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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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Manuscripts

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

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

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6 The heuristic intervention, context, agents, mechanisms, and outcomes (ICAMO) tool will be used to
7 refine the initial programme theory.
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10 11 **Ethics and dissemination**

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13 The study protocol was approved by the Institutional Review Boards of APIN Public Health Initiatives,
14 Institute of Tropical Medicine Antwerp, and the Benue State Ministry of Health and Human Services.
15 Study results will be disseminated through stakeholders meeting, peer-reviewed journals, and
16 conferences.
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21 **Key words:** realist evaluation, key population, HIV, community-based antiretroviral therapy
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24 25 **Strengths and limitations of this study**

- 26
27 • There are few studies that offer evidence on real-life implementation of community-based
28 ART approaches for key populations (KP-CBART) in Nigeria.
- 29
30 • Study results will inform policies, design, planning and implementation of health
31 programmes that will improve access to quality HIV services and treatment outcomes among
32 key population living with HIV (KPLHIV).
- 33
34 • This study will be the first to use the realist evaluation method to assess which contextual
35 factors and mechanisms influence the outcomes of the KP-CBART model in sub-Saharan
36 Africa (SSA).
- 37
38 • The strength of this study is its research methodology which involves a realist impact
39 evaluation of KP-CBART, including multiple case studies and the use of both quantitative and
40 qualitative methods (mixed method design) to explain the intervention, contexts, actors,
41 mechanisms, and outcomes of KP-CBART, providing us a better understanding on how
42 flexible/adaptive choice in service delivery geared towards the needs of KP and active KP
43 engagement (lay workers, peer counsellors) could lead to better KP health & well-being
44 outcomes
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51 52 **Introduction**

53 54 **Background**

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

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

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

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

54 55 **The Community-based ART service delivery for key populations**

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57 KP often experience stigma and discrimination in regular health care facilities (all levels of care), and
58 this impacts negatively on access to quality HIV care. Community-based approaches, that encourage
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3 the engagement of KP communities (to participate in program planning and support service
4 provision) combined with task shifting to lay workers, are strategies which may resolve gaps in access
5 to quality HIV care and treatment services. Community-based approaches to HIV control have proven
6 to be an effective method of reaching people in the general population, particularly for individuals
7 who are hard to reach in the sub-Saharan Africa setting (11). Innovative community-based ART
8 service delivery for HIV- positive key populations (KP-CBART) include community-based and venue-
9 based outreach (such as CBO offices, hotels, brothels, etc), community-based antiretroviral therapy
10 (CBART) initiation and refill and home-based ART (12). If adapted to the needs of KP, such programs
11 may engage the KP community and lay health workers, such as HIV adherence counsellors, peer
12 educators, or clinic defaulter trackers for HIV service delivery. Other key actors that may be involved
13 are KP-led and KP-friendly community-based organisations, civil society organizations, KP-network
14 and healthcare providers. Furthermore, a more comprehensive package of HIV services that can be
15 offered through CBART interventions include HIV testing and counselling, ART initiation, ART refill,
16 and (clinical and laboratory) patient monitoring on ARVs (13). The Nigeria HIV programme currently
17 implements both facility-based and community-based HIV service delivery for KP. Implementing
18 partners work with the KP secretariat (KP network/association) and KP led or KP friendly CBOs to
19 provide HIV prevention, care, and treatment services to the KP.
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32 Pilot experiences with KP-CBART improved early to mid-term clinical outcomes along the cascade of
33 HIV care (HIV testing uptake, linkage to care, ART initiation, retention-to-care, and virological
34 suppression) among HIV positive KP receiving care through KP-CBART in different sub-Sahara African
35 settings (14–19). Most studies on KP-CBART in sub-Saharan Africa described a high uptake of HIV
36 testing services (56% - 78.2%):between 79% and 100% of clients testing positive were linked to ART
37 (14–16,18). About 50% of HIV positive MSM and 100% FSW were initiated on ART in CBART
38 programmes in Nigeria and Tanzania, respectively (17,18). Furthermore, where evaluated, linkage to
39 care, retention in care and adherence to ART among KP receiving HIV care in CBART programmes
40 (between 6 and 18 months on ART) were better compared to facility-based care, while viral
41 suppression was not worse (14–19). These findings suggest that KP-CBART may complement facility-
42 based care for KP, with clinical outcomes (viral suppression and retention in care) that are similar or
43 better.
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53 **Rationale for the study**

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55 Community-based approaches to HIV care, including CBART, are central to achieving the ambitious
56 95-95-95 targets (95% of PLHIV aware of their status, of those 95% on ART, of those 95% virologically
57 suppressed) and thus control the HIV epidemic in sub-Saharan Africa. However, there are only a few
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3 studies in Sub Sahara African countries , including Nigeria, that offer evidence on implementation of
4 this strategy in non-research settings and its long term clinical and program outcomes along the
5 cascade of HIV care, the challenges/barriers and the facilitators (enablers) (20).
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9 KP-CBART is a complex health intervention, a multi-component health programme that implements
10 multiple strategies and activities, and interaction between actors and/or institutions and the
11 programme environment to generate outcomes. Hence, the choice of the realist evaluation method
12 to assess which context conditions and mechanisms influence the outcomes of KP-CBART. Realist
13 evaluation is a type of theory-driven evaluation, and is aimed at making the theories of the
14 programme or policy more explicit by describing and testing the programme theories or hypothesis
15 on how, and for whom, the programme work (or not work) and under what conditions (context),
16 they work (21). This proposal will be the first study to conduct a realist evaluation of KP-CBART in
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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

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3 improve uptake and utilisation of these services and retention-in-care. Optimal HIV prevention and
4 treatment for KP will translate to better health outcomes and well-being for KP .
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8 Involvement of KP community and lay workers in all components (e.g. accompany referral for ART,
9 HIV testing and linkage to ART, medication adherence, ART refill, clients tracing, and etc) of a
10 comprehensive HIV care package would make HIV service KP-friendly and thus, improve long term
11 outcomes/sustained engagement of HIV positive clients in care and clinical outcomes (figure 1).
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18 Insert **Figure 1. Starter hypothesis for the CBART model for KP**
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20 21 **Significance of the study**

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23 Evaluating the KP-CBART model will generate evidence-based information on differentiated ART
24 service delivery (and more specifically, community-based models) for HIV-positive key populations in
25 Nigeria, and can potentially inform (to adapt or contextualize) policies, design, planning and
26 implementation of health programmes that will improve access to quality HIV services and treatment
27 outcomes among KPLHIV in similar and other settings.
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33 34 **Research questions**

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36 How, why, for whom, and in what context conditions do community-based ART models of service
37 delivery contribute to observed clinical outcomes among key populations in Benue State, Nigeria?
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42 43 **Objectives:**

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45 This research work will evaluate the effectiveness of community-based ART programmes, more
46 specifically the KP-CBART, for key populations in Benue State - Nigeria using the realist evaluation
47 approach.
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50 51 **General objective:**

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- 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

