A realist evaluation of the antiretroviral treatment adherence club programme in the metropolitan area of the Western Cape Province, South Africa

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Declaration

I declare that this work 'A realist evaluation of the antiretroviral treatment adherence club programme in the metropolitan area of the Western Cape Province, South Africa' is my own work. I declared that this work has not been submitted for any degree or examination in any other university, and that all sources I have used or quoted have been indicated and acknowledged by complete references.

Student…….

27 February 2018

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Dedication

This work is dedicated to my family.

To my parents, Mr Alexander C Mukumbang and Mrs Mary-Laura Mukumbang

My brother, Frank A Che (CPT, US ARMY) and his family Nadine Che, Lenox A. Che and Neela A Che

My sister, Virly N Tchouake-Mukumbang and her children Ese Laura N. Davies and Afa-Maelle Tchouake Davies

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My wife, Patricia R Mukumbang and children Jayden C Mukumbang and Ferdie J Mukumbang

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Acronyms/Abbreviations

ART	- Antiretroviral therapy
ARV	- Antiretroviral
CAG	- Community ART Group
CDU	- Chronic/Central Dispensing Unit
HAART	- Highly active antiretroviral treatment
HAST	- HIV, AIDS, sexually transmission infection and tuberculosis
HBM	- Health belief model
HCT	- HIV counselling and testing
IMB	- Information-motivation-behaviour
ICAMO	- Intervention-context-actor-mechanism-outcome
ICDM	- Integrated chronic disease management
MMC	- Medical male circumcision
MSF	- Médecins Sans Frontières
MSM	- Men who have sex with men
MOU	- Maternity-obstetric unit
NIMART	- Nurse-initiated and managed antiretroviral treatment
PEP	- Post exposure prophylaxis
PMTCT	- Prevention of mother-to-child transmission
PrEP	- Pre-exposure prophylaxis
PRISMA	- Systematic reviews and meta-analyses
RAMESES	- Realist and Meta-narrative Evidence Syntheses: Evolving Standards
SAT	- Social action theory
SSA	- Sub-Saharan Africa
STIs	- Sexually transmitted infections
TAC	- Treatment action campaign
TB	- Tuberculosis
UNAIDS	- The joint United Nations programme on HIV/AIDS
WHO	- World Health Organization

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ABSTRACT

Introduction: In South Africa, 7.1 million people living with HIV/AIDS (PLWHA) of whom about 56% were accessing antiretroviral therapy (ART) in 2016, accounted for approximately 20% of people on ART globally. The successful initiation of PLWHA on ART has engendered challenges of poor retention in care and suboptimal adherence to medication. While standard treatment and care schemes show the potential to retain patients in ART care, their success is challenged by congested health-care facilities, long waiting times and shortages of health-care providers. The antiretroviral adherence club intervention was rolled out in primary health-care facilities in the Western Cape Province of South Africa to relieve clinic congestion and improve retention in care, and treatment adherence in the face of growing patient loads. Evidence from the literature suggests that these models of ART service delivery are more effective than corresponding facility-based care. Nevertheless, there is little understanding of how these care models work to achieve their intended outcomes. To this end, a theory-driven approach to evaluate the adherence club intervention was proposed.

Methods: We adopted the realist evaluation approach to evaluate what aspects of antiretroviral club intervention works, for what sections of the patient population, and under which community and health systems contexts, to inform guidelines for scaling up of the intervention. The study was conducted in three phases. First, we elicited the initial programme theory of the adherence club intervention using the elicitation approach. Second, we applied an explanatory theory-building multi-case study approach to testing the initial programme theory in three contrastive sites. Following the *retroduction* logic of making inferences, we configured information obtained from quantitative and qualitative approaches using the intervention-context-actor-mechanism-outcome heuristic tool to formulate generative theories. Third, we did a cross-case analysis to delineate the combination of the intervention, context and mechanism components from the three cases, which is used to explain the outcomes of the adherence club intervention.

Results: The initial programme theory revealed two plausible hypotheses. The first theory supposes that patients become encouraged, empowered and motivated, through the adherence club intervention to remain in care and adhere to the treatment. The second theory suggests that stable patients on ART are being nudged to remain in care and adhere to the treatment with the goal to

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decongest the primary health-care facilities. The refined programme theory showed that grouping clinically stable patients on ART a convenient space to receive a quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required while guided by rules and regulations works because their self-efficacy improves and they become motivated and nudged to remain in care and adhere to medication.

Conclusions: The successful implementation and rollout of the adherence club intervention are contingent on some important health system conditions. Prominent among these is the separation of the adherence club programme from other patients who are HIV-negative as much as possible. In addition, there should be available convenient space for the adherence club meetings, continuous support of the adherence club facilitators by clinicians and buy-in from the health workers at the health-care facility. In the context of chronic care integration, caution must be taken when integrating HIV-treatment services with other non-communicable chronic disease care as this has the potential to de-establish mechanisms that are critical to the success of ART service delivery.

