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Realist evaluation of community-based ART program for key populations in Benue State, Nigeria: a study protocol

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Abstract

Introduction

Key populations (KP) living with HIV are underserved and often face social and health system barriers to HIV care. To optimise access to quality HIV services among KP, the World Health Organization recommended community-based approaches to HIV service delivery for KP. However, to inform the successful roll out and scale-up of community-based ART service delivery models for KP (KP-CBART), there is a need to study the programme implementation.
This study aims to evaluate the outcomes of KP-CBART in Benue State Nigeria using a realist impact evaluation approach. Our evaluation question is: what are the mechanisms and context conditions that drive successful community-based implementation and how do these lead to better retention in care, treatment adherence, and viral suppression amongst which categories of KP?

Methods and analysis

This study will be conducted in 3 phases, relying on both quantitative and qualitative research methods (mixed method design, following the realist evaluation cycle). The first phase is the development of the initial programme theory grounded in a scoping review, programme and policy document review, and in-depth interviews with key stakeholders. In phase 2, findings from case studies of KP-CBART programme implementation in one Nigerian state are used to test the initial programme theory and to refine it. For the quantitative part, a retrospective cohort analysis will be

conducted to determine the primary outcomes. Semi-structured interviews of key informants will complement findings from the quantitative study.

The heuristic intervention, context, agents, mechanisms, and outcomes (ICAMO) tool will be used to refine the initial programme theory.

Ethics and dissemination

The study protocol was approved by the Institutional Review Boards of APIN Public Health Initiatives, Institute of Tropical Medicine Antwerp, and the Benue State Ministry of Health and Human Services. Study results will be disseminated through stakeholders meeting, peer-reviewed journals, and conferences.

Key words: realist evaluation, key population, HIV, community-based antiretroviral therapy

Strengths and limitations of this study

- There are few studies that offer evidence on real-life implementation of community-based ART approaches for key populations (KP-CBART) in Nigeria.
- Study results will inform policies, design, planning and implementation of health programmes that will improve access to quality HIV services and treatment outcomes among key population living with HIV (KPLHIV).
- This study will be the first to use the realist evaluation method to assess which contextual factors and mechanisms influence the outcomes of the KP-CBART model in sub-Saharan Africa (SSA).
- The strength of this study is its research methodology which involves a realist impact evaluation of KP-CBART, including multiple case studies and the use of both quantitative and qualitative methods (mixed method design) to explain the intervention, contexts, actors, mechanisms, and outcomes of KP-CBART, providing us a better understanding on how flexible/adaptive choice in service delivery geared towards the needs of KP and active KP engagement (lay workers, peer counsellors) could lead to better KP health & well-being outcomes

Introduction

Background

Nigeria is the most populous country in Africa with an estimated population size of 200 million people (1) and has the 4th highest number of people living with HIV/AIDS in the world (2). The National AIDS Indicator Survey (NAIIS) estimates show that approximately 1.76 million people are

living with HIV in Nigeria and HIV prevalence among the 15-64 age groups is 1.4% and in those under-15 years is 0.2% (2).

Key populations (KP) include sex workers, men who have sex with men (MSM), persons who inject drugs (PWID) and transgender people (TG). KP are disproportionately affected by HIV/AIDS and are at increased risk of contracting HIV (3). Compared to the adult general population (15-49 years) gay and other MSM, PWID, sex workers, and TG have 26, 29, 30, and 13 times more risk of contracting HIV, respectively (4). In 2019, KP and their sexual partners accounted for 62% of all new HIV infections in the world and more than 50% in sub-Saharan Africa (4). In Nigeria, KP make up only 3.4% of the overall population, yet account for 32% of new HIV infections (5). The 2014 Integrated Behavioral and Biological Science Survey in Nigeria puts the prevalence at 19.4% for Brothel-Based Sex workers (BBFSW), 8.6% for Non-Brothel-Based Females sex workers (NBBFSW), 22.9% for Men who have Sex with Men (MSM) and 3.4% for People who Inject Drugs (PWID).

KP are underserved and they have limited access to quality HIV services, including HIV prevention, care and treatment services. Factors limiting their (barriers to) access include social exclusion, LGBTI human rights infringements or violation of LGBTI rights , criminalisation of LGBTI , stigma, discrimination and violence (in the community) towards LGBTI (3)(6). The level of disease control in KP affects disease control in the general population through sexual contact between KP and their partners and clients (7). Therefore, to achieve the UNAIDS target of HIV epidemic control by 2030, with 95% of PLHIV knowing their HIV status; 95% antiretroviral therapy (ART) coverage among those who know their status; and 95% viral suppression among those on ART (8), there is a need to optimise access to quality HIV services for KP.

Data on ART coverage among KP in most African nations is scarce. In South Africa, Ghana and Togo ART coverage among MSM was 28.1% (2018), 3.7% (2017) and 14.1 % (2018) respectively. ART coverage among female sex workers (FSW) was 75.3% (2017), 23.6% (2018), and 87.6% (2018) – in South Sudan, South Africa, and Botswana, respectively (9). Therefore, to reduce barriers to access and improve KP engagement, the World Health Organization in (2016) recommended community-based approaches for KP living with HIV (3)(10). Such approaches to HIV service delivery have proven to be an effective strategy to reach people living with HIV in the general population (11).

The Community-based ART service delivery for key populations

KP often experience stigma and discrimination in regular health care facilities (all levels of care), and this impacts negatively on access to quality HIV care. Community-based approaches, that encourage

the engagement of KP communities (to participate in program planning and support service provision) combined with task shifting to lay workers, are strategies which may resolve gaps in access to quality HIV care and treatment services. Community-based approaches to HIV control have proven to be an effective method of reaching people in the general population, particularly for individuals who are hard to reach in the sub-Saharan Africa setting (11). Innovative community-based ART service delivery for HIV- positive key populations (KP-CBART) include community-based and venue-based outreach (such as CBO offices, hotels, brothels, etc), community-based antiretroviral therapy (CBART) initiation and refill and home-based ART (12). If adapted to the needs of KP, such programs may engage the KP community and lay health workers, such as HIV adherence counsellors, peer educators, or clinic defaulter trackers for HIV service delivery. Other key actors that may be involved are KP-led and KP-friendly community-based organisations, civil society organizations, KP-network and healthcare providers. Furthermore, a more comprehensive package of HIV services that can be offered through CBART interventions include HIV testing and counselling, ART initiation, ART refill, and (clinical and laboratory) patient monitoring on ARVs (13). The Nigeria HIV programme currently implements both facility-based and community-based HIV service delivery for KP. Implementing partners work with the KP secretariat (KP network/association) and KP led or KP friendly CBOs to provide HIV prevention, care, and treatment services to the KP.

Pilot experiences with KP-CBART improved early to mid-term clinical outcomes along the cascade of HIV care (HIV testing uptake, linkage to care, ART initiation, retention-to-care, and virological suppression) among HIV positive KP receiving care through KP-CBART in different sub-Sahara African settings (14–19). Most studies on KP-CBART in sub-Saharan Africa described a high uptake of HIV testing services (56% - 78.2%):between 79% and 100% of clients testing positive were linked to ART (14–16,18). About 50% of HIV positive MSM and 100% FSW were initiated on ART in CBART programmes in Nigeria and Tanzania, respectively (17,18). Furthermore, where evaluated, linkage to care, retention in care and adherence to ART among KP receiving HIV care in CBART programmes (between 6 and 18 months on ART) were better compared to facility-based care, while viral suppression was not worse (14–19). These findings suggest that KP-CBART may complement facility-based care for KP, with clinical outcomes (viral suppression and retention in care) that are similar or better.

Rationale for the study

Community-based approaches to HIV care, including CBART, are central to achieving the ambitious 95-95-95 targets (95% of PLHIV aware of their status, of those 95% on ART, of those 95% virologically suppressed) and thus control the HIV epidemic in sub-Saharan Africa. However, there are only a few

studies in Sub Sahara African countries , including Nigeria, that offer evidence on implementation of this strategy in non-research settings and its long term clinical and program outcomes along the cascade of HIV care, the challenges/barriers and the facilitators (enablers) (20).

KP-CBART is a complex health intervention, a multi-component health programme that implements multiple strategies and activities, and interaction between actors and/or institutions and the programme environment to generate outcomes. Hence, the choice of the realist evaluation method to assess which context conditions and mechanisms influence the outcomes of KP-CBART. Realist evaluation is a type of theory-driven evaluation, and is aimed at making the theories of the programme or policy more explicit by describing and testing the programme theories or hypothesis on how, and for whom, the programme work (or not work) and under what conditions (context), they work (21). This proposal will be the first study to conduct a realist evaluation of KP-CBART in Nigeria.

How the introduction and implementation of KP-CBART is experienced (and perceived) locally, by different stakeholders, such as KP communities but also local community leaders, local health administration, health personnel, community-based organizations (CBO), local police / law enforcement, local authorities as well as by the national programme partners such as the Ministry of Health, Agency for AIDS Control, implementing partners, facility staff, and KP communities and networks has not yet been fully explored. Furthermore, the perceptions / views of stakeholders regarding the extent to which medical tasks such as HIV testing services, ART initiation, and ART refill can be shifted to KP communities and lay workers in a community-based model of care is yet to be fully explored. Therefore, this proposal presents an opportunity to evaluate how community-based ART interventions can be adapted to the specific health needs of KP, and how KP communities can be actively involved in service delivery, as lay workers (peer counsellors, HIV counsellor testers, and outreach coordinators). This study will further the discussion on task-shifting and differentiated ART service delivery for PLHIV in challenging environments not only in terms of resource constraints but also in terms of stigma, discrimination and criminalization of KP in LMIC.

Intervention logic and working hypothesis

Our initial theory is that in resource-constrained settings with unfavorable policy against KP activities and low levels of trust between the health workers and members of KP, decentralisation of ART service delivery to KP communities together with training of HCW on KP sensitization and comprehensive ART will encourage KP to access HIV care and treatment services and this will

improve uptake and utilisation of these services and retention-in-care. Optimal HIV prevention and treatment for KP will translate to better health outcomes and well-being for KP .