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3 followed (23). An exploratory, sequential, mixed method realist study design using an (multiple)
4 embedded case study design of KP-CBART (24). This study will be conducted in phases relying on
5 both quantitative and qualitative research methods (see figure 2). The quantitative study is a
6 retrospective cohort analysis of program data.
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10 Multiple case studies of KP-CBART will be evaluated and findings from each of the case study will
11 produce a programme theory that can be compared and redefined as a middle range theory. The
12 complex interaction between the context, mechanisms, and outcomes (CMO) configuration of the
13 KP-CBART will be conceptualized and explained.
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16
17 The case is the KP-CBART programme as implemented in Benue state, Nigeria. The unit of analysis is
18 the health facility which is either a drop-in-centre or One Stop Shop clinic with(out) mobile health
19 team. A drop-in-centre is a safe place where KP can receive specific health interventions. One Stop
20 Shop clinic is a community-based health centre for members of KP only and comprehensive HIV
21 services are offered in this facility.
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25 Specific program theories for each of the 5 units of analysis will be developed based on thick
26 description (25), exploring implementation strategies and activities that produce the observed
27 outcomes, both intended and unintended, depending on the context conditions.
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31 Both qualitative and quantitative data will be collected and synthesized using the ICAMO heuristic
32 tool (26) to explain the causal mechanisms that trigger the patterns of outcomes in each context. The
33 three-phased model of study is as shown in Figure 2 and the summary of each of the research stages:
34 the objectives, outcomes, data, and analysis are presented in table 2 below.
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46 Insert Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbang FC et al, 2016
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Table 2: Summary of the Realist Evaluation cycle

Stage	Data source	Data analysis	Objectives
1.	Qualitative <ul style="list-style-type: none"> Literature on KP-CBART programme: internal and external documents, guidelines, SOPs, Programme implementation plan 	Qualitative <ul style="list-style-type: none"> Scoping review 	<ul style="list-style-type: none"> To elicit the initial programme theory of the KP-CBART. To identify the mechanisms and contextual factors responsible for programme outcomes
2.	Qualitative <ul style="list-style-type: none"> Interviews with programme beneficiaries: KP clients, CBO staff and IP staff Quantitative <ul style="list-style-type: none"> Routine program data 	Qualitative <ul style="list-style-type: none"> Retroductive, realist analysis Quantitative <ul style="list-style-type: none"> 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, criminalization 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

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3 During this stage, the initial programme theory will be developed. A programme theory is a
4 hypothesis that can be tested or redefined. This stage will be guided by the realist synthesis / scoping
5 review of the literature on KP-CBART. Interviews with programme managers and implementers will
6
7 be used to explore the contextual factors and to identify generative mechanisms that trigger
8
9 observed outcomes in the programme.
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12 In addition to the interviews, data will be collected by: review of relevant document on KP-CBART
13 programme in Nigeria and a review of evidence (systematic and scoping review) on the effect of the
14 programme on patients' clinical outcomes (retention, viral suppression). Programme documents such
15 as implementation guidelines, progress report, country operational plan, and etc will be reviewed.
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19 Findings from this stage will inform the development of an initial programme theory for the
20 implementation of KP_CBART program. Furthermore, salient context conditions such as social and
21 environmental (e.g. conflicts and ethnic crisis, IDPs, criminalisation policy.) at local, state and national
22 levels will be mapped during the document review and interview into determinant framework to
23 structure the analysis of the configured ICAMOs. This mapping will help to unpack the black box of
24 implementation that influence the programme outcomes.
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29 30 **Stage 2: Testing the programme theory**

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32 In this stage, the objective is to empirically test the elicited initial programme theories across
33 different settings.
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37 A mixed methods design using multiple case studies of KP-CBART and retrospective cohort studies
38 will be used for evaluation. A mixed method design employs both quantitative and qualitative
39 research methods in sequence. The quantitative strand will precede the qualitative strand and
40 findings from the quantitative will inform the qualitative strand. The quantitative study will rely on
41 retrospective study design and will assess the effects of KP-CBART among KP receiving treatment in
42 CBART in terms of linkage, medication adherence, retention in care, and viral suppression (based on
43 routine programme data) and associated factors. The qualitative part will assess how patients
44 perceive and experience KP-CBART services (is it KP-friendly, safer, less stigma/discrimination, and
45 more adapted / attuned to work/outside activities of KP). Both the programme beneficiaries
46 (patients) and staff will be interviewed.
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54 Findings from individual case studies will be reviewed and compared with the initial programme
55 theory (within case analysis).
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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 snowballing. 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.

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3 IDI and FGD guides will be developed and used to moderate the interview and discussion.
4 Participants for IDI and FGD will be drawn from a mix of study participants until data saturation is
5 reached. Interim analysis will be conducted to identify themes and assess data saturation.
6
7 Subsequently, interview guides may be adapted and more participants may be recruited until data
8 saturation is reached (27). Interviews will be conducted by the principal researcher and the duration
9 of interviews will be between 30 -45 minutes. The principal investigator will be supported by a
10 notetaker, and the responses will be audio recorded. The principal investigator and notetaker are
11 part of the programme staff, but are not directly involved in care delivery.
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20 **Quantitative data collection**

21
22 Patient-level data between January 2016 and January 2021 will be extracted from programme
23 database and facility M&E tools (registers and patient files). Standardized data extraction template
24 will be used to obtain information on all patients who tested HIV positive between January 2016 and
25 January 2020 from the electronic medical record (EMR) and facility-based record (health
26 management information system (MIS) tools i.e. registers and clients folders). Variables include
27 demographic data (age, sex, education, occupation, residence), clinical variables (HIV status, date of
28 HIV diagnosis, linkage to care, ART status, WHO stage, TB status, viral load suppression) and
29 treatment outcome (LTFU, dead, transferred out, active in care).
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39 **Data analysis**

40 **Qualitative analysis:** Thematic content analysis will be used to analyse the transcripts of the voice
41 recordings. NVIVO software will be used for coding and data storage.
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43

44 The main data analysis for the realist evaluation will be in four steps: thematic data analysis,
45 identifying the ICAMO configurations and synthesizing the programme theory per HF, overall
46 synthesis and refinement of the programme theory.
47
48

49 *Step 1: thematic data analysis* – thematic content analysis will be used to classify data (from multiple
50 case studies) into intervention, actor, context, mechanism and outcomes. The development of codes
51 and the codebook will be performed using Nvivo software by the principal investigator and co-
52 investigators. Thereafter, the initial programme theory is tested by comparing multiple cases using a
53 deductive analytical approach.
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3 *Step 2: Identifying the ICAMO configurations*- specific intervention, context, agents, mechanisms, and
4 outcome per case study will be grouped to form intermediate-level and high level codes (ICAMO
5 configurations). The case study ICAMO are generated using in-case analysis. Cross-case analysis is
6 used for synthesizing and refining the overall programme theory)
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10 *Step 3: Refining ICAMO configurations into programme theory* - ICAMO configurations in step 2 from
11 different cases will be compared and their explanatory power across studies will be examined (cross-
12 case analysis). "Causal loop thinking" will be used to develop the final ICAMO configurations and to
13 map out the interaction between the different components in the system.
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17
18 **Quantitative analysis:** Proportions will be calculated for categorical variables while means, medians
19 and interquartile ranges will be calculated for continuous variables. The chi-squared test will be used
20 to assess associations between categorical variables. Kaplan–Meier techniques will be used to
21 estimate retention over time. The log-rank test will be used to estimate differences between Kaplan-
22 Meier curves, stratified for different subgroups. We will employ bivariate and multivariate logistic
23 regression to estimate the association between explanatory variables and the different outcomes
24 (linkage, retention and virological suppression).
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32 **Monitoring and Quality Control**

