confidence, and decision-making agency.^{25,44} Likewise, GMVs can increase the efficiency of care delivery, improve quality of care, encourage self-efficacy, and increase levels of clinician-patient trust.⁴⁵ All of these mechanisms can positively impact the intermediate factors,⁴⁶⁻⁴⁸ and subsequently reduce CVD risk.

Both interventions can impact social network characteristics by enhancing group cohesion, establishing social support, and allowing for the exchange of shared experiences.⁴⁹ Social integration, or connectedness, is a very important network characteristic that can influence health and the impact of health-related interventions.⁵⁰ This can create a social environment that is conducive to making healthier choices, enhancing medication adherence, and improving retention in care,⁵¹ thereby maximizing the intervention's effectiveness.^{11,25} Social networks influence behavior through several theoretical mechanisms: information for behavior change, perceptions of social norms, how-to knowledge, and social comparisons.^{52,53} By way of these mechanisms, CVD risk reduction also can be achieved. In the BIGPIC study, we have selected three commonly used individual-level measures of social integration: in-degree centrality, closeness centrality, and transitive closure; and three network-level measures of social integration: network density, transitivity, and cohesion.

Contextual factors, facilitators and barriers that may impact integration of group medical visits and microfinance groups

We have used a combination of qualitative research methods, including traditional community assemblies (*baraza* [pl. *mabaraza*]) and focus group discussions (FGDs), to identify the contextual factors, facilitators, and barriers that may impact integration of GMVs and microfinance groups for our study population. In East Africa, *mabaraza* are used to address a wide variety of situations, ranging from local disputes to exchange of information. This unique and novel qualitative research setting has been used as a form of participatory action research by generating lively exchanges of interest to local communities while providing input related to chronic disease care. The *mabaraza* have allowed us to organize large and heterogeneous groups that complemented the purposive sampling inherent in FGDs, which targeted specific groups including rural health workers, microfinance group members, and chronic disease patients. We have thus far conducted five *mabaraza* and 16 FGDs using purposive sampling by age, sex, occupation, and distance from nearest health facility.

The qualitative sessions have been facilitated by use of pre-developed moderator guides that have served to promote discussions relating to chronic diseases and needed care for these conditions, facilitators and barriers to GMVs, and the role of microfinance in promoting health. Moderators fluent in the local languages and trained in the use of the guides led the

sessions. Beyond this initial structure, the discussions have been allowed to deviate as additional relevant issues emerged. In addition, participatory techniques have been applied to elicit emotional elements and promote group interactions.⁵⁴ All sessions have been audio-recorded, transcribed, and translated into English. Content analysis of the transcripts is being performed using both deductive (*a priori*) and inductive (emerging) codes.⁵⁵ The coded items will be grouped together into distinct themes, and relationships among these themes will be formulated.

Using the data gathered in the formative qualitative sessions, we have used a participatory, iterative design process,⁵⁶ to develop an integrated GMV-microfinance model for CVD risk reduction in our study population. Individuals across the stakeholder spectrum—including clinicians, pharmacists, nutritionists, CHWs, and community leaders—formed a “design team” that met regularly over several weeks creating the prototype intervention. Educational materials have been developed in English, Kiswahili, and other local languages using standard approaches to translation and back-translation. We have conducted acceptability testing of the prototype intervention using qualitative methods and a feasibility pilot,^{57,58} with iterative changes incorporated into the final intervention, an approach that we have previously used with positive community feedback.⁵⁹⁻⁶¹

Cluster Randomized Trial

We will conduct a four-arm cluster randomized trial as detailed above, comparing UC, MF, GMV, and GMV-MF. The primary outcome measure will be one-year change in SBP, and a key secondary outcome measure will be change in CVD risk score. Randomization will occur at the level of the health facility catchment area (cluster), and will be stratified by County, type of health facility, and level of pre-existing microfinance participation, in order to achieve balance across geography, health facility type, and level of microfinance participation. Each of the 24 health facility catchment areas will be randomly allocated across the four arms of the trial (six clusters per trial arm) (Figure 3). The randomization process will be conducted centrally by biostatisticians at Brown University.