Involvement of KP community and lay workers in all components (e.g. accompany referral for ART, HIV testing and linkage to ART, medication adherence, ART refill, clients tracing, and etc) of a comprehensive HIV care package would make HIV service KP-friendly and thus, improve long term outcomes/sustained engagement of HIV positive clients in care and clinical outcomes (figure 1).

Insert ***Figure 1. Starter hypothesis for the CBART model for KP***

Significance of the study

Evaluating the KP-CBART model will generate evidence-based information on differentiated ART service delivery (and more specifically, community-based models) for HIV-positive key populations in Nigeria, and can potentially inform (to adapt or contextualize) policies, design, planning and implementation of health programmes that will improve access to quality HIV services and treatment outcomes among KPLHIV in similar and other settings.

Research questions

How, why, for whom, and in what context conditions do community-based ART models of service delivery contribute to observed clinical outcomes among key populations in Benue State, Nigeria?

Objectives:

This research work will evaluate the effectiveness of community-based ART programmes, more specifically the KP-CBART, for key populations in Benue State - Nigeria using the realist evaluation approach.

General objective:

- To develop an empirically tested middle range theory explaining how, why and in which context conditions the KP-CBART model contributes to improved clinical outcomes for key populations using a single case study design

Specific objectives

(1) To develop an initial programme theory grounded in a scoping review of grey and peer-reviewed literature on the implementation of KP-CBART in resource constrained settings in SSA / or in LMIC

(2) To evaluate the application of the initial programme theory in multiple case studies:

- To assess the impact of KP-CBART on clinical outcomes (retention in care, viral suppression) along the cascade of care in five KP-CBART implementation sites in Benue State, Nigeria;
- To identify the contextual factors and generative mechanisms through which the observed outcomes were achieved in the 5 selected sites;
- To explore the causal configurations on the basis of the ICAMO heuristic tool which contributed to the observed outcomes in those 5 sites

(3) To refine the initial programme theory in order to provide insights/policy recommendations into the context conditions and social mechanisms underlying the implementation of KP-CBART

Methods

Study setting and participants

The study will be conducted in Benue State and is located in north-central Nigeria. According to the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), Benue state has the second highest HIV prevalence (4.9%) in Nigeria (2). In 2014, HIV prevalence among the BBFSW and NBFSW in Benue State was 36.5% and 14.2% respectively. These rates are the second highest for a state in Nigeria (22). This study will focus on MSM, FSW, PWID, and TG who are receiving HIV care and treatment through the KP-CBART model.

Description of the KP-CBART intervention in Benue State, Nigeria

In Benue State, the CBART model was adopted to reach KP living with HIV and to increase access and utilization of HIV services among the KP communities. The KP-CBART model was implemented since 2016. The programme is part of the national HIV programme that is being implemented by Partners, National and State Agency for the Control of AIDS and Ministry of Health with support from PEPFAR through the United States Centre for Disease Control and Prevention. Table 1 below describes the model, with mobile health teams providing ART to HIV positive clients in drop-in-centres (usually in a primary health care setting or offices of community-based organizations) and at hotspots for members of KP (hotels, club houses, and etc). The One Stop Shop clinic is a community-based health centre that provides comprehensive HIV services strictly to KP in an environment free of stigma and

discrimination. OSS and DIC are funded and managed by the implementing partners and donor agencies.

Table 1. Description of community-based ART models for key populations in Benue State, Nigeria

	Community drop-in-centre (DIC)	Community outreach venues with mobile ART team	Community-based one stop shop clinic
Target population	FSW, MSM, PWID	FSW, MSM, PWID	FSW, MSM, PWID
HIV care delivery point	A safe place where KP can meet/gather for social and clinical activities	DIC plus mobile health team (clinician, nurses and peer educators) to homes, and hotspots including hotels, brothels, bunkers	Provision of KP friendly health care services in a trusted community ART centre
Location	Semi-urban	Rural or semi-urban	Urban
Operation hours	Daily	Once or twice per week	5-days per week
Package of services	Peer-led HIV counselling and testing, antiretroviral treatment, accompany referral, tracking of clinic defaulters by peers and network, provision of condoms, KP sensitization training for HCWs	Peer-led HIV counselling and testing, antiretroviral treatment, accompany referral, tracking of defaulters by peers and network, provision of condoms, KP sensitization training for HCWs	Peer-led HIV counselling and testing, antiretroviral treatment , accompany referral, tracking of clinic defaulters by peers and network, provision of condoms, KP sensitization training for HCWs, cervical cancer screening)
Care providers	**Community health workers:** community ART Nurse, Community Pharmacist and Medical Laboratory Scientist **Lay health workers:** Peer educators, community mobilising officers, adherence counsellors	**Mobile ART Team (mART):** ART Clinician, Pharmacist, and Medical Laboratory Scientist from the OSS clinic **Lay health workers:** Peer educators/community mobilising officers	**Health professionals:** ART Clinician, ART Nurse, Community Pharmacist and Medical Laboratory Scientist **Lay health workers:** Peer educators, community mobilising officers, adherence counsellors
Roles of KP community or lay HCWs in HIV care	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral

Study design

This study will follow the realist evaluation approach (21) and will be conducted in an iterative manner. For the realist methodology the RAMESES II reporting standards for realist studies will be

followed (23). An exploratory, sequential, mixed method realist study design using an (multiple) embedded case study design of KP-CBART (24). This study will be conducted in phases relying on both quantitative and qualitative research methods (see figure 2). The quantitative study is a retrospective cohort analysis of program data.

Multiple case studies of KP-CBART will be evaluated and findings from each of the case study will produce a programme theory that can be compared and redefined as a middle range theory. The complex interaction between the context, mechanisms, and outcomes (CMO) configuration of the KP-CBART will be conceptualized and explained.

The case is the KP-CBART programme as implemented in Benue state, Nigeria. The unit of analysis is the health facility which is either a drop-in-centre or One Stop Shop clinic with(out) mobile health team. A drop-in-centre is a safe place where KP can receive specific health interventions. One Stop Shop clinic is a community-based health centre for members of KP only and comprehensive HIV services are offered in this facility.

Specific program theories for each of the 5 units of analysis will be developed based on thick description (25), exploring implementation strategies and activities that produce the observed outcomes, both intended and unintended, depending on the context conditions.

Both qualitative and quantitative data will be collected and synthesized using the ICAMO heuristic tool (26) to explain the causal mechanisms that trigger the patterns of outcomes in each context. The three-phased model of study is as shown in Figure 2 and the summary of each of the research stages: the objectives, outcomes, data, and analysis are presented in table 2 below.

Insert Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbang FC et al, 2016

Table 2: Summary of the Realist Evaluation cycle

Stage	Data source	Data analysis	Objectives
1.	Qualitative • Literature on KP-CBART programme: internal and external documents, guidelines, SOPs, Programme implementation plan	Qualitative • Scoping review	• To elicit the initial programme theory of the KP-CBART. • To identify the mechanisms and contextual factors responsible for programme outcomes
2.	Qualitative • Interviews with programme beneficiaries: KP clients, CBO staff and IP staff Quantitative • Routine program data	Qualitative • Retroductive, realist analysis Quantitative • Descriptive and inferential statistical analysis	To evaluate the application of the initial programme theory in multiple case studies
3.	Data from stage 1, 2, and 3	Mixed methods: triangulation	To develop generalizable theories of KP-CBART in LMIC / resource constrained settings)

Study population

Qualitative study: HIV programme managers (implementing partners), managers of CBOs working with KP, healthcare providers, community facilitators, members of KP (representative of KP network) and KP clients.

Quantitative study: All HIV positive KP (18 years or older) enrolled into the community-based ART program between 2015 and January-2021 in Benue State, Nigeria.

Study period: January 2016 - December 2022

Data collection and analysis

Data collection will be from June 2021 to Sept 2022.

Besides data on the processes and the effectiveness of KP-CBART implementation, data on the specific context conditions including implementation challenges, and mechanisms that are influencing intermediary and final outcomes responsible for observed changes in the programme will be analysed.

Programme outcomes refer to short-term to long-term changes. For HIV positive KP, **intermediary outcomes** include clinical outcomes such as retention in care, viral suppression, and adherence to ART while **final outcomes** are HIV related mortality, incidence of HIV/AIDS (new HIV infection) and overall clients health and well-being. For the health system, access and availability of ART services, responsiveness and acceptability of services, decongestion of health facilities and reduced workload. The **context** (figure 1) will encompass factors within the national/state policy context (weak national health policies for KPLHIV, criminalzation policy, stigma and discrimination), the local community (culture, belief, harassment by the law enforcement agents, geographic access (location and number of OSS and DIC), the management and coordination of the CBART program by donors and partners) and the service delivery points (OSS, DIC, outreach venues). Context also includes health system issues such as logistics, supply of drugs, and viral load testing for HIV positive KP.This study is embedded in the already established HIV program for KP in Benue State, Nigeria and data will be sourced from the program database (mention already a bit what's in there). Data that allow analysis of outcomes, context conditions, and identify the mechanisms of the KP-CBART intervention will be collected. This evaluation will be conducted in three phases as shown in figure 2 and explained below:

Phase 1- Eliciting the initial programme theory

During this stage, the initial programme theory will be developed. A programme theory is a hypothesis that can be tested or redefined. This stage will be guided by the realist synthesis / scoping review of the literature on KP-CBART. Interviews with programme managers and implementers will be used to explore the contextual factors and to identify generative mechanisms that trigger observed outcomes in the programme.

In addition to the interviews, data will be collected by: review of relevant document on KP-CBART programme in Nigeria and a review of evidence (systematic and scoping review) on the effect of the programme on patients' clinical outcomes (retention, viral suppression). Programme documents such as implementation guidelines, progress report, country operational plan, and etc will be reviewed.