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SECTION 1

STUDY OVERVIEW

The study overview sets the scene of the study and contains three main components structured in three chapters.

In **Chapter 1**, a reflection on the access, treatment and care of people living with HIV/AIDS (PLWHA) in South Africa in the past 20 years and implications for the future is presented. The response of the South African health system to the high HIV incidence and prevalence and how these responses have changed the landscape of the epidemic are also presented. A critical description of the various policies, programmes and interventions for prevention and treatment that were employed to address the epidemic and the continuous fight that is being mounted to end AIDS by 2030 is also presented. Finally, in this chapter, the role of differentiated care models to HIV treatment and care forms the focus, with particular attention to the adherence care intervention.

In **Chapter 2**, the philosophical paradigm that informed the realist evaluation approach is presented. Here, the focus was to establish the link between the ontological position, the epistemological principles and the methodological assumptions of critical realism and how these inform the methodological practice of the realist approach to evaluation.

In **Chapter 3**, the study protocol is described. This protocol was published in the British Medical Journal (BMJ Open) in 2016 before the study had officially started **(Appendix 2.1)**.

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CHAPTER ONE

Access, treatment and care of people living with HIV/AIDS in South Africa: Reflections on the past 20 years and implications for the future

Introduction

South Africa has a high HIV epidemic with an estimated seven million people living with HIV as at 2016 [1]. While this figure, at first glance might indicate escalating infection incidence, it could also be an indication of the effectiveness of the South African health system towards the fight against the HIV epidemic. The latter point of view is strengthened when we compare estimated incidence rates of the HIV infection in South Africa vis-à-vis the prevalence rates (**Figure 1.1**).

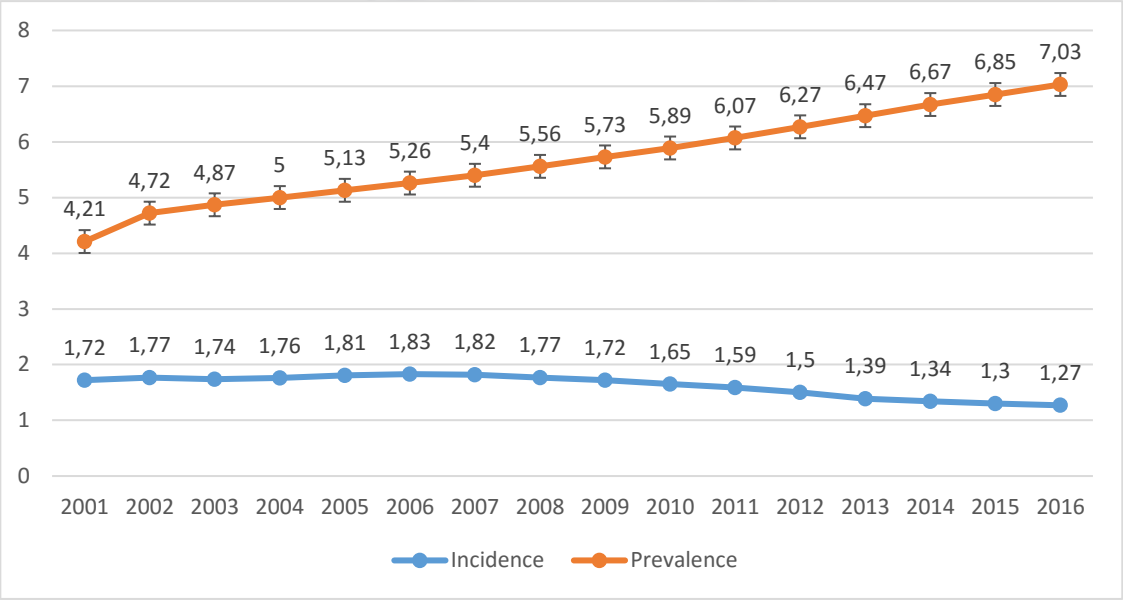

Figure 1.1: HIV incidence and prevalence in the general South African population, 2001-2016

Notes: Data in the constructed graph are obtained from Stats South Africa's Mid-year population estimate reports. Data from 1996-2000 are not included in the representation because these were mostly obtained from Antenatal Surveillance.

The trends observed indicate a slow decrease in the incidence of the HIV infection from 2006 to present date despite a steady increase in the prevalence within the same period. This could suggest the success of the national HIV response especially the HIV prevention strategies and the overall effectiveness of the health system [2]. The concomitant steady rise of the HIV

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prevalence is, therefore, indicative of more PLWHA and surviving in South Africa. The effectiveness of the South African health system in combating the HIV/AIDS epidemic is further confirmed by the declining trend in the number of people dying from HIV/AIDS (**Figure 1.2**). The decline in the total number of deaths mirrored the decline in HIV-related deaths in the country. This decline is widely attributed to the unprecedented scale-up of antiretroviral therapy (ART) services, where 3.5 million PLWHA in South Africa were initiated on the treatment as of June 2016 [3].