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34 Data for quantitative study will be extracted from the project electronic medical record by the
35 Strategic Information Unit. No names or data which could lead to the indirect identification of
36 participants will be encoded in the study database. The technical lead for Strategic Information Unit
37 will validate data and ensure correctness of data. Missing data will be completed and inconsistent
38 data will be verified by checking source data (registers and patient records).
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43 For the qualitative study, data will be triangulated by the researcher. As part of qualitative data
44 validation, anonymized findings will be shared with key informants (KP opinion leader and clinicians
45 of the OSS clinic) and during a group discussion with KP.
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50 **Patient and Public Involvement**

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

1
2
3 explain the outcomes and impacts of the intervention. Anticipated limitations of this study are the
4 inherent challenges of the realist evaluation method. Differentiating between the contextual factors
5 and the mechanisms could be a limitation as many realist researchers have reported such challenges
6 (28). The ICAMO configurational mapping is subject to the interpretation of the researchers and this
7 can introduce some level of subjectivity into the interpretation of study results. Furthermore, the
8 process of iterative cycle of interview with key actors in the program (stakeholders) can induce
9 confirmation bias during the ICAMO configuration analysis. Another limitation is the conduct of
10 observational retrospective cohort study which can induce selection bias during the conduct of the
11 quantitative study. Investigators will ensure that these limitations are addressed during the conduct
12 of the research.
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22 **Authors' contributions**

23 OI, SVB, and TD: conceptualisation and design of the study. CM, JVO, PJ, PO, and LL reviewed the
24 original manuscript.
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30 **Funding statement**

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35 The funders were not involved in the study design or the writing of the study protocol
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42 **Competing interests statement**

43 Authors declare no conflict of interest
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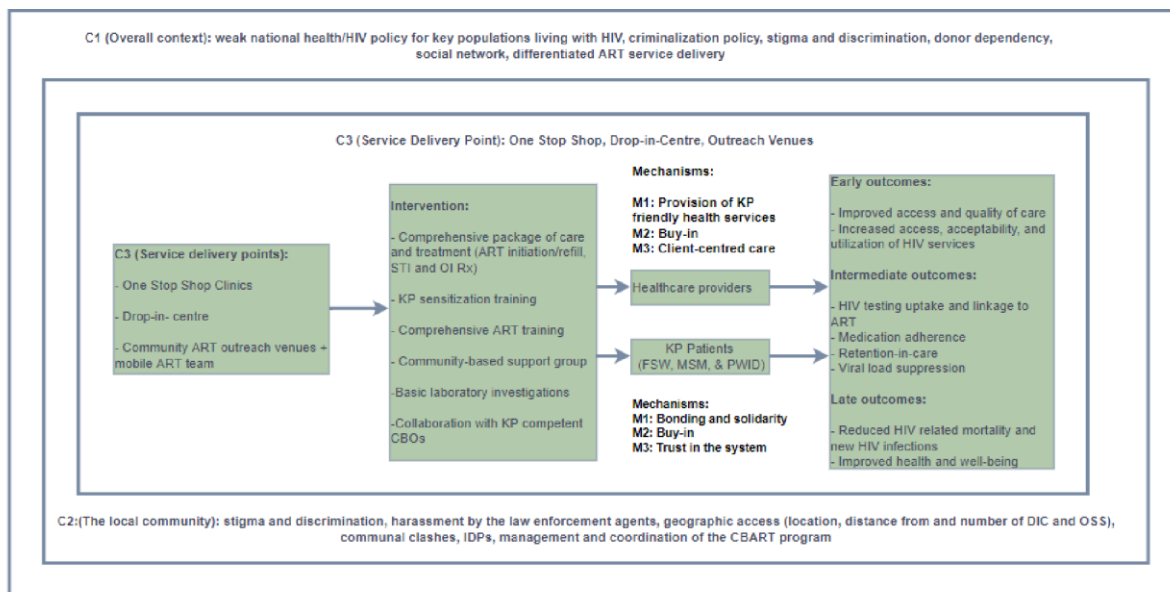


Figure 1. Starter hypothesis for the CBART model for KP

[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]

review only

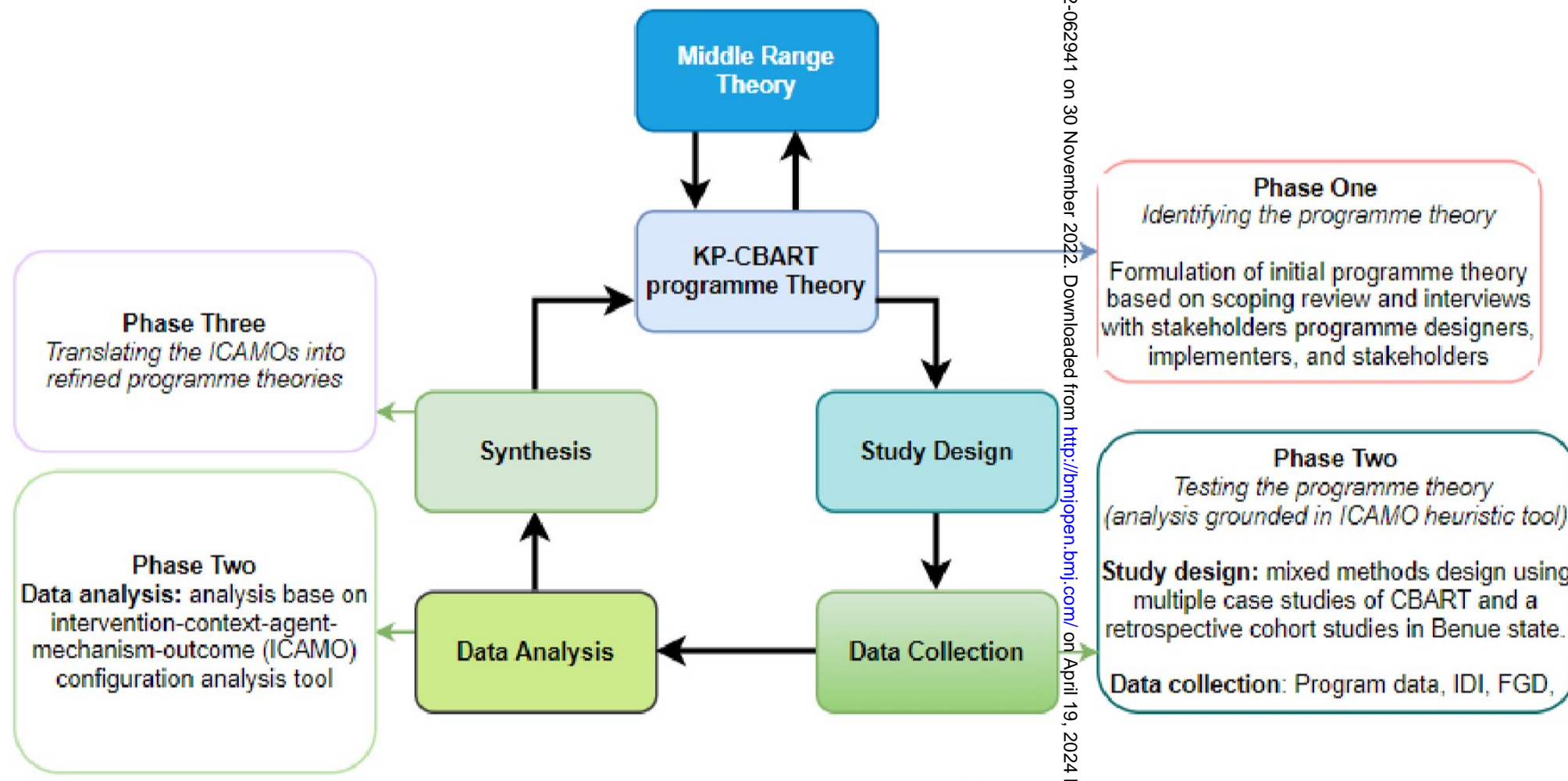


Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbana FC et al, 2016

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

BMJ Open

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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Manuscripts

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

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3 40 size for the qualitative part, an estimated 90 purposively selected study participants will be
4
5 41 interviewed. In phase 3, findings will be synthesised into a middle range theory through cross-case
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7 42 analysis. The heuristic intervention, context, agents, mechanisms, and outcomes (ICAMO) tool will be
8
9 43 used to refine the initial programme theory.