Findings from this stage will inform the development of an initial programme theory for the implementation of KP_CBART program. Furthermore, salient context conditions such as social and environmental (e.g. conflicts and ethnic crisis, IDPs, criminalisation policy.) at local, state and national levels will be mapped during the document review and interview into determinant framework to structure the analysis of the configured ICAMOs. This mapping will help to unpack the black box of implementation that influence the programme outcomes.

Stage 2: Testing the programme theory

In this stage, the objective is to empirically test the elicited initial programme theories across different settings.

A mixed methods design using multiple case studies of KP-CBART and retrospective cohort studies will be used for evaluation. A mixed method design employs both quantitative and qualitative research methods in sequence. The quantitative strand will precede the qualitative strand and findings from the quantitative will inform the qualitative strand. The quantitative study will rely on retrospective study design and will assess the effects of KP-CBART among KP receiving treatment in CBART in terms of linkage, medication adherence, retention in care, and viral suppression (based on routine programme data) and associated factors. The qualitative part will assess how patients perceive and experience KP-CBART services (is it KP-friendly, safer, less stigma/discrimination, and more adapted / attuned to work/outside activities of KP). Both the programme beneficiaries (patients) and staff will be interviewed.

Findings from individual case studies will be reviewed and compared with the initial programme theory (within case analysis).

The context specific theories are presented to key stakeholders in each setting (validation workshop/discussion). Additionally, alternative explanations that might account for the same findings will be considered such as counterfactual method.

Stage 3- Synthesizing refined context-specific programme theories into a Middle Range Theory

The objective of this stage is to synthesize findings into a middle range theory ("decontextualization") through cross-case analysis. Lessons learned from the MRT will inform the adaptation and scale-up of the program in other settings.

Qualitative sampling and recruitment method:

Potential study respondents will be identified through purposive sampling technique and snow-balling. For clients receiving in care in the KP-CBART programme, invitation for interviews will be sent via text messages and phone calls through HCWs and KP peers working in the programme. Respondents will also be recruited for an interview at the venue of service delivery (DIC or OSS). For those who are not interested in the programme, the KP peer educator, members of the KP-friendly/led CBOs and KP network/association will be consulted to reach them.

We intend to interview the following people to allow for maximum variation of respondents:

	Study participant	No. of interviewees per site
1.	KP clients (FSW, MSM, PWID)	5 per KP sub-group
2.	Community-based organizations (peer educators)	5
3.	CBART staff) clinicians, nurse, adh. counsellors	5
4.	Programme managers/designers (Implementing partners, Agency for Control of AIDS, Ministry of Health, KP secretariat)	2 per agency

Because of the iterative nature of realist evaluation, there is possibility that participants will be re-interviewed. As the knowledge of the programme increases through refinement (document review). For the FGD, homogenous groups and maximum variation of key stakeholders will be ensured to capture data qualitatively.

Qualitative data collection

Internal and external KP-CBART programme documents will be reviewed to develop the initial program theories. In-depth interview (IDI) and focus group discussions (FGD) will be conducted to explore how programme managers, KPs and their providers experience, view, and perceive the KP-CBART model and how it addresses barriers to linkage, retention, and adherence.

IDI and FGD guides will be developed and used to moderate the interview and discussion. Participants for IDI and FGD will be drawn from a mix of study participants until data saturation is reached. Interim analysis will be conducted to identify themes and assess data saturation. Subsequently, interview guides may be adapted and more participants may be recruited until data saturation is reached (27). Interviews will be conducted by the principal researcher and the duration of interviews will be between 30 -45 minutes. The principal investigator will be supported by a notetaker, and the responses will be audio recorded. The principal investigator and notetaker are part of the programme staff, but are not directly involved in care delivery.

Quantitative data collection

Patient-level data between January 2016 and January 2021 will be extracted from programme database and facility M&E tools (registers and patient files). Standardized data extraction template will be used to obtain information on all patients who tested HIV positive between January 2016 and January 2020 from the electronic medical record (EMR) and facility-based record (health management information system (MIS) tools i.e. registers and clients folders). Variables include demographic data (age, sex, education, occupation, residence), clinical variables (HIV status, date of HIV diagnosis, linkage to care, ART status, WHO stage, TB status, viral load suppression) and treatment outcome (LTFU, dead, transferred out, active in care).

Data analysis

Qualitative analysis: Thematic content analysis will be used to analyse the transcripts of the voice recordings. NVIVO software wil be used for coding and data storage.

The main data analysis for the realist evaluation will be in four steps: thematic data analysis, identifying the ICAMO configurations and synthesizing the programme theory per HF, overall synthesis and refinement of the programme theory.

Step 1: thematic data analysis – thematic content analysis will be used to classify data (from multiple case studies) into intervention, actor, context, mechanism and outcomes. The development of codes and the codebook will be performed using Nvivo software by the principal investigator and co-investigators. Thereafter, the initial programme theory is tested by comparing multiple cases using a deductive analytical approach.

Step 2: Identifying the ICAMO configurations- specific intervention, context, agents, mechanisms, and outcome per case study will be grouped to form intermediate-level and high level codes (ICAMO configurations). The case study ICAMO are generated using in-case analysis. Cross-case analysis is used for synthesizing and refining the overall programme theory)

Step 3: Refining ICAMO configurations into programme theory - ICAMO configurations in step 2 from different cases will be compared and their explanatory power across studies will be examined (cross-case analysis). "Causal loop thinking" will be used to develop the final ICAMO configurations and to map out the interaction between the different components in the system.

Quantitative analysis: Proportions will be calculated for categorical variables while means, medians and interquartile ranges will be calculated for continuous variables. The chi-squared test will be used to assess associations between categorical variables. Kaplan–Meier techniques will be used to estimate retention over time. The log-rank test will be used to estimate differences between Kaplan-Meier curves, stratified for different subgroups. We will employ bivariate and multivariate logistic regression to estimate the association between explanatory variables and the different outcomes (linkage, retention and virological suppression).

Monitoring and Quality Control

Data for quantitative study will be extracted from the project electronic medical record by the Strategic Information Unit. No names or data which could lead to the indirect identification of participants will be encoded in the study database. The technical lead for Strategic Information Unit will validate data and ensure correctness of data. Missing data will be completed and inconsistent data will be verified by checking source data (registers and patient records).

For the qualitative study, data will be triangulated by the researcher. As part of qualitative data validation, anonymized findings will be shared with key informants (KP opinion leader and clinicians of the OSS clinic) and during a group discussion with KP.

Patient and Public Involvement

Study participants and the public are not involved in the planning of the design, conduct, and dissemination of the results of this research. However, the views and perceptions of the programme managers and designers will inform the development of the initial programme theory of the KP-CBART. To maximise the impact of the study, research findings will be disseminated to KP community groups and networks, healthcare providers, HIV programme managers, and health policy makers.

Ethical approval and dissemination of results

Ethical approval was obtained from the Institutional Research Board of APIN Public Health Initiatives (IRB046-FR), Benue State Ministry of Health and Human Services (MOH/STA/204/VOL.1/154), and the Institute of Tropical medicine Antwerp (1503/21). The results of this study will be shared with all stakeholders (study participants and programme staff) and published in scientific journals and presented at scientific conferences in the form of oral presentations or posters.

Discussion

This study protocol will describe the KP-CBART model as being implemented in Benue Nigeria and explore the mechanisms and contextual factors which generate intermediate outcomes, such as medication adherence, retention-in-care, viral load suppression, and long term outcomes, such as reduction in HIV incidence and improved health and well-being. The results of this study will inform adaptations of the KP-CBART program to better meet the health needs of KP in Nigeria, and assist in national policy & programme design for the implementation of KP-CBART. A CBART model that fits better the needs of KP is expected to improve clinical outcomes.

Findings from previous studies on KP-CBART in Nigeria are not sufficient to conceptualise and scale-up the programme. The adopted research methods in these studies are inadequate to explain causation in complex health interventions such as the KP-CBART. Most of these previous studies are quantitative and are designed to determine the programme outcomes (such as viral load suppression and retention -in care) and associated factors. Therefore, the realist evaluation method, a theory based evaluation, to evaluate KP-CBARTin Nigeria will bridge the deficiency of other research methods and offer a causal explanation of outcomes and their generative mechanisms. The realist evaluation method is well suited for this evaluation because the complex nature of the programme.

The study will tease out the various components in the programme and the contexts. We will determine the contextual factors at the micro, meso, and macro levels (individual clients, service delivery points, local community, and state/national) and the mechanisms that generate the programme outcomes. We will describe the various interventions offered by the programme and how the actors respond to them. These findings will inform health policies, adaptation, and scale up of community-based ART interventions for HIV positive KP in Nigeria and similar settings in sub-Saharan Africa.

The strength of this proposed study is its research methodology which involves a realist impact evaluation of KP-CBART, including multiple case studies and a qualitative mixed method designs to

explain the outcomes and impacts of the intervention. Anticipated limitations of this study are the inherent challenges of the realist evaluation method. Differentiating between the contextual factors and the mechanisms could be a limitation as many realist researchers have reported such challenges (28). The ICAMO configurational mapping is subject to the interpretation of the researchers and this can introduce some level of subjectivity into the interpretation of study results. Furthermore, the process of iterative cycle of interview with key actors in the program (stakeholders) can induce confirmation bias during the ICAMO configuration analysis. Another limitation is the conduct of observational restrospective cohort study which can induce selection bias during the conduct of the quantitative study. Investigators will ensure that these limitations are addressed during the conduct of the research.

Authors' contributions

OI, SVB, and TD: conceptualisation and design of the study. CM, JVO, PJ, PO, and LL reviewed the original manuscript.