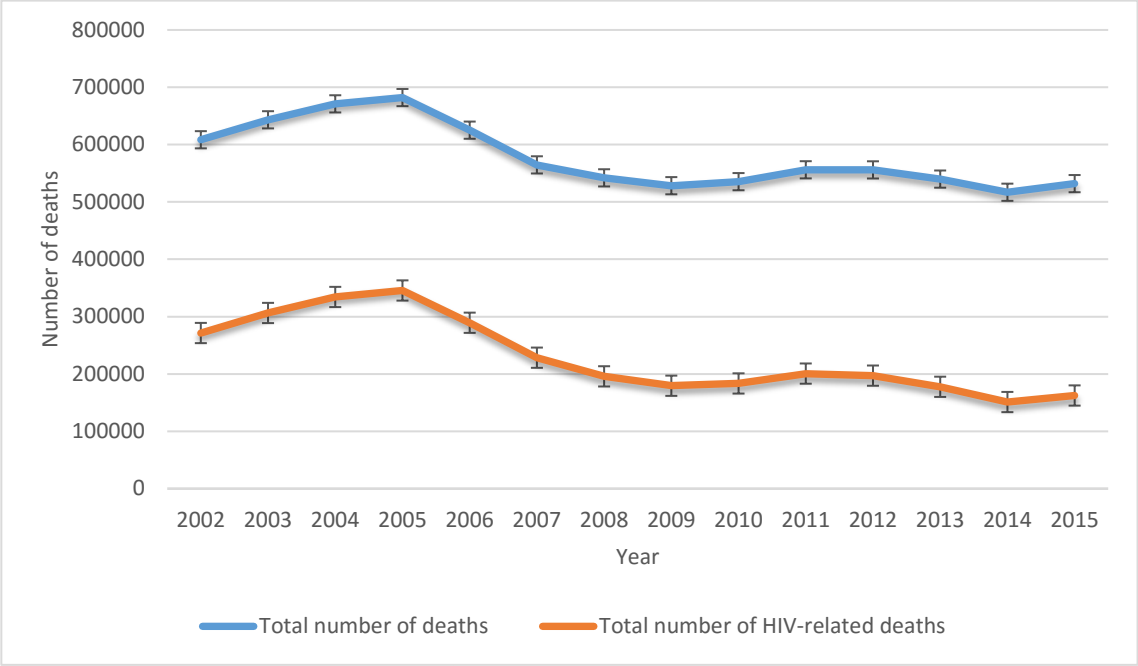

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Figure 1.2: Total number of deaths compared to number of HIV-related deaths

The success of the rapid scale-up has, however, put pressure on health services to deliver consistent quality care, including timely access to medication, follow-up of defaulters and monitoring of drug resistance. In focusing on enrolment of new patients on ART, the door was left open for existing patients defaulting on treatment compliance or becoming part of the loss-to-follow-up cohort [4]. The consequences of poor retention in care and suboptimal adherence to medication have been highlighted [5]. These include the possible medication resistance and the emergence of HIV-resistant strains, the occurrence of opportunistic infections, and increased morbidity and mortality [6]. At the level of the health system, it could mean increased expenditure and complications related to switching to second- and third-line regimens and increased severity of AIDS-related co-morbidities [7].

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Health system's response

The South African health system's response to the HIV epidemic was influenced by the policies and objectives of the National Strategic Plan (NSP) for HIV, Sexually Transmissible Infections and tuberculosis (TB) (2012-2016), the goals of UNAIDS (3' by 5', 15 by 15 and 90-90-90), the implementation of the World Health Organization's (WHO) treatment guidelines and the Southern African HIV Clinicians Society guidelines. Based on these guidelines and research evidence from studies conducted in South Africa and areas of similar context, the Department of Health (DOH) developed guidelines which are implemented in the public health sector.

The first reaction to the HIV epidemic in South Africa occurred between the 1980s and 1990s when the South African government launched a prevention campaign of condom distribution and 'safe-sex' education [8]. The distribution of condoms in the public sector was a key part of the government's HIV-prevention strategy. Through this strategy, the number of male condoms distributed increased from 8 million in 1994 to an estimated 376 million in 2006 [9]. Subsequently, the female condom was introduced in 1996 to increase HIV-prevention options for women, and in 2006, an estimated 3.6 million female condoms were distributed [10].