10 44

11 45 **Ethics and dissemination**

12
13 46 The study protocol was approved by the Institutional Review Boards of APIN Public Health Initiatives
14
15 47 (IRB022-FR), Institute of Tropical Medicine Antwerp (1503/21), and the Benue State Ministry of
16
17 48 Health and Human Services (MOH/STA/204/VOL1/154). Written informed consent will be obtained
18
19 49 from all study participants. Study results will be disseminated through stakeholders meeting, peer-
20
21 50 reviewed journals, and conferences.

22 51

23 52 **Keywords:** realist evaluation, key population, HIV, community-based antiretroviral therapy
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25 53

26 54 **Strengths and limitations of this study**

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28
29 55 • A strength of this study is its research methodology, which involves a realist impact
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31 56 evaluation of community-based ART service delivery models for key populations (KP-CBART),
32
33 57 including multiple case studies and the use of mixed method design to explain the
34
35 58 intervention, contexts, actors, mechanisms, and outcomes of KP-CBART.
- 36
37 59 • Data collection and verification will be rigorous: researchers will use multiple data sources
38
39 60 and triangulate findings from the quantitative and qualitative arms of the study.
- 40
41 61 • This study will reflect the reality of KP-CBART; how results for different treatment outcomes
42
43 62 complement each other will be verified to improve our understanding of the effect of the KP-
44
45 63 CBART program on different health indicators.
- 46
47 64 • The refined programme theory will build on the knowledge of HIV programmes theory and
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49 65 community-based ART interventions for key populations in sub-Saharan Africa and multiple
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51 66 case studies of KP-CBART in Benue state Nigeria, thus allowing for accumulation of
52
53 67 knowledge.
- 54
55 68 • This study will not produce universally applicable findings; as the study relies on the concept
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57 69 of generative causality, the evaluation will only indicate conditions in which KP-CBART works
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59 70 (or not) and how they do so.
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61 71

72 Introduction

73 Background

74 Nigeria is the most populous country in Africa with an estimated population size of 200 million
75 people (1) and has the 4th highest number of people living with HIV/AIDS in the world (2). The
76 National AIDS Indicator Survey (NAIS) estimates show that approximately 1.76 million people are
77 living with HIV in Nigeria and HIV prevalence among the 15-64 age groups is 1.4% and in those under-
78 15 years is 0.2% (2).

79 Across the African continent, the burden of HIV/AIDS and incidence rates remain the highest among
80 Key populations (KP). KP include sex workers, men who have sex with men (MSM), persons who
81 inject drugs (PWID), transgender people (TG), prisoners and detainees (3). These groups are
82 disproportionately affected by HIV/AIDS and are at increased risk of contracting HIV (4). Compared to
83 the adult general population (15-49 years) gay and other MSM, PWID, sex workers, and TG have 26,
84 29, 30, and 13 times more risk of contracting HIV, respectively (5). In 2019, KP and their sexual
85 partners accounted for 62% of all new HIV infections in the world and more than 50% in sub-Saharan
86 Africa (5). Despite representing a relatively small proportions of populations in East and Southern
87 Africa, KP individuals account for 25% of new HIV infections in the region (3). In Nigeria, these groups
88 make up only 3.4% of the overall population, yet account for 32% of new HIV infections (6). The 2020
89 Integrated Behavioral and Biological Science Survey in Nigeria puts the prevalence at 16.7% for
90 females sex workers (FSW), 20.9% for MSM, 9.5% for PWID, and 6.2% for TG people (7).

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

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

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3 105 South Sudan, South Africa, and Botswana, respectively (13). Therefore, to reduce barriers to access
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5 106 and improve KP engagement, the World Health Organization in (2016) recommended community-
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7 107 based approaches for KP living with HIV (4)(14). Such approaches to HIV service delivery have proven
8
9 108 to be an effective strategy to reach people living with HIV in the general population (15).

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11 109

110 **The community-based ART service delivery for key populations**

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

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

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3 138 programmes (between 6 and 18 months on ART) were better compared to facility-based care, while
4
5 139 viral suppression was not worse (18–23). These findings suggest that KP-CBART may complement
6
7 140 facility-based care for KP, with clinical outcomes such as viral suppression and retention in care that
8
9 141 are similar or better.

10 142 **Rationale for the study**

13 143 Community-based approaches to HIV care, including CBART, are central to achieving the ambitious
14
15 144 95-95-95 targets (95% of PLHIV aware of their status, of those 95% on ART, of those 95% virologically
16
17 145 suppressed) and thus control the HIV epidemic in sub-Saharan Africa. However, there are only a few
18
19 146 studies in Sub Sahara African countries , including Nigeria, that offer evidence on implementation of
20
21 147 this strategy in non-research settings and its long term clinical and program outcomes along the
22
23 148 cascade of HIV care, the barriers and the enablers (24).

24 149 KP-CBART is a complex health intervention, a multi-component health programme that implements
25
26 150 multiple strategies and activities, and interaction between actors and/or institutions and the
27
28 151 programme environment to generate outcomes. Hence, the choice of the realist evaluation method
29
30 152 to assess which context conditions and mechanisms influence the outcomes of KP-CBART. Realist
31
32 153 evaluation is a type of theory-driven evaluation, and is aimed at making the theories of the
33
34 154 programme or policy more explicit by describing and testing the programme theories or hypothesis
35
36 155 on how, and for whom the programme work or not work, and under what conditions (context), they
37
38 156 work (25). This proposal will be the first study to conduct a realist evaluation of KP-CBART in Nigeria.

39 157 How the introduction and implementation of KP-CBART is experienced and perceived locally, by
40
41 158 different stakeholders, such as KP communities but also local community leaders, local health
42
43 159 administration, health personnel, community-based organizations (CBO), local police, local
44
45 160 authorities as well as by the national programme partners such as the Ministry of Health, Agency for
46
47 161 AIDS Control, implementing partners, facility staff, and KP communities and networks has not yet
48
49 162 been fully explored. Furthermore, the perceptions and views of stakeholders regarding the extent to
50
51 163 which medical tasks such as HIV testing services, ART initiation, and ART refill can be shifted to KP
52
53 164 communities and lay workers in a community-based model of care is yet to be fully explored.