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Competing interests statement

Authors declare no conflict of interest

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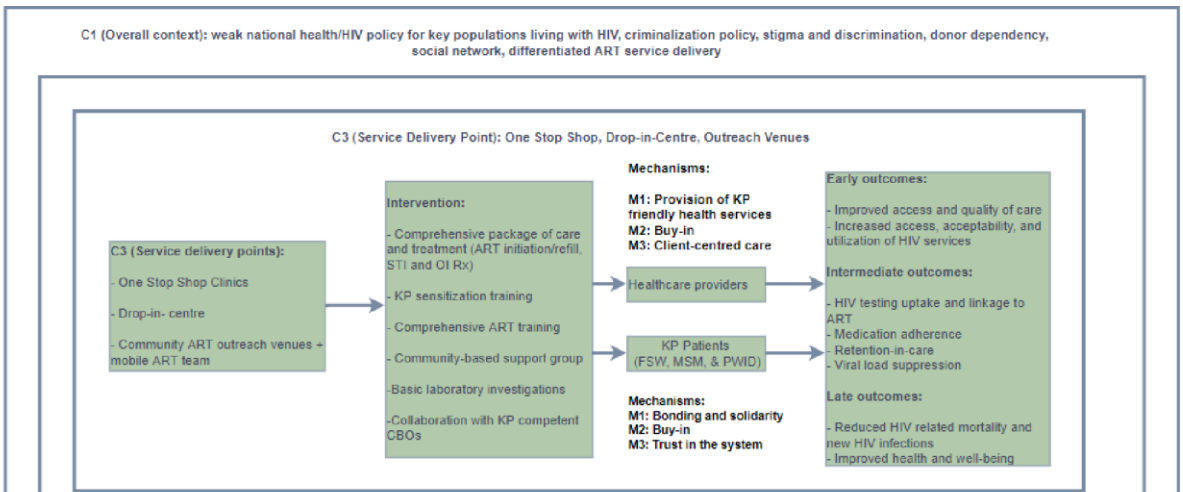

Figure 1. Starter hypothesis for the CBART model for KP

[CBART-community-based antiretroviral therapy, KP-key population, KP-CBART- community-based ART service delivery models for KP, C-context, mART- mobile ART, CBO-community-based organization, M- mechanism, Rx-treatment, STI- sexually transmitted infection, OI- opportunistic infection]

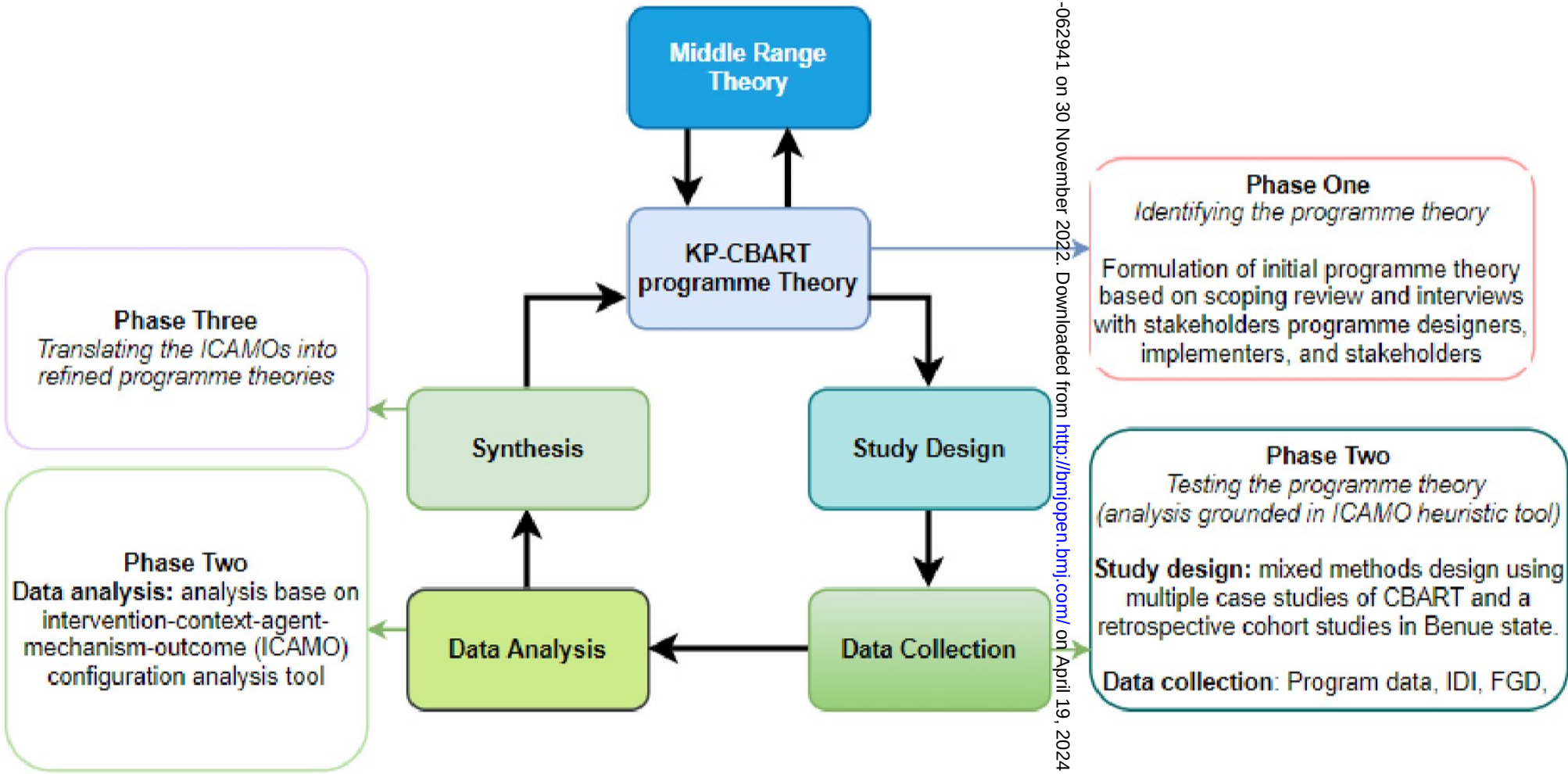

Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbang FC et al, 2016

[Abbreviations: KP-CBART- community-based ART service delivery models for KP, IDI-indepth interview, FGD-focus group discussion]

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Outcomes of a community-based antiretroviral therapy program for key populations living with HIV in Benue State, Nigeria: protocol for a realist evaluation

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Outcomes of a community-based antiretroviral therapy program for key populations living with HIV in Benue State, Nigeria: protocol for a realist evaluation

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Abstract

Introduction

Key populations (KP) living with HIV are underserved and often face social and health system barriers to HIV care. To optimise access to quality HIV services among KP, the World Health Organization recommended community-based approaches to HIV service delivery for KP. However, to inform the successful roll out and scale-up of community-based ART service delivery models for KP (KP-CBART), there is a need to study the programme implementation. This study aims to evaluate the outcomes of KP-CBART in Benue State Nigeria using a realist impact evaluation approach. Our evaluation question is: what are the mechanisms and context conditions that drive successful community-based implementation and how do these lead to better retention in care, treatment adherence, and viral suppression amongst which categories of KP?

Methods and analysis

This study will be conducted in three phases, relying on a mixed method design and following the realist evaluation cycle. The first phase is the development of the initial programme theory grounded in a scoping review, programme and policy document review, and in-depth interviews with key stakeholders. In phase 2, findings from case studies of KP-CBART programme implementation in one Nigerian state are used to test the initial programme theory and to refine it. The quantitative part is a retrospective cohort study. All HIV positive KP clients enrolled into the KP-CBART between 2016 and 2020 will be included in the study. While maximum variation and data saturation will inform sample

size for the qualitative part, an estimated 90 purposively selected study participants will be interviewed. In phase 3, findings will be synthesised into a middle range theory through cross-case analysis. The heuristic intervention, context, agents, mechanisms, and outcomes (ICAMO) tool will be used to refine the initial programme theory.

Ethics and dissemination

The study protocol was approved by the Institutional Review Boards of APIN Public Health Initiatives (IRB022-FR), Institute of Tropical Medicine Antwerp (1503/21), and the Benue State Ministry of Health and Human Services (MOH/STA/204/VOL1/154). Written informed consent will be obtained from all study participants. Study results will be disseminated through stakeholders meeting, peer-reviewed journals, and conferences.

Keywords: realist evaluation, key population, HIV, community-based antiretroviral therapy

Strengths and limitations of this study

- A strength of this study is its research methodology, which involves a realist impact evaluation of community-based ART service delivery models for key populations (KP-CBART), including multiple case studies and the use of mixed method design to explain the intervention, contexts, actors, mechanisms, and outcomes of KP-CBART.
- Data collection and verification will be rigorous: researchers will use multiple data sources and triangulate findings from the quantitative and qualitative arms of the study.
- This study will reflect the reality of KP-CBART; how results for different treatment outcomes complement each other will be verified to improve our understanding of the effect of the KP-CBART program on different health indicators.
- The refined programme theory will build on the knowledge of HIV programmes theory and community-based ART interventions for key populations in sub-Saharan Africa and multiple case studies of KP-CBART in Benue state Nigeria, thus allowing for accumulation of knowledge.
- This study will not produce universally applicable findings; as the study relies on the concept of generative causality, the evaluation will only indicate conditions in which KP-CBART works (or not) and how they do so.

Introduction

Background

Nigeria is the most populous country in Africa with an estimated population size of 200 million people (1) and has the 4th highest number of people living with HIV/AIDS in the world (2). The National AIDS Indicator Survey (NAIIS) estimates show that approximately 1.76 million people are living with HIV in Nigeria and HIV prevalence among the 15-64 age groups is 1.4% and in those under-15 years is 0.2% (2).