Despite these prevention efforts to curb the spread of the HIV infection in South Africa, the country reported a huge amount of deaths related to HIV infection between 1996 and 2006. More than 330,000 people were estimated to have died from HIV/AIDS prematurely between 2000 and 2005 [11]. This number has been associated with the 'denialist' response of the South African government to the HIV epidemic during this period [9], which challenged the medical evidence that HIV causes AIDS. Owing to the denialist position, the NSP (2000-2005) for South Africa had three major foci: (1) to reduce new infections, especially among the youth, (2) to reduce the impact of HIV/AIDS on infected individuals, families and communities, and (3) support for HIV-infected or -affected children. Within this plan, there was a notable absence in the provision of antiretroviral (ARV) drugs.

In 2002, a second component was added to the condom distribution HIV-prevention strategy following civil society protests and constitututing the rollout of niverapine to prevent mother-to-child transmission of HIV [9]. In the same year, the idea to develop an ART programme was conceived. The South African government established a joint Health and Treasury Task Team to propose options for expanding HIV treatment beyond prevention of mother-to-child transmission (PMTCT) and post-exposure prophylaxis [12]. When ART programmes officially started in April 2004, facilities needed to be 'accredited' after passing a 23-item requirement.

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This was to ensure that the facilities were prepared for the ART service delivery. The downside of the accreditation process was that it slowed down the ART initiation, as this took some facilities longer to fulfil all the requirements. Other challenges faced at the facility level included patients who were co-infected with TB, shortage of human resources, and incorrect disease stage classification [13]. Notwithstanding these challenges, an estimated 488,739 people were initiated on ART in the public sector within four years [10].

The conflicts seen during the denialism period led to a staged political response, driven through the second NSP (2007-2011) – massive scale-up of ART – which led to a drop in the death rate between 2008 and 2011 (**Figure 1.2**). This second NSP had four priorities: (1) prevention, (2) treatment, care and support, (3) legal and human rights, and (4) research, monitoring and evaluation. The two main over-arching objectives were to reduce the HIV-incidence rate by 50% and initiate ART in 80% of those who need it [10].

In 2011, following the UNAIDS goal to achieve the global target of reaching 15 million people with HIV treatment by 2015, the South African government made a renewed commitment to scale-up the national HIV response. Consequently, the third NSP on HIV, TB and STIs (2012-2016) set as a target that 80% of PLWHA should be on ARV drugs by 2016. This was also the first time that TB was included in the strategy towards the complementary fight against the HIV epidemic in South Africa. The plan sought to reach the marginalised populations such as sex workers, men who have sex with men, adolescents and truck drivers [9]. The improved initiation of PLWHA on ART also contributed to the further decrease of the death rate of PLWHA and also reduced the incidence of HIV in recent years. Despite a slow start, the South African ART programme is now the largest in the world, [8] with an estimated 21% of the world's ARVs consumed by patients enrolled in the country's health services [14]. In **Figure 1.3** the number of people initiated on ART from 2009-2016 is shown.

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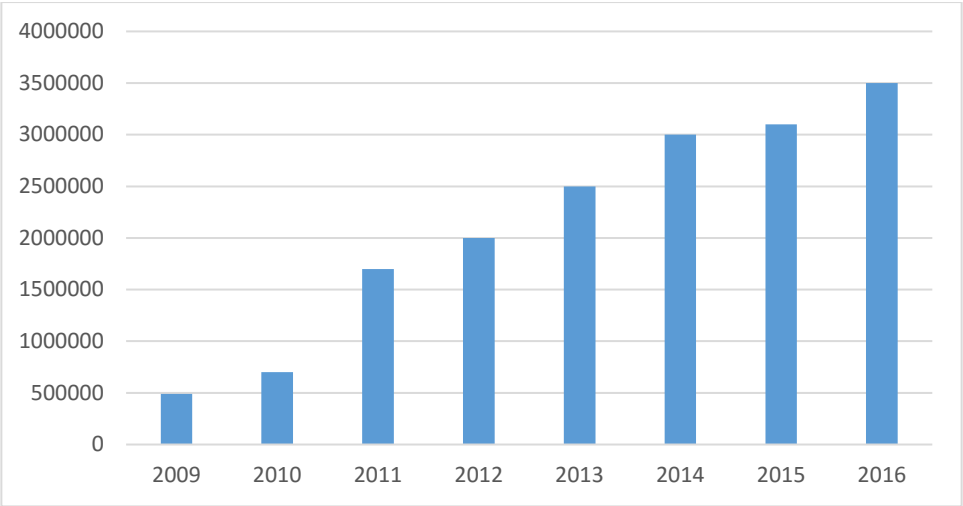

Figure 1.3: Number of people initiated on ART

Two main ART programme streams

The South African National HIV programme adopted two main programme streams in the fight against the HIV epidemic. these are the PMTCT programme and the massive rollout of ART to the general population.