54 165 Therefore, this proposal presents an opportunity to evaluate how community-based ART
55
56 166 interventions can be adapted to the specific health needs of KP, and how KP communities can be
57
58 167 actively involved in service delivery, as lay workers (i.e. peer counsellors, HIV counsellor testers, and
59
60 168 outreach coordinators). This study will further the discussion on task-shifting and differentiated ART
61
62 169 service delivery for PLHIV in challenging environments not only in terms of resource constraints but
63
64 170 also in terms of stigma, discrimination and criminalization of KP in LMIC.

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3 171
4 172 **Intervention logic and working hypothesis**
5 173 The *starter hypothesis for the CBARTI for KP (figure 1)* explains the assumptions regarding how the
6 174 CBART model would achieve better health outcomes for key population groups (KP) and it is
7 175 informed by the intervention logic model, strategic workplan, and the professional experience of the
8 176 principal researcher as an HIV programme officer in the programme.

9 177
10 178 Our working programme hypothesis of the CBART programme is as follow:

- 11 179 1. In resource-constrained settings with an unfavorable policy environment (in terms of
12 180 criminalization policy against KP activities), potential arrest by police, poor geographic access,
13 181 inadequate number of KP friendly healthcare facilities within the state/community and low levels
14 182 of trust between the health workers and members of KP (**context**), decentralisation of ART
15 183 service delivery to KP communities together with training of HCW on KP sensitization and
16 184 comprehensive ART will enhance trust (**mechanism**) and psychological safety (**mechanism**) in the
17 185 programme and encourage (**mechanism**) KP to access HIV care and treatment services and this
18 186 will improve uptake and utilisation of these services and retention-in-care (**intermediary**
19 187 **outcome**) (figure 1). Optimal HIV prevention and treatment for KP will translate to better health
20 188 outcomes and well-being for KP (**final outcome**).
- 21 189
22 190 2. Involvement of KP community and lay workers in all components (e.g. accompany referral for
23 191 ART, HIV testing and linkage to ART, medication adherence, ART refill, clients tracing, and etc) of
24 192 a comprehensive HIV care package (**context**) would make HIV service KP-friendly (**mechanism**)
25 193 and thus, improve long term outcomes/sustained engagement of HIV-positive clients in care and
26 194 clinical outcomes (**outcome**).

27 195

28 196 **Significance of the study**

29 197 Evaluating the KP-CBART model will generate evidence-based information on differentiated ART
30 198 service delivery and more specifically, community-based models for HIV-positive key populations in
31 199 Nigeria, and can potentially inform policies, design, planning and implementation of health
32 200 programmes that will improve access to quality HIV services and treatment outcomes among KPLHIV
33 201 in similar and other settings.

34 202

203 **Research questions**

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

206

207 **Objectives**

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

211 *General objective*

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

215 *Specific objectives*

- 216 (1) To develop an initial programme theory grounded in a scoping review of grey and peer-reviewed
217 literature on the implementation of KP-CBART in resource constrained settings in SubSaharan
218 Africa (SSA)
- 219 (2) To evaluate the application of the initial programme theory in multiple case studies:
 - 220 • To assess the impact of KP-CBART on clinical outcomes (retention in care, viral suppression)
221 along the cascade of care in five KP-CBART implementation sites in Benue State, Nigeria
 - 222 • To identify the contextual factors and generative mechanisms through which the observed
223 outcomes were achieved in the 5 selected sites
 - 224 • To explore the causal configurations on the basis of the ICAMO heuristic tool which
225 contributed to the observed outcomes in those 5 sites
- 226 (3) To refine the initial programme theory in order to provide insights/policy recommendations into
227 the context conditions and social mechanisms underlying the implementation of KP-CBART

228

229 **Methods and analysis**

230 **Study setting and participants**

231 The study will be conducted in Benue State and is located in north-central Nigeria. According to the
232 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS), Benue state has the second highest HIV
233 prevalence (4.9%) in Nigeria (2). In 2014, HIV prevalence among the BBFSW and NBFSW in Benue

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

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

238 In Benue State, the CBART model was adopted to reach KP living with HIV and to increase access and
 239 utilization of HIV services among the KP communities. The KP-CBART model was implemented since
 240 2016. The programme is part of the national HIV programme that is being implemented by Partners,
 241 National and State Agency for the Control of AIDS and Ministry of Health with support from PEPFAR
 242 through the United States Centre for Disease Control and Prevention. Table 1 below describes the
 243 model, with mobile health teams providing ART to HIV positive clients in drop-in-centres (usually in a
 244 primary health care setting or offices of community-based organizations) and at hotspots for
 245 members of KP (hotels, club houses, and etc). The One Stop Shop clinic is a community-based health
 246 centre that provides comprehensive HIV services strictly to KP in an environment free of stigma and
 247 discrimination. OSS and DIC are funded and managed by the implementing partners and donor
 248 agencies.

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

250

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

251

252

253 **Study design**

254

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

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

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

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

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

1
2
3 275 three-phased model of study is as shown in figure 2 and the summary of each of the research stages:
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5 276 the objectives, outcomes, data, and analysis are presented in table 2 below.
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7 277

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9 278

The realist evaluation methodological approach

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11 279 The realist perspective argues that the best form of evidence comes from theoretically oriented and
12
13 280 locally situated programmes or policy interventions. RE is a primary research and the focus is
14
15 281 explanatory rather than judgemental. It seeks to answer the ‘how?’, ‘why?’, ‘for whom?’, ‘to what
16
17 282 extent?’ and ‘in what circumstances?’. RE tests and builds theories, and uses an iterative approach.

18
19 283 What distinguishes the RE approach from other theory-based evaluation is the development of the
20
21 284 context-mechanism-outcome configurations. The RE develops a contextual understanding that
22
23 285 explains the mechanisms that generate different outcomes. According to Astbury B et al,
24
25 286 2010, “Mechanism is the hidden entities, processes, or structures which operate in particular
26
27 287 contexts to generate outcomes of interest” (32). Mechanism can also be defined as the way the
28
29 288 programme’s resources or opportunities interact with the reasoning of individuals and lead to
30
31 289 changes in behaviour (27).

31
32 290 In terms of RE application, findings can be used in making decisions about programmes, using the
33
34 291 outcomes to influence how program and its effect are perceived or using the outcomes to justify
35
36 292 decisions about the programme. RE is best fit for complex programmes or policies in the early or pilot
37
38 293 phase of interventions or interventions for scale up. Complex interventions have a number of
39
40 294 interacting components that are dependent and interdependent on each other, number and
41
42 295 difficulty of behaviours by those delivering or receiving intervention, variability of outcomes, and a
43
44 296 number of targeted groups or organizational levels. The RE aims to overcome these challenges in
45
46 297 evaluating health programmes or policies.

45
46 298 The KP-CBART programme in Benue State, Nigeria, is a complex health intervention that the country
47
48 299 is willing to scale up. In this proposed study, we will develop an initial programme theory (IPT) for the
49
50 300 KP-CBART programme that will be tested and refined. The development of the IPT will take into
51
52 301 account findings from similar HIV programmes in sub-Saharan Africa through a scoping review and
53
54 302 identification of existing theories of KP-CBART. Also, the experience of the lead researcher in the KP-
55
56 303 CBART programme and the programme intervention logic will shape the IPT.
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304 **Table 2. Summary of the realist evaluation cycle**

Stage	Data source	Data analysis	Objectives
1.	Qualitative <ul style="list-style-type: none"> Literature on KP-CBART programme: internal and external documents, guidelines, SOPs, Programme implementation plan 	Qualitative <ul style="list-style-type: none"> Scoping review 	<ul style="list-style-type: none"> To elicit the initial programme theory of the KP-CBART. To identify the mechanisms and contextual factors responsible for programme outcomes
2.	Qualitative <ul style="list-style-type: none"> Interviews with programme beneficiaries: KP clients, CBO staff and IP staff Quantitative <ul style="list-style-type: none"> Routine program data 	Qualitative <ul style="list-style-type: none"> Retroductive, realist analysis Quantitative <ul style="list-style-type: none"> 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)

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3 308 **Study population**

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5 309 **Quantitative study:** All HIV positive KP (18 years or older) enrolled into the community-based ART
6
7 310 program between 2015 and January-2021 in Benue State, Nigeria.