Across the African continent, the burden of HIV/AIDS and incidence rates remain the highest among Key populations (KP). KP include sex workers, men who have sex with men (MSM), persons who inject drugs (PWID), transgender people (TG), prisoners and detainees (3). These groups are disproportionately affected by HIV/AIDS and are at increased risk of contracting HIV (4). Compared to the adult general population (15-49 years) gay and other MSM, PWID, sex workers, and TG have 26, 29, 30, and 13 times more risk of contracting HIV, respectively (5). In 2019, KP and their sexual partners accounted for 62% of all new HIV infections in the world and more than 50% in sub-Saharan Africa (5). Despite representing a relatively small proportions of populations in East and Southern Africa, KP individuals account for 25% of new HIV infections in the region (3). In Nigeria, these groups make up only 3.4% of the overall population, yet account for 32% of new HIV infections (6). The 2020 Integrated Behavioral and Biological Science Survey in Nigeria puts the prevalence at 16.7% for females sex workers (FSW), 20.9% for MSM, 9.5% for PWID, and 6.2% for TG people (7).

KP are underserved and they have limited access to quality HIV services, including HIV prevention, care and treatment services. Factors limiting their (barriers to) access include social exclusion, LGBTI human rights infringements or violation of LGBTI rights , criminalisation of LGBTI , stigma, discrimination and violence (in the community) towards LGBTI (8)(9) (4)(10). The level of disease control in KP affects disease control in the general population through sexual contact between KP and their partners and clients (11). Therefore, to achieve the UNAIDS target of HIV epidemic control by 2030, with 95% of PLHIV knowing their HIV status; 95% antiretroviral therapy (ART) coverage among those who know their status; and 95% viral suppression among those on ART (12), there is a need to optimise access to quality HIV services for KP.

Viral load suppression among KP in most African nations is low and may continue to fuel the HIV epidemic in the general population (3). In Africa, the average proportion of HIV infected MSM using ART is 24%, while on average 25% are virally suppressed (3). In South Africa, Ghana and Togo ART coverage among MSM was 28.1% in 2018, 3.7% in 2017 and 14.1 % in 2018 respectively. ART coverage among female sex workers (FSW) was 75.3% in 2017, 23.6% in 2018, and 87.6% in 2018 – in

South Sudan, South Africa, and Botswana, respectively (13). Therefore, to reduce barriers to access and improve KP engagement, the World Health Organization in (2016) recommended community-based approaches for KP living with HIV (4)(14). Such approaches to HIV service delivery have proven to be an effective strategy to reach people living with HIV in the general population (15).

The community-based ART service delivery for key populations

KP often experience stigma and discrimination in regular health care facilities across all levels of care, and this impacts negatively on access to quality HIV care. Community-based approaches, that encourage the engagement of KP communities , to participate in program planning and support service provision, combined with task shifting to lay workers, are strategies which may resolve gaps in access to quality HIV care and treatment services. Community-based approaches to HIV control have proven to be an effective method of reaching people in the general population, particularly for individuals who are hard to reach in the sub-Saharan Africa setting (15). Innovative community-based ART service delivery for HIV- positive key populations (KP-CBART) include community-based and venue-based outreach (such as CBO offices, hotels, brothels, etc), community-based antiretroviral therapy (CBART) initiation and refill and home-based ART (16). If adapted to the needs of KP, such programs may engage the KP community and lay health workers, such as HIV adherence counsellors, peer educators, or clinic defaulter trackers for HIV service delivery. Other key actors that may be involved are KP-led and KP-friendly community-based organisations, civil society organizations, KP-network and healthcare providers. Furthermore, a more comprehensive package of HIV services that can be offered through CBART interventions include HIV testing and counselling, ART initiation, ART refill, and patient monitoring on ARVs in the clinic and laboratory (17). The Nigeria HIV programme currently implements both facility-based and community-based HIV service delivery for KP. Implementing partners work with the KP network and association, and KP led or KP friendly CBOs to provide HIV prevention, care, and treatment services to the KP.

Pilot experiences with KP-CBART improved early to mid-term clinical outcomes along the cascade of HIV care and treatment (HIV testing uptake, linkage to care, ART initiation, retention-to-care, and virological suppression) among HIV positive KP receiving care through KP-CBART in different sub-Sahara African settings (18–23). Most studies on KP-CBART in sub-Saharan Africa described a high uptake of HIV testing services (56% - 78.2%):between 79% and 100% of clients testing positive were linked to ART (18–20,22). About 50% of HIV positive MSM and 100% FSW were initiated on ART in CBART programmes in Nigeria and Tanzania, respectively (21,22). Furthermore, where evaluated, linkage to care, retention in care and adherence to ART among KP receiving HIV care in CBART

programmes (between 6 and 18 months on ART) were better compared to facility-based care, while viral suppression was not worse (18–23). These findings suggest that KP-CBART may complement facility-based care for KP, with clinical outcomes such as viral suppression and retention in care that are similar or better.

Rationale for the study

Community-based approaches to HIV care, including CBART, are central to achieving the ambitious 95-95-95 targets (95% of PLHIV aware of their status, of those 95% on ART, of those 95% virologically suppressed) and thus control the HIV epidemic in sub-Saharan Africa. However, there are only a few studies in Sub Sahara African countries , including Nigeria, that offer evidence on implementation of this strategy in non-research settings and its long term clinical and program outcomes along the cascade of HIV care, the barriers and the enablers (24).

KP-CBART is a complex health intervention, a multi-component health programme that implements multiple strategies and activities, and interaction between actors and/or institutions and the programme environment to generate outcomes. Hence, the choice of the realist evaluation method to assess which context conditions and mechanisms influence the outcomes of KP-CBART. Realist evaluation is a type of theory-driven evaluation, and is aimed at making the theories of the programme or policy more explicit by describing and testing the programme theories or hypothesis on how, and for whom the programme work or not work, and under what conditions (context), they work (25). This proposal will be the first study to conduct a realist evaluation of KP-CBART in Nigeria.

How the introduction and implementation of KP-CBART is experienced and perceived locally, by different stakeholders, such as KP communities but also local community leaders, local health administration, health personnel, community-based organizations (CBO), local police, local authorities as well as by the national programme partners such as the Ministry of Health, Agency for AIDS Control, implementing partners, facility staff, and KP communities and networks has not yet been fully explored. Furthermore, the perceptions and views of stakeholders regarding the extent to which medical tasks such as HIV testing services, ART initiation, and ART refill can be shifted to KP communities and lay workers in a community-based model of care is yet to be fully explored. Therefore, this proposal presents an opportunity to evaluate how community-based ART interventions can be adapted to the specific health needs of KP, and how KP communities can be actively involved in service delivery, as lay workers (i.e. peer counsellors, HIV counsellor testers, and outreach coordinators). This study will further the discussion on task-shifting and differentiated ART service delivery for PLHIV in challenging environments not only in terms of resource constraints but also in terms of stigma, discrimination and criminalization of KP in LMIC.

Intervention logic and working hypothesis

The *starter hypothesis for the CBARTl for KP (figure 1*) explains the assumptions regarding how the CBART model would achieve better health outcomes for key population groups (KP) and it is informed by the intervention logic model, strategic workplan, and the professional experience of the principal researcher as an HIV programme officer in the programme.

Our working programme hypothesis of the CBART programme is as follow:

1. In resource-constrained settings with an unfavorable policy environment (in terms of criminalization policy against KP activities), potential arrest by police, poor geographic access, inadequate number of KP friendly healthcare facilities within the state/community and low levels of trust between the health workers and members of KP **(context),** decentralisation of ART service delivery to KP communities together with training of HCW on KP sensitization and comprehensive ART will enhance trust **(mechanism)** and psychological safety **(mechanism)** in the programme and encourage **(mechanism)** KP to access HIV care and treatment services and this will improve uptake and utilisation of these services and retention-in-care **(intermediary outcome)** (figure 1). Optimal HIV prevention and treatment for KP will translate to better health outcomes and well-being for KP **(final outcome)** .

2. Involvement of KP community and lay workers in all components (e.g. accompany referral for ART, HIV testing and linkage to ART, medication adherence, ART refill, clients tracing, and etc) of a comprehensive HIV care package **(context)** would make HIV service KP-friendly **(mechanism)** and thus, improve long term outcomes/sustained engagement of HIV-positive clients in care and clinical outcomes **(outcome).**

Significance of the study

Evaluating the KP-CBART model will generate evidence-based information on differentiated ART service delivery and more specifically, community-based models for HIV-positive key populations in Nigeria, and can potentially inform policies, design, planning and implementation of health programmes that will improve access to quality HIV services and treatment outcomes among KPLHIV in similar and other settings.

Research questions

How, why, for whom, and in what context conditions do community-based ART models of service delivery contribute to observed clinical outcomes among key populations in Benue State, Nigeria?

Objectives

This research work will evaluate the effectiveness of community-based ART programmes, more specifically the KP-CBART, for key populations in Benue State - Nigeria using the realist evaluation approach.

General objective

- To develop an empirically tested middle range theory explaining how, why and in which context conditions the KP-CBART model contributes to improved clinical outcomes for key populations using a single case study design

Specific objectives

(1) To develop an initial programme theory grounded in a scoping review of grey and peer-reviewed literature on the implementation of KP-CBART in resource constrained settings in SubSaharan Africa (SSA)

(2) To evaluate the application of the initial programme theory in multiple case studies:

- To assess the impact of KP-CBART on clinical outcomes (retention in care, viral suppression) along the cascade of care in five KP-CBART implementation sites in Benue State, Nigeria
- To identify the contextual factors and generative mechanisms through which the observed outcomes were achieved in the 5 selected sites
- To explore the causal configurations on the basis of the ICAMO heuristic tool which contributed to the observed outcomes in those 5 sites

(3) To refine the initial programme theory in order to provide insights/policy recommendations into the context conditions and social mechanisms underlying the implementation of KP-CBART

Methods and analysis

Study setting and participants

The study will be conducted in Benue State and is located in north-central Nigeria. According to the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), Benue state has the second highest HIV prevalence (4.9%) in Nigeria (2). In 2014, HIV prevalence among the BBFSW and NBFSW in Benue

State was 36.5% and 14.2% respectively. These rates are the second highest for a state in Nigeria (26). This study will focus on MSM, FSW, PWID, and TG who are receiving HIV care and treatment through the KP-CBART model.