Study Participants

Within each County, AMPATH has initiated community-level and facility-based screening of glucose and BP.^{62,63} Adult individuals with elevated BP (SBP $\geq$ 140 or diastolic BP (DBP) $\geq$ 90) or elevated point-of-care random blood glucose ($\geq$ 7.8 mmol/L) will be referred to the local rural health facility for further evaluation and confirmation of disease status. After repeat BP and fasting glucose are measured, those who meet the designated cutoffs (repeat SBP $\geq$ 140 or DBP $\geq$ 90; fasting glucose $\geq$ 7 mmol/L) will be registered into the AMPATH CDM Program. Inclusion criteria for this study will be all adults $\geq$ 35 years of age in the CDM Program who have diabetes (fasting glucose $\geq$ 7 mmol/L)⁹ or are at increased risk for developing diabetes (impaired fasting glucose (fasting glucose 5.6 – 6.9 mmol/L)⁶⁴ or elevated Leicester Risk Assessment score ($\geq$ 7)⁶⁵). The Leicester Risk Assessment score (Appendix B) was adapted from the prospectively validated FINDRISC score,⁶⁶ and has been prospectively validated in multiethnic populations to predict development of diabetes.⁶⁵ Exclusion criteria include: acute illness requiring immediate medical attention, terminal illness, and inability to provide informed consent. Individuals who are pregnant or

have HIV will also be excluded, as they are automatically referred to a higher level of care within the AMPATH care system. We intend to enroll 2880 individuals, based on the following assumptions: 1) 44.9% of the population is age 20,⁶⁰ and 2) approximately 10% of adults will meet eligibility criteria.⁶⁷ Eligible individuals will be offered enrollment into the study by trained research personnel at the health facility or an alternative mutually convenient location. Those who provide informed consent will be enrolled.

Intervention and Control

Usual Clinical Care (UC): This will be the current standard of care delivered by the AMPATH CDM Program, in accordance with the management protocol for diabetes and hypertension (Appendix A). Non-hypertensive individuals with DM will not be pharmacologically treated for BP reduction; those with BP 120-139/80-89 will be advised on lifestyle changes to reduce BP as recommended by the 2013 Standards of Medical Care in Diabetes.⁶⁸ Care will be provided to each individual at the rural health facility by a rural clinician mentored by the CDM Program, including regular monthly consultation, vital signs, physical examination, and prescriptions. CHWs will assist with linkage and retention of patients to the care program, and provide health education.

Usual Clinical Care Plus Microfinance Groups (MF): Participants in geographic regions randomized to the MF arm will receive usual clinical care as described above. In addition, participants will be encouraged to create microfinance groups organized and supported by AMPATH's Safety Net Program. The rural clinician and the CHW will organize a meeting with AMPATH's Safety Net Program representatives, who will introduce the concept of microfinance groups, the potential benefits, and encourage the formation of new groups to meet monthly. Given our pilot work, we have realized that the microfinance groups need to incorporate an element of self-selection and self-formation, so that individuals have the freedom to choose with whom they will create a group. The groups are therefore formed voluntarily and usually along geographical boundaries, which facilitate participation, retention, and meeting logistics. However, AMPATH's Safety Net Program and CDM Program have been able to successfully ensure that 50% of each group's members will be study participants by encouraging the formation of an initial core with a minimum number of study participants and allowing initial core group members to invite others up to a maximum group size (30 members).⁴⁰

Group Medical Visits (no microfinance) (GMV): Participants from Counties randomized to this arm will be invited to join a group that will attend monthly group medical visits at the rural health facility. Each GMV will be staffed by both the rural clinician and the local CHW (educator). The prototype of the GMV will be based on the model used for diabetes and hypertension in the USA,⁶⁹ as well as the pilot work that we have completed in Kenya,⁴⁰ and adapted and contextualized as described above using the participatory design process. Briefly, groups will consist of the same patients at each GMV. Each visit will begin with the measurement of resting electronic BP (all patients)⁷⁰ and fasting blood glucose (DM patients), the ascertainment of medication regimens for BP and DM, and extent of adherence to the prescribed regimen.⁷¹ In the next phase, the CHW will facilitate a group discussion about a self-care or health education topic chosen by the group at the previous meeting. At