8
9 311 **Qualitative study:** HIV programme designers and managers, managers of CBOs working with KP,
10
11 312 healthcare providers, community facilitators, members of KP (representative of KP network) and KP
12
13 313 clients.

14 314 **Study period:** January 2016 - December 2022.
15
16 315

17
18 316 **Data collection and analysis**

19 317 Data collection will be from June 2021 to Sept 2022.

20
21
22 318 Besides data on the processes and the effectiveness of KP-CBART implementation, data on the
23
24 319 specific context conditions including implementation challenges, and mechanisms that are
25
26 320 influencing intermediary and final outcomes responsible for observed changes in the programme will
27
28 321 be analysed.

29
30 322 Programme outcomes refer to short-term to long-term changes. For HIV positive KP, **intermediary**
31
32 323 **outcomes** include clinical outcomes such as retention in care, viral suppression, and adherence to
33
34 324 ART while **final outcomes** are HIV related mortality, incidence of HIV/AIDS and overall clients health
35
36 325 and well-being. For the health system, access and availability of ART services, responsiveness and
37
38 326 acceptability of services, decongestion of health facilities and reduced workload. The **context** (figure
39
40 327 1) will encompass factors within the national or state policy context (e.g. weak national health
41
42 328 policies for KPLHIV, criminalization policy, stigma and discrimination), the local community (e.g.
43
44 329 culture, belief, harassment by the law enforcement agents, geographic access (i.e. location and
45
46 330 number of OSS and DIC), the management and coordination of the CBART program by donors and
47
48 331 partners and the service delivery points (e.g. OSS, DIC, outreach venues). Context also includes health
49
50 332 system issues such as logistics, supply of drugs, and viral load testing for HIV positive KP. This study is
51
52 333 embedded in the already established HIV program for KP in Benue State, Nigeria and data will be
53
54 334 sourced from the program database. Data that allow analysis of outcomes, context conditions, and
55
56 335 identify the mechanisms of the KP-CBART intervention will be collected. This evaluation will be
57
58 336 conducted in three phases as shown in figure 2 and explained below:

59
60 337 **Phase 1: Eliciting the initial programme theory**

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

1
2
3 340 literature on KP-CBART. Interviews with programme managers and implementers will be used to
4
5 341 explore the contextual factors and to identify generative mechanisms that trigger observed
6
7 342 outcomes in the programme.

8
9 343 In addition to the interviews, data will be collected by: review of relevant document on KP-CBART
10
11 344 programme in Nigeria and a review of evidence, a scoping review, on the effect of the programme on
12
13 345 patients' clinical outcomes such as retention, viral suppression. Programme documents such as
14
15 346 implementation guidelines, progress report, country operational plan, and etc will be reviewed. We
16
17 347 will search Google scholar, PubMed, Web of Science, and Google search for articles on KP-CBART
18
19 348 using the terms "key populations", "community based ART", "HIV", and "Africa" for paper published
20
21 349 in English between 2010 and 2020 . Also, we will specifically search the website of KP implementing
22
23 350 organizations in Nigeria.

24
25 351 Findings from this stage will inform the development of an initial programme theory for the
26
27 352 implementation of KP_CBART program. Furthermore, salient context conditions such as social and
28
29 353 environmental (e.g. conflicts and ethnic crisis, IDPs, criminalisation policy) at local, state and national
30
31 354 levels will be mapped during the document review and interview into determinant framework to
32
33 355 structure the analysis of the configured ICAMOs. This mapping will help to unpack the black box of
34
35 356 implementation that influence the programme outcomes.

36
37 357

38 358 **Stage 2: Testing the programme theory**

39
40 359 In this stage, the objective is to empirically test the elicited initial programme theories across
41
42 360 different settings.

43
44 361 A mixed methods design using multiple case studies of KP-CBART and retrospective cohort studies
45
46 362 will be used for evaluation. A mixed method design employs both quantitative and qualitative
47
48 363 research methods in sequence. The quantitative strand will precede the qualitative strand and
49
50 364 findings from the quantitative will inform the qualitative strand. The quantitative study will rely on
51
52 365 retrospective study design and will assess the effects of KP-CBART among KP receiving treatment in
53
54 366 CBART in terms of linkage, medication adherence, retention in care, and viral suppression (based on
55
56 367 routine programme data) and associated factors. The qualitative part will assess how patients
57
58 368 perceive and experience KP-CBART services (e.g. is it KP-friendly, safer, less stigma and
59
60 369 discrimination, and more adapted or attuned to work outside activities of KP). Both the programme
61
62 370 beneficiaries and staff will be interviewed.

1
2
3 371 For the quantitative arm, a retrospective cohort analysis will be conducted. All HIV positive KP clients
4 372 enrolled into the KP-CBART between 2016 and 2020 will be included in the study. Maximum variation
5 373 and data saturation will inform the sample size for the qualitative arm. An estimated 90 purposively
6 374 selected study participants will be interviewed.

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9
10 375 Findings from individual case studies will be reviewed and compared with the initial programme
11 376 theory (within case analysis). The context specific theories are presented to key stakeholders in each
12 377 setting (validation workshop/discussion). Additionally, alternative explanations that might account
13 378 for the same findings will be considered such as counterfactual method.

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19 20 380 **Stage 3: Synthesizing refined context-specific programme theories into a middle range theory**

21
22 381 The objective of this stage is to synthesize findings into a middle range theory (that is generalisable
23 382 theory) through cross-case analysis. Lessons learned from the MRT will inform the adaptation and
24 383 scale-up of the program in other settings.

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28 384

29 30 385 **Quantitative data collection**

31
32 386 Patient-level data between January 2016 and January 2021 will be extracted from programme
33 387 database and facility M&E tools (registers and patient files). Standardized data extraction template
34 388 will be used to obtain information on all patients who tested HIV positive between January 2016 and
35 389 January 2020 from the electronic medical record (EMR) and facility-based record (health
36 390 management information system (MIS) tools i.e. registers and clients folders). Variables include
37 391 demographic data (age, sex, education, occupation, residence), clinical variables (HIV status, date of
38 392 HIV diagnosis, linkage to ART, WHO stage, ART status, TB status, virological suppression) and
39 393 treatment outcomes. Patients' ART status can either be active on ART or inactive on ART (attrition).
40 394 Being active on ART means the patient did not interrupt treatment up to 28 days since their last
41 395 expected ART refill or clinical appointment. Attrition refers to those who were LTFU, died or stopped
42 396 ART. LTFU is defined as no clinical contact or drug refill for more than 28 days since the last expected
43 397 contact. Linkage to ART refers to the proportion of newly identified HIV positive patients that are
44 398 enrolled and initiated on ART. Virological suppression refers to viral load value that is higher than
45 399 1000 copies per millilitre (mL). Adherence will be assessed using patient self-report and pill count
46 400 during each clinic or outreach visit. Patients who missed more than 3 doses/month were categorized
47 401 having a poor adherence to medication. Good adherence to medication will defined as >90% ART pill
48 402 intake.