1. Prevention of mother-to-child transmission programme

In South Africa, the first PMTCT programme was started at two maternity-obstetric units (MOUs) in Khayelitsha, Cape Town (Western Cape Province) from 1998 - 1999 despite the absence of a national policy [15]. In 2002, an official national PMTCT programme was started [16]. The programme included the provision of niverapine to pregnant women and their children, with services such as voluntary counselling and testing [16]. In 2008, the programme was expanded to having dual prophylaxis with azidothymidine and niverapine from 28 weeks gestation, niverapine treatment provided to pregnant women during labour and for their babies within 72 hours of delivery, and highly active antiretroviral treatment (HAART) for pregnant women with CD4 counts <200 cells/mm^3. In 2010, the PMTCT programme was further revised to include lifelong ART (dual ART) from 14 weeks onwards in the pregnancy for HIV-positive women with CD4 counts <350 cells/mm^3. In addition, daily niverapine was continued for all breastfeeding infants whose mothers were not on HAART. Through the provision of ARVs since 1995, an estimated 1.6 million new HIV infections among children have been averted [10].

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2. Massive rollout of ART

According to Bekker et al. [16], it took ten years for South Africa to initiate 2.5 million people on ART from the time ARVs were approved for the treatment of HIV and AIDS. Over time, revisions to the national treatment guidelines have meant that more patients were eligible to be initiated on lifesaving therapy [17]. The initial shift from clinical eligibility at a CD4 count from <200 to <350 cells/µl resulted in adult ART coverage dropping from 79% to 52% [17]. South Africa adopted the 2009 WHO guidelines for the treatment of adults and adolescents in April 2012 [18], which improved ART coverage in adults to 81% [19]. Twelve months after the release of the WHO 2013 guidelines for the treatment and care of adults and adolescents, the South African government adopted the "test and treat" guidelines. These guidelines imply that all people who test HIV positive should be initiated on ART without delay.

Interventions/programmes in the ART programme

The HIV epidemic with the corresponding TB epidemic has served as key drivers of innovation in service delivery, monitoring and evaluation in the South African health system. The most prominent of these include task shifting, the establishment of a robust monitoring and evaluation (M&E) system, drug dispensing/distribution innovations, interventions and improve adherence to medication and retention in care.

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HIV counselling and testing campaign

The HIV-counselling and testing (HCT) campaign was an intervention designed to reach 15 million South Africans from April 2010 to June 2011. The strategy offered free HIV testing to everyone who was sexually active, above 15 years old attending a clinic or hospital regardless of whether they have HIV symptoms or not [20]. The aim of the campaign was four-fold to (1) increase the health-seeking behaviour, (2) encourage South Africans to know their HIV status, (3) empower those who test HIV negative to retain their status, and (4) facilitate access to wellness and treatment services for those who test HIV positive [20]. The business sector nested in this plan, committed South African companies to testing two million of the 15 million targeted by the Government. Before this campaign, an estimated 2.6 million people had gone for HIV counselling and testing, but since the launch, 18 million people have been tested.

Voluntary medical male circumcision

Following disputed evidence that male circumcision has the potential to reduce the risk of HIV transmission [21, 22], the South African health system designed a programme to promote the

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procedure in South Africa. The integration of voluntary medical male circumcision (VMMC) with existing HIV-prevention strategies was expected to improve the prevention of HIV among men, indirectly benefitting women. Consequently, as part of the fourth NSP (2012-2016), the National Department of Health (NDoH) developed the Strategic Plan for the Scale-up of Medical Male Circumcision (MMC) in South Africa. According to this strategic plan, 4.3 million circumcisions were to be performed by the end of 2016. Less than 40% of uncircumcised men in South Africa were willing to undergo circumcision [23]. This had implications for achieving the NDoH's goal of 4.3 million MMCs by 2016 [24], as only an estimated 2 million men, aged 15 to 49 years, were circumcised in South Africa as at 2016.

Task shifting

During the initial implementation of the ART programme developed in 2004, teams of health-care professionals were predominantly experts. This ART programme was hospital-based, staff intensive (doctor-led) and bureaucratic [16]. With the rapid rollout of ART, ART clinics became overburdened and overcrowded revealing challenges related to access to treatment and poor follow-up systems to enforce retention in care. Between 2008 and 2011, as the demands for initiating and managing more patients on ART increased, major changes in professional practice occurred, most notably a shift towards nurse-initiated and managed antiretroviral treatment (NIMART). In 2008, a joint statement by Médecins Sans Frontières (MSF), Reproductive Health and Research Unit of the University of Witwatersrand, the Southern African Clinician Society, and Treatment Action Campaign called on the South African government to issue clear directives for NIMART. This call also included guidelines for the expanded roles for pharmacy assistance and lay counsellors in comprehensive delivery of HIV/AIDS services. Since then, task shifting has been widely promoted as a mechanism for expanding ART access [17].