the end of the group discussion, the group will determine the next GMV's self-care or health education topic. During this time, the rural clinician reviews the BP, glucose, and adherence data to determine a clinical management plan as per the CDM clinical algorithm (Appendix A). This management plan is communicated to each individual patient by the rural clinician in a brief individual consultation after the group discussion has ended. If the patient does not adhere to the medication regimen, the rural clinician will not change the regimen. Instead, s/he will assess barriers to adherence and try to help the patient identify solutions to those barriers. In addition, the individual consultation time can be used to perform a physical examination or other assessments as clinically required. After all patients have had individual consultations with the rural clinician, the group may re-convene if necessary for a question-and-answer period, as well as any concluding reflections.

Group Medical Visits Integrated into Microfinance (GMV-MF): In this arm, clinical care will be provided in the form of group medical visits, and the participants will be actively recruited to create microfinance groups, as described above. Thus, the monthly group medical visit will be integrated into the microfinance groups, wherein the visit will consist of an initial microfinance portion, followed by the group medical visit.

Outcomes—The primary outcome measure will be one-year absolute mean change in SBP. A key secondary outcome measure is one-year change in overall CVD risk as measured by the QRISK2 score, which has been validated for calculating 10-year CVD event risk for Black Africans.^{72,73} Other secondary outcome measures will include: 1) percentage of participants with controlled BP; 2) change in individual CVD risk factors (e.g. lipids, smoking); 3) change in behaviors (e.g. physical activity, diet); and 4) change in process measures during intervention periods (e.g. health care utilization, medication adherence, clinic attendance).

Analytic Approach—We will use an analysis of covariance model with cluster effects to estimate and draw inference about treatment effects for both primary and key secondary outcomes, using an intention-to-treat approach. The model specification for the primary outcome is:

$$y_{ij} = \alpha + \gamma_j + \beta_1 x_{ij1} + \beta_2 x_{ij2} + \beta_3 x_{ij3} + \theta b_{ij} + e_{ij}$$

where y_{ij} is SBP at the end of follow-up for the i th individual in the j th cluster, b_{ij} is baseline SBP, and the indicators x_{ij1} , x_{ij2} , x_{ij3} represent treatment group membership, with usual care as the reference. Hence, each β coefficient represents the difference in mean change in SBP between usual care and one of the three active intervention arms. The intercept is α and γ_j is the effect of the j th cluster. Cluster effects γ_j will initially be modeled as fixed effects, but we will use a mixed model structure and assign a normal distribution if the data support this assumption. We will compare key variables (e.g. age, demographics, risk factors, co-morbidities including diabetes status, and process measures) across the trial arms to ensure balance of the randomization process, and adjust the model as needed to estimate treatment effects. For modeling QRISK2, we will use the transformation $\log(-\log(\text{QRISK2}))$, because

the risk score ranges between 0% and 100%. Further statistical details, including analysis of inherent additive ordering, effect modification by gender, mediation analysis of changes in social network characteristics, moderation analysis of baseline social network characteristics, and approach to missing data, are included in Appendix C.

Statistical Power

We examined whether our target sample size (24 health facilities (clusters) with 2880 individuals) will achieve adequate power to detect improvement in SBP in the three intervention arms compared to usual care (i.e. three major comparisons (GMV vs UC; MF vs UC; GMV-MF vs UC)). Based on other CVD risk reduction trials in LMICs⁷⁴ and the preliminary results from our pilot data,⁴⁰ we expect a 5-mmHg reduction in SBP in the GMV or MF arms compared to the UC arm, and a 10-mmHg reduction in SBP in the GMV-MF arm compared to the UC arm. Our type I and type II error rates were conventionally set at 5% ($\alpha=0.05$) and 20% ($\beta=0.20$), respectively, yielding a sample size powered at 80% ($1-\beta=0.80$). We used a Bonferroni correction to account for multiple comparisons and accounted for within-cluster correlation using intraclass correlation (ICC) values ranging from 0.01 to 0.15, consistent with prior studies using SBP outcome.⁷⁴ We analyzed scenarios over a range of standard deviation (SD) values for change in SBP found in the literature, from 10 to 20,^{74,75} and we assumed that up to 15% of enrolled participants will be lost to follow-up.^{67,76} The Table presents the minimum detectable difference (MDD) for each pairwise comparison across different combinations of ICC and SD of change in SBP, and shows that over a wide range of plausible ICC and SD values, we anticipate being able to detect a mean difference in change in SBP consistent with the published literature^{11,69,74} and our preliminary data.⁴⁰ Further details related to statistical power, including detailed sample size information for each cluster and secondary outcome power considerations, are included in Appendix C.