Description of the KP-CBART intervention in Benue State, Nigeria

In Benue State, the CBART model was adopted to reach KP living with HIV and to increase access and utilization of HIV services among the KP communities. The KP-CBART model was implemented since 2016. The programme is part of the national HIV programme that is being implemented by Partners, National and State Agency for the Control of AIDS and Ministry of Health with support from PEPFAR through the United States Centre for Disease Control and Prevention. Table 1 below describes the model, with mobile health teams providing ART to HIV positive clients in drop-in-centres (usually in a primary health care setting or offices of community-based organizations) and at hotspots for members of KP (hotels, club houses, and etc). The One Stop Shop clinic is a community-based health centre that provides comprehensive HIV services strictly to KP in an environment free of stigma and discrimination. OSS and DIC are funded and managed by the implementing partners and donor agencies.

Table 1. Description of community-based ART models for key populations in Benue State, Nigeria

	Community drop-in-centre (DIC)	Community outreach venues with mobile ART team	Community-based one stop shop clinic
Target population	FSW, MSM, PWID	FSW, MSM, PWID	FSW, MSM, PWID
HIV care delivery point	A safe place where KP can meet/gather for social and clinical activities	DIC plus mobile health team (clinician, nurses and peer educators) to homes, and hotspots including hotels, brothels, bunkers	Provision of KP friendly health care services in a trusted community ART centre
Location	Semi-urban	Rural or semi-urban	Urban
Operation hours	Daily	Once or twice per week	5-days per week
Package of services	Peer-led HIV counselling and testing, antiretroviral treatment, accompany referral, tracking of clinic defaulters by peers and network, provision of condoms, KP sensitization training for HCWs	Peer-led HIV counselling and testing, antiretroviral treatment, accompany referral, tracking of defaulters by peers and network, provision of condoms, KP sensitization training for HCWs	Peer-led HIV counselling and testing, antiretroviral treatment , accompany referral, tracking of clinic defaulters by peers and network, provision of condoms, KP sensitization training for HCWs, cervical cancer screening)

Care providers	**Community health workers:** community ART Nurse, Community Pharmacist and Medical Laboratory Scientist **Lay health workers:** Peer educators, community mobilising officers, adherence counsellors	**Mobile ART Team (mART):** ART Clinician, Pharmacist, and Medical Laboratory Scientist from the OSS clinic **Lay health workers:** Peer educators/community mobilising officers	**Health professionals:** ART Clinician, ART Nurse, Community Pharmacist and Medical Laboratory Scientist **Lay health workers:** Peer educators, community mobilising officers, adherence counsellors
Roles of KP community or lay HCWs in HIV care	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral	Community sensitization and mobilisation, HTS, adherence counselling, ART refill and referral

Study design

This study will follow the realist evaluation approach (25) and will be conducted in an iterative manner. For the realist methodology the RAMESES II reporting standards for realist studies will be followed (27). An exploratory, sequential, mixed method realist study design using an embedded case study design of KP-CBART (28). This study will be conducted in phases relying on both quantitative and qualitative research methods (see figure 2 (29)). The quantitative study is a retrospective cohort analysis of program data.

Multiple case studies of KP-CBART will be evaluated and findings from each of the case study will produce a programme theory that can be compared and redefined as a middle range theory. The complex interaction between the context, mechanisms, and outcomes (CMO) configuration of the KP-CBART will be conceptualized and explained.

The case is the KP-CBART programme as implemented in Benue state, Nigeria. The unit of analysis is the health facility which is either a drop-in-centre or One Stop Shop clinic with or without mobile health team. A drop-in-centre is a safe place where KP can receive specific health interventions. One Stop Shop clinic is a community-based health centre for members of KP only and comprehensive HIV services are offered in this facility.

Specific program theories for each of the 5 units of analysis will be developed based on thick description (30), exploring implementation strategies and activities that produce the observed outcomes, both intended and unintended, depending on the context conditions.

Both qualitative and quantitative data will be collected and synthesized using the ICAMO heuristic tool (31) to explain the causal mechanisms that trigger the patterns of outcomes in each context. The

three-phased model of study is as shown in figure 2 and the summary of each of the research stages: the objectives, outcomes, data, and analysis are presented in table 2 below.

The realist evaluation methodological approach

The realist perspective argues that the best form of evidence comes from theoretically oriented and locally situated programmes or policy interventions. RE is a primary research and the focus is explanatory rather than judgemental. It seeks to answer the 'how?', 'why?', 'for whom?', 'to what extent?' and 'in what circumstances?'. RE tests and builds theories, and uses an iterative approach.

What distinguishes the RE approach from other theory-based evaluation is the development of the context-mechanism-outcome configurations. The RE develops a contextual understanding that explains the mechanisms that generate different outcomes. According to Astbury B et al, 2010,"Mechanism is the hidden entities, processes, or structures which operate in particular contexts to generate outcomes of interest" (32). Mechanism can also be defined as the way the programme's resources or opportunities interact with the reasoning of individuals and lead to changes in behaviour (27).

In terms of RE application, findings can be used in making decisions about programmes, using the outcomes to influence how program and its effect are perceived or using the outcomes to justify decisions about the programme. RE is best fit for complex programmes or policies in the early or pilot phase of interventions or interventions for scale up. Complex interventions have a number of interacting components that are dependent and interdependent on each other, number and difficulty of behaviours by those delivering or receiving intervention, variability of outcomes, and a number of targeted groups or organizational levels. The RE aims to overcome these challenges in evaluating health programmes or policies.

The KP-CBART programme in Benue State, Nigeria, is a complex health intervention that the country is willing to scale up. In this proposed study, we will develop an initial programme theory (IPT) for the KP-CBART programme that will be tested and refined. The development of the IPT will take into account findings from similar HIV programmes in sub-Saharan Africa through a scoping review and identification of existing theories of KP-CBART. Also, the experience of the lead researcher in the KP-CBART programme and the programme intervention logic will shape the IPT.

Table 2. Summary of the realist evaluation cycle

Stage	Data source	Data analysis	Objectives
1.	Qualitative • Literature on KP-CBART programme: internal and external documents, guidelines, SOPs, Programme implementation plan	Qualitative • Scoping review	• To elicit the initial programme theory of the KP-CBART. • To identify the mechanisms and contextual factors responsible for programme outcomes
2.	Qualitative • Interviews with programme beneficiaries: KP clients, CBO staff and IP staff Quantitative • Routine program data	Qualitative • Retroductive, realist analysis Quantitative • Descriptive and inferential statistical analysis	To evaluate the application of the initial programme theory in multiple case studies
3.	Data from stage 1, 2, and 3	Mixed methods: triangulation	To develop generalizable theories of KP-CBART in LMIC / resource constrained settings)

Study population

Quantitative study: All HIV positive KP (18 years or older) enrolled into the community-based ART program between 2015 and January-2021 in Benue State, Nigeria.

Qualitative study: HIV programme designers and managers, managers of CBOs working with KP, healthcare providers, community facilitators, members of KP (representative of KP network) and KP clients.

Study period: January 2016 - December 2022.

Data collection and analysis

Data collection will be from June 2021 to Sept 2022.

Besides data on the processes and the effectiveness of KP-CBART implementation, data on the specific context conditions including implementation challenges, and mechanisms that are influencing intermediary and final outcomes responsible for observed changes in the programme will be analysed.

Programme outcomes refer to short-term to long-term changes. For HIV positive KP, **intermediary outcomes** include clinical outcomes such as retention in care, viral suppression, and adherence to ART while **final outcomes** are HIV related mortality, incidence of HIV/AIDS and overall clients health and well-being. For the health system, access and availability of ART services, responsiveness and acceptability of services, decongestion of health facilities and reduced workload. The **context** (figure 1) will encompass factors within the national or state policy context (e.g. weak national health policies for KPLHIV, criminalzation policy, stigma and discrimination), the local community (e.g. culture, belief, harassment by the law enforcement agents, geographic access (i.e. location and number of OSS and DIC), the management and coordination of the CBART program by donors and partners and the service delivery points (e.g. OSS, DIC, outreach venues). Context also includes health system issues such as logistics, supply of drugs, and viral load testing for HIV positive KP.This study is embedded in the already established HIV program for KP in Benue State, Nigeria and data will be sourced from the program database. Data that allow analysis of outcomes, context conditions, and identify the mechanisms of the KP-CBART intervention will be collected. This evaluation will be conducted in three phases as shown in figure 2 and explained below:

Phase 1: Eliciting the initial programme theory

During this stage, the initial programme theory will be developed. A programme theory is a hypothesis that can be tested or redefined. This stage will be guided by the scoping review of the

literature on KP-CBART. Interviews with programme managers and implementers will be used to explore the contextual factors and to identify generative mechanisms that trigger observed outcomes in the programme.

In addition to the interviews, data will be collected by: review of relevant document on KP-CBART programme in Nigeria and a review of evidence, a scoping review, on the effect of the programme on patients' clinical outcomes such as retention, viral suppression. Programme documents such as implementation guidelines, progress report, country operational plan, and etc will be reviewed. We will search Google scholar, PubMed, Web of Science, and Google search for articles on KP-CBART using the terms "key populations", "community based ART", "HIV", and "Africa" for paper published in English between 2010 and 2020 . Also, we will specifically search the website of KP implementing organizations in Nigeria.

Findings from this stage will inform the development of an initial programme theory for the implementation of KP_CBART program. Furthermore, salient context conditions such as social and environmental (e.g. conflicts and ethnic crisis, IDPs, criminalisation policy) at local, state and national levels will be mapped during the document review and interview into determinant framework to structure the analysis of the configured ICAMOs. This mapping will help to unpack the black box of implementation that influence the programme outcomes.