The goal of task shifting was to provide more points of care, improve access to treatment, increase adherence and to foster the management of the patients who were already on ART [25]. Through this framework, the doctors focused on providing care for inpatients and complicated cases, while the nurses assessed patients to diagnose and treat opportunistic infections and start and monitor them on ART rather than only supporting doctors [26]. In studies on the expansion of the primary care nurses' role to include ART initiation and maintenance, this was demonstrated to be done safely [25]. Although health outcomes and quality of care were shown to improve, it may not have reduced the time to initiate ART or

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impact on mortality.

Improved information system for the management of HIV and TB

The collection of reliable data is the first step to assess the status of HIV/AIDS in communities [27]. The HIV-treatment programme has prompted the development of a robust information system to collect longitudinal data on the clinical status, drug switching, drug-related adverse events, treatment adherence, CD4 cell count and viral load measurements and treatment outcomes [10]. In the initial stages, this information system was paper-based. Because of the scale-up of ART, many treatment sites in South Africa were not able to cope with the monitoring of large patient cohorts with paper-based systems only.

Scaling-up of ART led to the development of a three-tiered health information system in 2010 to support the treatment and management of HIV and AIDS in alignment with the WHO's monitoring recommendations [28]. This three-tiered approach to monitoring includes a paper-based system making up tier 1, an electronic version of the paper register as the middle tier or tier 2, and a networked electronic medical records systems for the ART programme at the 3rd tier [29]. Examples of networked electronic medical records systems for the ART programme include eKappa and Tier.net used in the Western Cape Province. While these systems are not nationally standardised yet, they provide a wealth of data on the status of the ART rollout programme [10]. According to Karim et al. [10], the detailed data collected in HIV-treatment programmes have enabled a high-level performance management approach, where ART rollout programme indicators are used to provide feedback to health service managers.

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Optimising ART pharmaceutical supply chain management systems

Although South Africa runs a free essential medicines programme at primary health-care level, there are persistent challenges that hinder sustainable access to medicines including ART [30]. ARV stock-outs have been reported in various parts of South Africa since 2009, with varying causes [16]. Some of the identified causes of the stock-out include poor forecasting by the management team, ordering problems, manufacturing capability and simple delivery logistics. Owing to these challenges, pharmaceutical supply-chain management systems, through a government and private partnership, have been established in the Western Cape Province, South Africa.

Through this business model, a private service provider has been appointed to provide selected pharmaceutical services to public sector patients in the Western Cape. These services include

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primarily the centralised dispensing of prescriptions for chronic conditions [31]. Using this Chronic Dispensing Unit (CDU), medicines are dispensed under legislatively compliant conditions and handed to patients through various community-based distribution models. The aim is to reduce pharmacists' workload, reduce patient waiting times and decongest health-care facilities [30]. Owing to the success of the CDU in the Western Cape Province, plans are on the way by the South African health systems to establish partnerships with private enterprises for the distribution of chronic medication [32].

Interventions to improve retention in care and adherence to medication

As the need and calls to initiate more PLWHA on ART, various models have been designed to improve access to treatment, retain patients in care and enhance adherence to medication [33]. These observations led to the design and implementation of a range of interventions to address issues of retention in care and treatment adherence among patients on ART. These interventions range from an individual-level to relational (patient-provider relationships such as continuity of care) to health systems interventions (e.g. task shifting and medication distribution systems). Interventions for improving retention in care and adherence at the individual and relational level and for which there is evidence include psychosocial assessment and treatment, medication adherence counselling, home visits/a buddy system, directly observed therapy, reminder systems through short message service (SMS), improving clinic accessibility, and social support.

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Recently, there has been a push towards adopting other forms of differentiated care models [34]. Differentiated care is a client-centred approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of PLWHA while reducing unnecessary burdens on the health system [34]. By providing differentiated care, resources can be refocussed to those most in need through the health system. Differentiated models of care are thought to address the diverse needs of PLWHA and offers alternative strategies for community delivery of ART to accommodate the growing number of people initiated on ART.

Various strategies have been designed and adopted (mostly unofficially) to improve access to treatment and care, retain patients in care and improve adherence to medication. The part of the differentiated care that has received more focus is differentiated ART delivery, which focuses on facilitating access to ARVs [34]. The implementation of models of differentiated ART delivery is largely for stable patients. Patients identified to be 'stable' on ART and have a

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proven record of clinic attendance are provided with pre-packed medication to avoid long waiting times at the pharmacy to collect their medication. Through this strategy, community drug distribution points such as churches and town halls have been used at various points.

Key successes

Through the various interventions and programmes implemented via the health system, the South African HIV programme noted some key successes. First, it the total number of people who have been initiated on ART in the ART programme. As demonstrated in **Figure 1.3**, the number of people initiated on ART has increased year on year. Today, an estimated 3.5 million people have been initiated on ART. This has resulted in increased ART coverage, which in turn leads to lower adult mortality rates. In addition, there has been a reduction in the mother-to-child HIV transmission. In 2010, the first national population-based survey on the effect of the South African PMTCT programme on early HIV transmission from mother to child reported an overall transmission rate of 3.5%. A repeat of the survey in 2011, showed that the transmission rate was reduced to 2.7% [15]. Currently, the mother-to-child transmission rate of HIV in South Africa is 1.5%. This has resulted in lower child mortality rates.