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3 403 **Qualitative sampling and recruitment methods**

4
5 404 Potential study respondents will be identified through purposive sampling and snow- balling. For
6
7 405 clients in care in the KP-CBART programme, the invitation for interviews will be sent via text
8
9 406 messages and phone calls through HCWs and KP peers working in the programme. Respondents will
10
11 407 also be recruited for an interview at the venue of service delivery (DIC or OSS). For those who are not
12
13 408 interested in the programme, the KP peer educator, members of the KP-friendly or KP-led CBOs and
14
15 409 KP network will be consulted to reach them.

16 410 We intend to interview the people indicated in table 3 to allow for maximum variation of
17
18 411 respondents.

19
20 412 **Table 3. Qualitative participants**

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

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32 413
33 414 Interviews and FGD will be conducted in the offices of the KP-led CBOs, the DIC, and OSS clinics. Only
34
35 415 members of the KP communities have access to these facilities. If patients would prefer another
36
37 416 location, the study team will adapt. This may be of particular importance for those patients who
38
39 417 dropped out of care.

40
41 418 Two FGD discussions per stakeholder group and per CBART model will be conducted and each
42
43 419 discussion group will consist of 8 persons. Groups will be homogenous (avoid power imbalance
44
45 420 between participants), to ensure that participants feel free to share experiences, views and
46
47 421 perceptions. Sensitive topics will be addressed during IDI. We anticipate interviewing 90 clients, of
48
49 422 which about 31 in an in-depth interview. Based on the interim analysis we will assess whether
50
51 423 saturation was reached. Subsequently, the number of participants to be interviewed may be adapted.

52
53 424
54 425 Because of the iterative nature of realist evaluation, there is possibility that participants will be re-
55
56 426 interviewed. As the knowledge of the programme increases through refinement (document review).
57
58 427 For the FGD, homogenous groups and maximum variation of key stakeholders will be ensured to
59
60 428 capture data qualitatively.

430 **Qualitative data collection**

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

435 IDI and FGD guides will be developed and used to moderate the interview and discussion.

436 Participants for IDI and FGD will be drawn from a mix of study participants until data saturation is
437 reached. Interim analysis will be conducted to identify themes and assess data saturation.

438 Subsequently, interview guides may be adapted and more participants may be recruited until data
439 saturation is reached (33). Interviews will be conducted by the principal researcher and the duration
440 of interviews will be between 30-45 minutes. The principal investigator will be supported by a
441 notetaker, and the responses will be audio recorded. The principal investigator and notetaker are
442 part of the programme staff, but are not directly involved in care delivery.

443

444 **Data analysis**

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

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

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

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

1
2
3 462 *Step 2: Identifying the ICAMO configurations-* specific intervention, context, agents, mechanisms, and
4 463 outcome per case study will be grouped to form intermediate-level and high level codes (ICAMO
5 464 configurations). The case study ICAMO are generated using in-case analysis. Cross-case analysis is
6 465 used for synthesizing and refining the overall programme theory)

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10 466 *Step 3: Refining ICAMO configurations into programme theory* - ICAMO configurations in step 2 from
11 467 different cases will be compared and their explanatory power across studies will be examined (cross-
12 468 case analysis). "Causal loop thinking" will be used to develop the final ICAMO configurations and to
13 469 map out the interaction between the different components in the system.

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471 **Monitoring and quality control**

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

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

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481 **Patient and public involvement**

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

49
50 487

51 488 **Ethics and dissemination**

52 489 **Ethical approval**

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56 490 Ethical approval was obtained from the Institutional Research Board of APIN Public Health Initiatives
57 491 (IRB046-FR), Benue State Ministry of Health and Human Services (MOH/STA/204/VOL.1/154), and
58 492 the Institute of Tropical medicine Antwerp (1503/21).

493 **Informed consent requirements and procedures and data confidentiality**

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

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

506 **Specific patient benefits and risks (qualitative research strand)**

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

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

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

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

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3 526 There are no direct benefits to members of KP living with HIV whose data will be collected and
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5 527 analysed for this study. During the course of interview, if any interviewee shows/expresses signs of
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7 528 medical or psychological need, such participants will be referred to the ART Clinician/Nurse and the
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9 529 Adherence Counselors (working within the program) to receive medical and/or psychological
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11 530 assessment and treatment. Key populations with children less than 17 years will be referred to the
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13 531 Orphan and Vulnerable Children (OVC) program for economic and social support.

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14 533 **Feedback and dissemination of results**

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17 534 The results of this study will be shared with all stakeholders (study participants and programme staff)
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19 535 and published in scientific journals and presented at scientific conferences in the form of oral
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21 536 presentations or posters.

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23 538 **Discussion**

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26 539 This study protocol will describe the KP-CBART model as being implemented in Benue Nigeria and
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28 540 explore the mechanisms and contextual factors which generate intermediate outcomes, such as
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30 541 medication adherence, retention-in-care, viral load suppression, and long term outcomes, such as
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32 542 reduction in HIV incidence and improved health and well-being. The results of this study will inform
33
34 543 adaptations of the KP-CBART program to better meet the health needs of KP in Nigeria, and assist in
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36 544 national policy & programme design for the implementation of KP-CBART. A CBART model that fits
37
38 545 better the needs of KP is expected to improve clinical outcomes.

39 546 Findings from previous studies on KP-CBART in Nigeria are not sufficient to conceptualise and scale-
40
41 547 up the programme. The adopted research methods in these studies are inadequate to explain
42
43 548 causation in complex health interventions such as the KP-CBART. Most of these previous studies are
44
45 549 quantitative and are designed to determine the programme outcomes (such as viral load suppression
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47 550 and retention -in care) and associated factors. Therefore, the realist evaluation method, a theory
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49 551 based evaluation, to evaluate KP-CBART in Nigeria will bridge the deficiency of other research
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51 552 methods and offer a causal explanation of outcomes and their generative mechanisms. The realist
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53 553 evaluation method is well suited for this evaluation because the complex nature of the programme.

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55 554 The study will tease out the various components in the programme and the contexts. We will
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57 555 determine the contextual factors at the micro, meso, and macro levels (individual clients, service
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59 556 delivery points, local community, and state/national) and the mechanisms that generate the
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557 programme outcomes. We will describe the various interventions offered by the programme and
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559 how the actors respond to them. These findings will inform health policies, adaptation, and scale up

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3 559 of community-based ART interventions for HIV positive KP in Nigeria and similar settings in sub-
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5 560 Saharan Africa.

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7 561 The key strength of this proposed study is its research methodology which involves a realist impact
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9 562 evaluation of KP-CBART, including multiple case studies and a qualitative mixed method designs to
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11 563 explain the outcomes and impacts of the intervention. Anticipated limitations of this study are the
12
13 564 inherent challenges of the realist evaluation method. Differentiating between the contextual factors
14
15 565 and the mechanisms could be a limitation as many realist researchers have reported such challenges
16
17 566 (34). The ICAMO configurational mapping is subject to the interpretation of the researchers and this
18
19 567 can introduce some level of subjectivity into the interpretation of study results. Furthermore, the
20
21 568 process of iterative cycle of interview with key actors in the program (stakeholders) can induce
22
23 569 confirmation bias during the ICAMO configuration analysis. Another limitation is the conduct of
24
25 570 observational retrospective cohort study which can induce selection bias during the conduct of the
26
27 571 quantitative study. Investigators will ensure that these limitations are addressed during the conduct
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29 572 of the research.