Cost-Effectiveness Analysis—For each intervention arm, costs and potential cost offsets from the societal (participant plus health system) and health system perspectives will be captured using validated cost tracking forms and questionnaires that capture all relevant labor, materials, supplies, contracted services costs for all activities required to deliver the interventions, and cost offsets that may result from improved health.^{77,78} Only incremental (variable and fixed) costs will be included in the analysis. We will also identify which activities drive the overall costs, and how costs would change if specific activities are added or eliminated.

Once costs and effectiveness are calculated for each intervention arm, we will then generate incremental cost-effectiveness ratios from both the societal and health system perspectives.⁷⁹ In addition, we will examine whether the cost-effectiveness results are affected by changes in model parameters, such as key assumptions made in the cost analysis. We will perform 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. Our cost-effectiveness results will also be presented in the form of cost-effectiveness acceptability curves,⁸⁰ which will show the probability that each intervention is cost-effective for a range of monetary values that a decision-maker might be willing to pay for a unit change in effectiveness. We

will conduct our cost-effectiveness analysis in terms of improvements in SBP, reductions in QRISK2 CVD risk score, and per disability-adjusted life year saved.

Data Collection, Management, and Security—Data for this study will derive from two sources: 1) clinical data extracted from the AMPATH electronic health record, and 2) data collected by non-blinded research staff directly from participants during dedicated research study visits (baseline data; 3-month social network, intermediate factors, and interim clinical data; and 12-month outcome data). The data collection instruments include previously validated surveys, scales, and instruments that have been tailored to the local context, including health behavior surveys,⁸¹ medical utilization and cost assessment surveys,^{82,83} social network and cohesion surveys,^{84,85} quality of life and perceived stress scales,^{86,87} household wealth assessment,⁸⁸ and medication adherence assessment.⁷¹

All clinical patient-level data will be retrieved from the AMPATH electronic health record via access that will be controlled through user authentication. Data collected by the research staff will be collected via paper forms or electronic data capture using REDCap.⁸⁹ All paper data collection forms will be reviewed by the Study Coordinator and Data Manager for completeness and the presence of pre-specified “danger” values. Once validated, any sheets containing directly identifiable information and consent documentation will be separated and added to the research site's secure storage locker. The remaining, de-identified pages will then be placed in a separate storage locker prior to data entry. Only key investigators and study personnel will have access to individually identifiable private information about human subjects. Data collected on paper forms will be transferred to the password-protected REDCap research database. Electronically captured data will be collected using the REDCap Mobile App, which enables offline data collection, then transferred to REDCap through a secure connection tunnel. All data on mobile devices will be encrypted and stored on the device's internal memory, and all data will be stored on dedicated, password-protected computers. All data management will be carried out by CITI-certified research staff members, and the statistical team will use only de-identified data. The Brown University Center for Statistical Sciences has implemented a Netscreen SSG 550 firewall, which provides network security and is configured to give our statistical team full control over who has access to the network and systems. The firewall also helps provide the security needed for acquiring confidential data and keeping it secure.

An independent Data Safety and Monitoring Board will be established for this study. This Board will convene prior to initiation of the trial portion of the study, at the time that interim data analyses are available at the discretion of the Chair, and when the final data analysis is available. The Board will monitor and provide guidance to the study team regarding study recruitment, follow-up rates, adverse events, and overcoming any unanticipated challenges. The protocol has been approved by all institutional review boards of all participating institutions, and the study is registered on www.clinicaltrials.gov (identifier NCT02501746).