Challenges

Notwithstanding the great success that the South African ART programme has achieved, challenges remain. Key challenges faced by the South African health system regarding the HIV programme include sustained high HIV incidence among key populations and patient retention in care and adherence to ART.

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High HIV incidence

Despite the fact that the overall HIV incidence in South Africa is decreasing year on year, as displayed in **Figure 1.1**, with over 400 000 new HIV infections a year, the country remains first in HIV incidence in the world. Young women between the ages of 20–24 years old have the highest HIV-prevalence and incidence rates in South Africa. A third of all new HIV infections in South Africa is estimated to occur in adolescent girls (15–24-year-olds) who are up to eight times more likely to be infected with HIV than their male counterparts. This indicates that challenges remain regarding the design and implementation of effective targeted HIV-prevention strategies.

In a survey on HIV-prevalence and treatment rates among sex workers in South African

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metropolitan areas, revealed an estimated 70% in Johannesburg were HIV positive, while in Durban 53% had an HIV-infection rate and almost 40% in Cape Town [35]. This Integrated Biological and Behavioural survey also revealed that nearly eight in ten sex workers between ages 30 and 34 years were HIV infected in Johannesburg and Durban [35]. There is also evidence that sex workers are unsure what to do when they experience condom failure during penetrative sexual encounters with male clients [36]. These findings reveal that the South African health system is failing to address the high HIV incidence among sex workers and also highlight the need for additional efforts and resources to achieve and maintain optimal levels of engagement with the sex worker population to reverse the trajectory and severity of the HIV epidemic [35].

The results of a study conducted by the Human Sciences Research Council revealed that the HIV prevalence among men who have sex with men (MSM) in the three largest cities in South Africa is higher compared to national estimates [37]. In this study, it was found that in Cape Town, the overall HIV prevalence among MSM was 22.3%, in Johannesburg this was 26.8%, and in Durban, the prevalence was 48.2%. In each of these cities, it was noticed that the HIV prevalence was higher among MSM aged 25 years and older than among MSM in the 18–24-years age category. These findings, as in the two previous scenarios (young women and sex workers) demonstrate the urgent need for interventions on the high HIV prevalence among MSM.

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Retention in care

According to the NDoH, the rate at which patients on ART are retained in South Africa is on the decline [32]. the loss-to-follow-up rates of patients on ART was observed to have increased as the South African ART programme matured [38]. Therefore, as the antiretroviral treatment centres become crowded it impacts on the capacity of the facility to enrol new patients on ART. In **Table 1.1**, comonly identified factors affecting retention in care and adherence to medication are presented.

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Table 1.1 Factors influening retention in care and adherence to medication in South Africa

Category	Barriers
Individual-related factors	• Age (being younger) • Depression (Mental health) • Forgetfulness • Substance abuse • Poor self-efficacy • Low health literacy • Perceived wellness
Medication-related factors	• Medication side effects • Medication dosing (Complex regimen) • Treatment fatigue
Health system factors	• Access to ART (Medication stock-outs) • Relationship with health-care providers • Staff shortages • Long waiting times • Poor services delivery
Socio-economic factors	• Poverty • Lack of family support • Food insecurity • Stigma and discrimination • Transportation challenges
Socio-cultural factors	• Alternative treatment • Male dominance and gender-based violence • Religious beliefs

Various programmes and interventions have been designed and implemented by the South African health system with a varying level of success. Some of these have been discussed on "innovations in the art programme" and some are discussed in the section that follows.

Lessons learnt and the way forward

In the course of attempting to address the challenges of retention in care and adherence to medication, various strategies were proposed. Among these are differentiated care models and care integration.

Differentiated care

Although there is a wealth of evidence suggesting that differentiated care models have the potential to improve access to ART, care and management of PLWHA, challenges remain regarding conceptualising and implementing these models at large scale [39]. While many different differentiated care models exist, identifying which one is appropriate for which context poses the first challenge to health-care managers. Other models to improve access to

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ART include multi-month prescriptions where stable patients receive refills of ARV medications for three or more months instead of one month at a time. Therefore, stable patients have four clinic visits per year instead of 12 to reduce their burden and that on facilities.

Another model, the fast-track refills is meant to reduce the waiting times of the patients when they arrive at the clinic for their medication. This medication could already be prepacked by the CDU or the local pharmacy, and the patient collects it on arrival at a designated person or office.