Stage 2: Testing the programme theory

In this stage, the objective is to empirically test the elicited initial programme theories across different settings.

A mixed methods design using multiple case studies of KP-CBART and retrospective cohort studies will be used for evaluation. A mixed method design employs both quantitative and qualitative research methods in sequence. The quantitative strand will precede the qualitative strand and findings from the quantitative will inform the qualitative strand. The quantitative study will rely on retrospective study design and will assess the effects of KP-CBART among KP receiving treatment in CBART in terms of linkage, medication adherence, retention in care, and viral suppression (based on routine programme data) and associated factors. The qualitative part will assess how patients perceive and experience KP-CBART services (e.g. is it KP-friendly, safer, less stigma and discrimination, and more adapted or attuned to work outside activities of KP). Both the programme beneficiaries and staff will be interviewed.

For the quantitative arm, a retrospective cohort analysis will be conducted. All HIV positive KP clients enrolled into the KP-CBART between 2016 and 2020 will be included in the study. Maximum variation and data saturation will inform the sample size for the qualitative arm. An estimated 90 purposively selected study participants will be interviewed.

Findings from individual case studies will be reviewed and compared with the initial programme theory (within case analysis). The context specific theories are presented to key stakeholders in each setting (validation workshop/discussion). Additionally, alternative explanations that might account for the same findings will be considered such as counterfactual method.

Stage 3: Synthesizing refined context-specific programme theories into a middle range theory

The objective of this stage is to synthesize findings into a middle range theory (that is generalisable theory) through cross-case analysis. Lessons learned from the MRT will inform the adaptation and scale-up of the program in other settings.

Quantitative data collection

Patient-level data between January 2016 and January 2021 will be extracted from programme database and facility M&E tools (registers and patient files). Standardized data extraction template will be used to obtain information on all patients who tested HIV positive between January 2016 and January 2020 from the electronic medical record (EMR) and facility-based record (health management information system (MIS) tools i.e. registers and clients folders). Variables include demographic data (age, sex, education, occupation, residence), clinical variables (HIV status, date of HIV diagnosis, linkage to ART, WHO stage, ART status, TB status, virological suppression) and treatment outcomes. Patients' ART status can either be active on ART or inactive on ART (attrition). Being active on ART means the patient did not interrupt treatment up to 28 days since their last expected ART refill or clinical appointment. Attrition refers to those who were LTFU, died or stopped ART. LTFU is defined as no clinical contact or drug refill for more than 28 days since the last expected contact. Linkage to ART refers to the proportion of newly identified HIV positive patients that are enrolled and initiated on ART. Virological suppression refers to viral load value that is higher than 1000 copies per mililitre (mL). Adherence will be assessed using patient self-report and pill count during each clinic or outreach visit. Patients who missed more than 3 doses/month were categorized having a poor adherence to medication. Good adherence to medication will defined as >90% ART pill intake.

Qualitative sampling and recruitment methods

Potential study respondents will be identified through purposive sampling and snow- balling. For clients in care in the KP-CBART programme, the invitation for interviews will be sent via text messages and phone calls through HCWs and KP peers working in the programme. Respondents will also be recruited for an interview at the venue of service delivery (DIC or OSS). For those who are not interested in the programme, the KP peer educator, members of the KP-friendly or KP-led CBOs and KP network will be consulted to reach them.

We intend to interview the people indicated in table 3 to allow for maximum variation of respondents.

Table 3. Qualitative participants

	Study participant	No. of interviewees per site
1.	KP clients (FSW, MSM, PWID)	5 per KP sub-group
2.	Community-based organizations (peer educators)	5
3.	CBART staff) clinicians, nurse, adh. counsellors	5
4.	Programme managers/designers (Implementing partners, Agency for Control of AIDS, Ministry of Health, KP secretariat)	2 per agency

Interviews and FGD will be conducted in the offices of the KP-led CBOs, the DIC, and OSS clinics. Only members of the KP communities have access to these facilities. If patients would prefer another location, the study team will adapt. This may be of particular importance for those patients who dropped out of care.

Two FGD discussions per stakeholder group and per CBART model will be conducted and each discussion group will consist of 8 persons. Groups will be homogenous (avoid power imbalance between participants), to ensure that participants feel free to share experiences, views and perceptions. Sensitive topics will be addressed during IDI. We anticipate interviewing 90 clients, of which about 31 in an in-depth interview. Based on the interim analysis we will assess whether saturation was reached. Subsequently, the number of participants to be interviewed may be adapted.

Because of the iterative nature of realist evaluation, there is possibility that participants will be re-interviewed. As the knowledge of the programme increases through refinement (document review). For the FGD, homogenous groups and maximum variation of key stakeholders will be ensured to capture data qualitatively.

Qualitative data collection

Internal and external KP-CBART programme documents will be reviewed to develop the initial program theories. IDI and FGD will be conducted to explore how programme managers, KPs and their providers experience, view, and perceive the KP-CBART model and how it addresses barriers to linkage, retention, and adherence.

IDI and FGD guides will be developed and used to moderate the interview and discussion. Participants for IDI and FGD will be drawn from a mix of study participants until data saturation is reached. Interim analysis will be conducted to identify themes and assess data saturation. Subsequently, interview guides may be adapted and more participants may be recruited until data saturation is reached (33). Interviews will be conducted by the principal researcher and the duration of interviews will be between 30-45 minutes. The principal investigator will be supported by a notetaker, and the responses will be audio recorded. The principal investigator and notetaker are part of the programme staff, but are not directly involved in care delivery.

Data analysis

Quantitative analysis: Proportions will be calculated for categorical variables while means, medians and interquartile ranges will be calculated for continuous variables. The chi-squared test will be used to assess associations between categorical variables. Kaplan–Meier techniques will be used to estimate retention over time. The log-rank test will be used to estimate differences between Kaplan-Meier curves, stratified for different subgroups. We will employ bivariate and multivariate logistic regression to estimate the association between explanatory variables and the different outcomes (linkage, retention and virological suppression).

Qualitative analysis: Thematic content analysis will be used to analyse the transcripts of the voice recordings. NVIVO software wil be used for coding and data storage.

The main data analysis for the realist evaluation will be in four steps: thematic data analysis, identifying the ICAMO configurations and synthesizing the programme theory per HF, overall synthesis and refinement of the programme theory.

Step 1: thematic data analysis – thematic content analysis will be used to classify data (from multiple case studies) into intervention, actor, context, mechanism and outcomes. The development of codes and the codebook will be performed using Nvivo software by the principal investigator and co-investigators. Thereafter, the initial programme theory is tested by comparing multiple cases using a deductive analytical approach.

Step 2: Identifying the ICAMO configurations- specific intervention, context, agents, mechanisms, and outcome per case study will be grouped to form intermediate-level and high level codes (ICAMO configurations). The case study ICAMO are generated using in-case analysis. Cross-case analysis is used for synthesizing and refining the overall programme theory)

Step 3: Refining ICAMO configurations into programme theory - ICAMO configurations in step 2 from different cases will be compared and their explanatory power across studies will be examined (cross-case analysis). "Causal loop thinking" will be used to develop the final ICAMO configurations and to map out the interaction between the different components in the system.

Monitoring and quality control

Data for quantitative study will be extracted from the project electronic medical record by the Strategic Information Unit. No names or data which could lead to the indirect identification of participants will be encoded in the study database. The technical lead for Strategic Information Unit will validate data and ensure correctness of data. Missing data will be completed and inconsistent data will be verified by checking source data (registers and patient records).

For the qualitative study, data will be triangulated by the researcher. As part of qualitative data validation, anonymized findings will be shared with key informants (KP opinion leader and clinicians of the OSS clinic) and during a group discussion with KP.

Patient and public involvement

Study participants and the public are not involved in the planning of the design, conduct, and dissemination of the results of this research. However, the views and perceptions of the programme managers and designers will inform the development of the initial programme theory of the KP-CBART. To maximise the impact of the study, research findings will be disseminated to KP community groups and networks, healthcare providers, HIV programme managers, and health policy makers.

Ethics and dissemination

Ethical approval

Ethical approval was obtained from the Institutional Research Board of APIN Public Health Initiatives (IRB046-FR), Benue State Ministry of Health and Human Services (MOH/STA/204/VOL.1/154), and the Institute of Tropical medicine Antwerp (1503/21).

Informed consent requirements and procedures and data confidentiality

Written informed consent and approval will be obtained for each participants of the qualitative research strand. To ensure respect for self-autonomy, only study participants who are above the age of consent (18 years and above) and gave their informed consent will participate in this study. For the qualitative research, all data sources (coded voice recordings and transcripts) will be de-identified and held in strict confidentiality by the researchers. Deidentification/coding will occur prior to audiorecording, immediately after informed consent is taken. Only personal data (i.e. sex and age) that are key to this research will be collected. The coding/de-identification will mitigate the risk of identification of subjects during data collection and analysis.

Participants will be asked to use pseudonyms to identify themselves and only these codes will be analysed. The database (containing both qualitative and quantitative data) will only be accessible to the principal investigator and the co-investigators. All audio files after validation of the pseudonymised transcription will be deleted.

Specific patient benefits and risks (qualtitative research strand)

The risk of stigmatization of the key populations during the conduct of this research will be minimized by ensuring that everyone involved in organizing interviews, data collection and data analysis for the purpose this research signs a privacy and confidentiality agreement. The researchers will liaise with the attending health workers (ART clinician) and community facilitators (peer educators) in the community based centre and drop-in-centre to purposively select study participants. The peer educators will work with key opinion leaders of the different key population subgroups to contact and invite study participants for interview.

Members of key populations (i.e. MSM or FSW) who enrolled in community care and are active in care and those that refused community care or interrupted their care will be purposively selected for interview. Also, healthcare workers and volunteers who directly provide services to clients and those holding managerial positions will be selected for interview or focused group discussion. Only study participants who fit into the above profile and willing to participate and verbal enough to share their experiences will be recruited into the study.