Discussion

The burden of CVD in LMICs, in light of readily identifiable and implementable interventions, is unsettling. Cost-effective, culturally appropriate, and context-specific

innovative approaches to CVD risk reduction are therefore critical to controlling this global epidemic. The BIGPIC study has been designed with these objectives in mind, and offers several unique elements. First, we are implementing group medical visits for chronic disease management in a LMIC setting, while tailoring the implementation to account for contextual and cultural factors. Second, we are leveraging microfinance to improve cardiovascular health, and evaluating for possible synergy by integrating with group medical visits. Third, we are evaluating for the possible mediating and moderating influence of social network characteristics on the effect of group medical visits and microfinance. Finally, we are pursuing a participatory methodology in which community members and stakeholders will be empowered to inform the research, influence the intervention, and impact the research products. We are a team of transdisciplinary investigators engaging in transdisciplinary implementation research, proposing a cohesive, unified analytic framework derived from outcomes research, biostatistics, economics, social network analysis, and qualitative research. While this research is situated within a particular sociocultural and institutional context, we aim to produce generalizable methods and results that can be applied in other settings. We therefore hope that this project will provide a model for the evaluation of other new approaches to non-communicable disease management in low-resource settings worldwide.

We acknowledge that there are potential challenges and limitations to our approach. First, there are no guidelines and no consensus with respect to accurately determining individuals who are at increased risk of diabetes in our research setting in sub-Saharan Africa. We elected to utilize the Leicester Risk Assessment score since it was adapted from the prospectively validated FINDRISC score,⁶⁶ and is among the few diabetes risk prediction scores that has been prospectively validated in multi-ethnic populations.⁶⁵ Second, we recognize that there are several models of group medical visits,^{16,19,90-92} and our prototype is just one possibility. However, given the promising data from our pilot study,⁴⁰ we feel confident that our chosen prototype is appropriate for this study. Finally, blinding of the study participants and study personnel is not possible due to the structure of the interventions. This may lead to differential dropout and missing data, although we anticipate that the likelihood of this is quite low since there is very little geographic overlap among clusters in the trial arms. To the extent that this is observed, we will make adjustments as indicated in our analysis protocol (Appendix C). These challenges notwithstanding, we anticipate that this study will generate important results and lessons for the global cardiovascular community.

Trial Status

For the qualitative portion of the study, data collection is complete and data analysis is ongoing. The cluster randomized controlled trial portion of this study has not yet begun. We anticipate that enrollment will begin by the final quarter of 2016. We anticipate that the trial outcome results will be available in 2019.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
AMPATH catchment area, indicating the geographic areas involved this study: Busia County, Kisumu County, Trans Nzoia County, and Uasin Gishu County.

Figure 2. Conceptual figure depicting relationships of group medical visits, microfinance groups, changes in social network characteristics, intermediate factors, and CVD risk reduction.

Figure 3.

Enrollment, randomization, and follow-up scheme. UC = usual care, MF = microfinance; GMV = group medical visit; GMV-MF = group medical visit and microfinance; CVD = cardiovascular disease; SBP = systolic blood pressure.

Table. Estimated minimum detectable difference of change in systolic blood pressure, with power fixed at 80%, over a realistic range of intra-class coefficient (ICC) values and standard deviation (SD) of change in systolic blood pressure.

SD	ICC									
	0.01	0.03	0.05	0.07	0.09	0.11	0.13	0.15		
10	2.7	4.0	5.0	5.8	6.5	7.2	7.8	8.3		
12	3.2	4.8	6.0	7.0	7.8	8.6	9.3	10.0		
14	3.7	5.6	7.0	8.1	9.1	10.0	10.9	11.6		
16	4.3	6.4	8.0	9.3	10.4	11.5	12.4	13.3		
18	4.8	7.2	9.0	10.5	11.8	12.9	14.0	15.0		
20	5.3	8.0	10.0	11.6	13.1	14.4	15.5	16.6		