30 573

31 574 **Contributors**

32 575 OI conceptualized the study. OI, SVB, and TD designed the study and wrote the main manuscript. CM,
33 576 JVO, PJ, PO, and LL reviewed the manuscript.

34 577

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40 583 The funders were not involved in the study design or the writing of the study protocol

41 584

42 585 **Competing interests**

43 586 The authors declare no conflicts of interest.

44 587

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699 **FIGURE TITLES AND LEGENDS**

700

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

702

703 **Figure 2. Realist evaluation of community-based ART service delivery models for key populations**

704 Adapted from Mukumbang et al, 2016 (29).

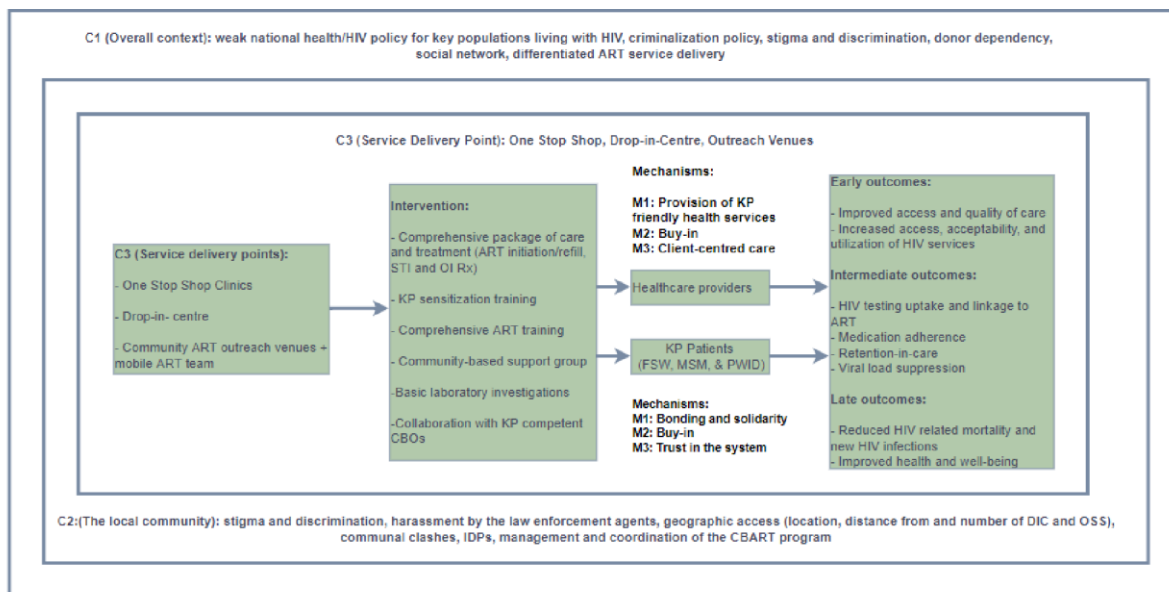


Figure 1. Starter hypothesis for the CBART model for KP

[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]

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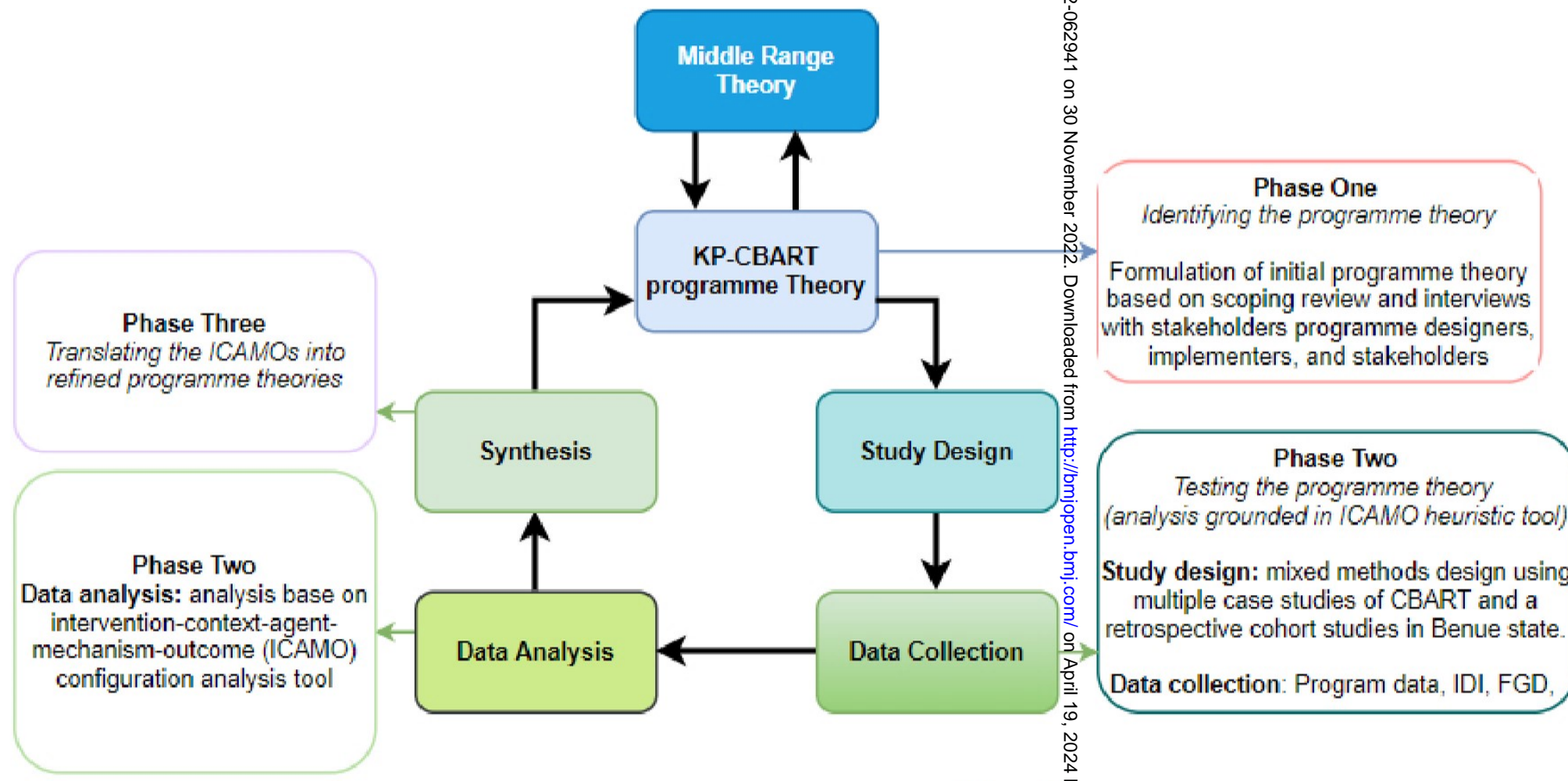


Figure 2: Realist evaluation of KP-CBART, adapted from Mukumbana FC et al, 2016

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