The vast majority of research activities will be embedded within routinely provided HIV care services. As such there is little additional exposure for the different stakeholder groups. Participants will be consulted to determine the location where the interviews and/or group discussion will be organized.

The database will not be shared with third parties. The database will be maintained securely for at least five years after study completion. No patient identifiers will be used in the analysis and in any eventual publication.

There are no direct benefits to members of KP living with HIV whose data will be collected and analysed for this study. During the course of interview, if any interviewee shows/expresses signs of medical or psychological need, such participants will be referred to the ART Clinician/Nurse and the Adherence Counselors (working within the program) to receive medical and/or psychological assessment and treatment. Key populations with children less than 17 years will be referred to the Orpan and Vulnerable Children (OVC) program for economic and social support.

Feedback and dissemnination of results

The results of this study will be shared with all stakeholders (study participants and programme staff) and published in scientific journals and presented at scientific conferences in the form of oral presentations or posters.

Discussion

This study protocol will describe the KP-CBART model as being implemented in Benue Nigeria and explore the mechanisms and contextual factors which generate intermediate outcomes, such as medication adherence, retention-in-care, viral load suppression, and long term outcomes, such as reduction in HIV incidence and improved health and well-being. The results of this study will inform adaptations of the KP-CBART program to better meet the health needs of KP in Nigeria, and assist in national policy & programme design for the implementation of KP-CBART. A CBART model that fits better the needs of KP is expected to improve clinical outcomes.

Findings from previous studies on KP-CBART in Nigeria are not sufficient to conceptualise and scale-up the programme. The adopted research methods in these studies are inadequate to explain causation in complex health interventions such as the KP-CBART. Most of these previous studies are quantitative and are designed to determine the programme outcomes (such as viral load suppression and retention -in care) and associated factors. Therefore, the realist evaluation method, a theory based evaluation, to evaluate KP-CBARTin Nigeria will bridge the deficiency of other research methods and offer a causal explanation of outcomes and their generative mechanisms. The realist evaluation method is well suited for this evaluation because the complex nature of the programme.

The study will tease out the various components in the programme and the contexts. We will determine the contextual factors at the micro, meso, and macro levels (individual clients, service delivery points, local community, and state/national) and the mechanisms that generate the programme outcomes. We will describe the various interventions offered by the programme and how the actors respond to them. These findings will inform health policies, adaptation, and scale up

of community-based ART interventions for HIV positive KP in Nigeria and similar settings in sub-Saharan Africa.

The key strength of this proposed study is its research methodology which involves a realist impact evaluation of KP-CBART, including multiple case studies and a qualitative mixed method designs to explain the outcomes and impacts of the intervention. Anticipated limitations of this study are the inherent challenges of the realist evaluation method. Differentiating between the contextual factors and the mechanisms could be a limitation as many realist researchers have reported such challenges (34). The ICAMO configurational mapping is subject to the interpretation of the researchers and this can introduce some level of subjectivity into the interpretation of study results. Furthermore, the process of iterative cycle of interview with key actors in the program (stakeholders) can induce confirmation bias during the ICAMO configuration analysis. Another limitation is the conduct of observational restrospective cohort study which can induce selection bias during the conduct of the quantitative study. Investigators will ensure that these limitations are addressed during the conduct of the research.

Contributors

OI conceptualized the study. OI, SVB, and TD designed the study and wrote the main manuscript. CM, JVO, PJ, PO, and LL reviewed the manuscript.

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Competing interests

The authors declare no conflicts of interest.

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FIGURE TITLES AND LEGENDS

Figure 1. Starter hypothesis for the community-based ART model for key populations

Figure 2. Realist evaluation of community-based ART service delivery models for key populations
Adapted from Mukumbang et al, 2016 (29).

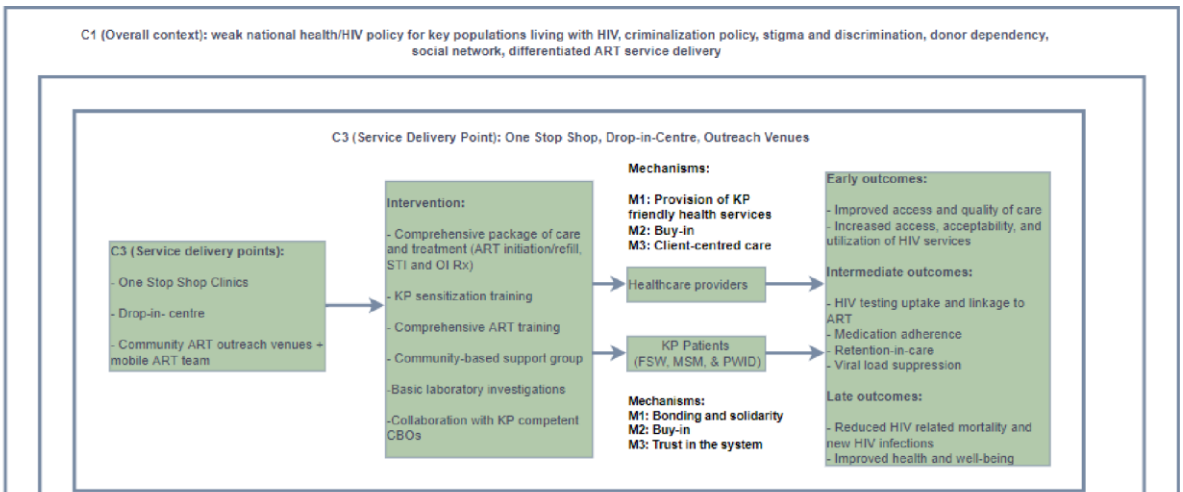

Figure 1. Starter hypothesis for the CBART model for KP

[CBART-community-based antiretroviral therapy, KP-key population, KP-CBART- community-based ART service delivery models for KP, C-context, mART- mobile ART, CBO-community-based organization, M- mechanism, Rx-treatment, STI- sexually transmitted infection, OI- opportunistic infection]

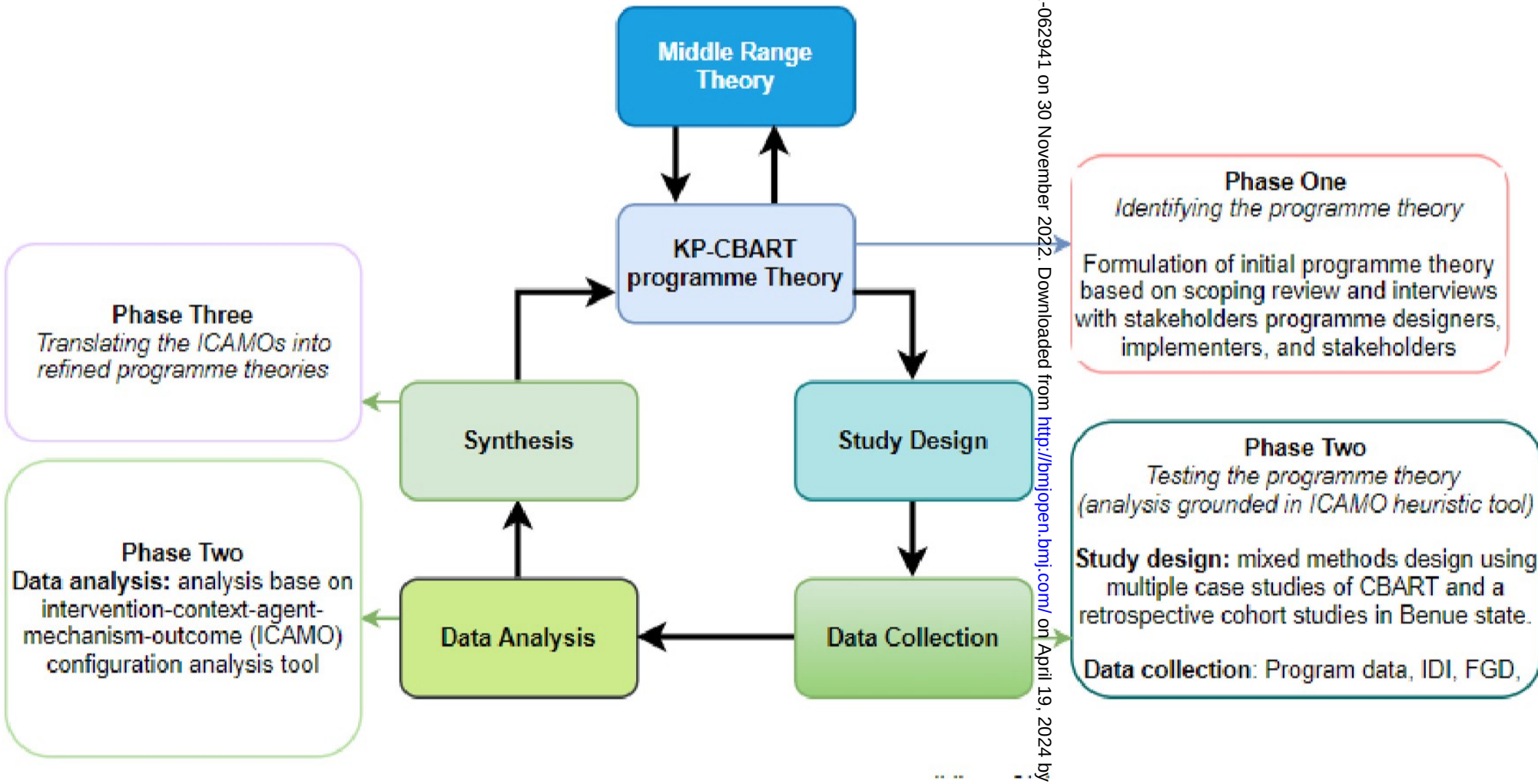

Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbang FC et al, 2016

[Abbreviations: KP-CBART- community-based ART service delivery models for KP, IDI-indepth interview, FGD-focus group discussion]