The adherence club intervention implemented in the Western Cape Province (**Figure 1.4**) as well as in various parts of South Africa encompasses multi-month prescription and fast-track refill strategies. Evidence from various studies demonstrates that the adherence club models are more effective in retaining patients in care and improving adherence to medication compared to the regular clinic services [40–42]. Recent evidence also indicates that patients receiving care in the adherence care model show more satisfaction with ART care compared to those who receive care from the standard ART scheme [43]. In addition, there is evidence that the adherence club model of ART care is cost-effective compared to standard care [44].

Based on this body of evidence suggesting the efficacy and effectiveness of the adherence club model, there is a drive to incorporate this model into the national ART strategy [45]. The WHO recommends the use of differentiated care models to improve access to treatment, enhance care for people living with HIV and promote adherence to treatment in its guidelines advocating for the "test and treat" model for managing HIV [46]. The second argument in favour of using differentiated care models of ART is that a "one-size-fits-all" model potentially does not provide sustainable access to ART and support services for the diverse groups of PLWHA to achieve the ambitious goal of ending AIDS by 2030 [47].

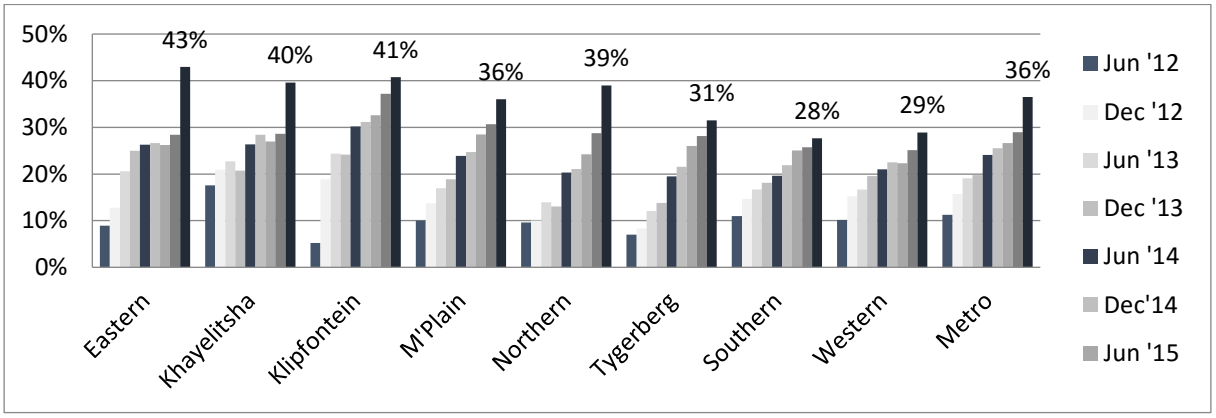

Figure 1.4: Percentage of patients retained and receiving care in adherence clubs June 2012 to June 2016

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Care integration

While there has been a drive in recent times to use various models to enhance the management of PLWHA, there is also a move from implementation scientists and public health practitioners to incorporate other chronic diseases to managing HIV. The different phases from diagnosis to complete self-management of HIV services could also be integrated. Therefore, two main levels of integration are identified, i.e. chronic care integration and integration of treatment with prevention approaches.

1. Chronic care integration

The success of the ART programme has transitioned the HIV infection to become a chronic disease [48]. Levitt et al. [48] argue that with the rising incidence of chronic non-communicable diseases (NCD), particularly cardiovascular disease and diabetes, in conjunction with the HIV epidemic are heading for a collision course in South Africa. According to the second National Burden of Disease study and cause of death profile conducted by Pillay-van Wyk et al. [49], the first two broad causes of death in South Africa were HIV/AIDS and TB and NCD. Mental health disorders such as depression, often co-exist with NCD, and HIV is said to increase the risk of developing NCD, which aggravate the severity of the HIV disease.

In response to the co-occurrence of these two epidemics (NCD and HIV), the NDoH has introduced an integrated chronic disease management (ICDM) model [32]. The logic behind this integration is on the premise that the ART programme has shown considerable strengths and innovations that could easily be extended to enhance the management of NCD patient groups, who essentially have similar needs as patients on ART [48]. This model of care advocates for the rationalisation of the frequency of the clinical consultations, the facility visits for the collection of repeat prescriptions and counselling sessions. In **Figure 1.5** below, the minimum package of adherence intervention is indicated considering the integrated care of patients.

Proponents of this type of integration argue that it has the potential to reduce the stigma and discrimination behaviours associated with HIV. Furthermore, that this type of integration would enhance the use of scare human resources. While the ICDM model can enhance the management of the NCD, it is not exactly clear how it would enhance the HIV-treatment and care services especially in the context of the “test and treat” rollout. A study conducted to evaluate the implementation of the (ICDM) model showed challenges related to structure

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(malfunctioning of equipment and staff shortage), process (irregular prepacking of drugs) and outcome (long waiting times) [50]. The lessons learnt from this is related to having a reliable medication supply system, sufficient staff, and equipment in good working condition for the ICDM model to succeed.

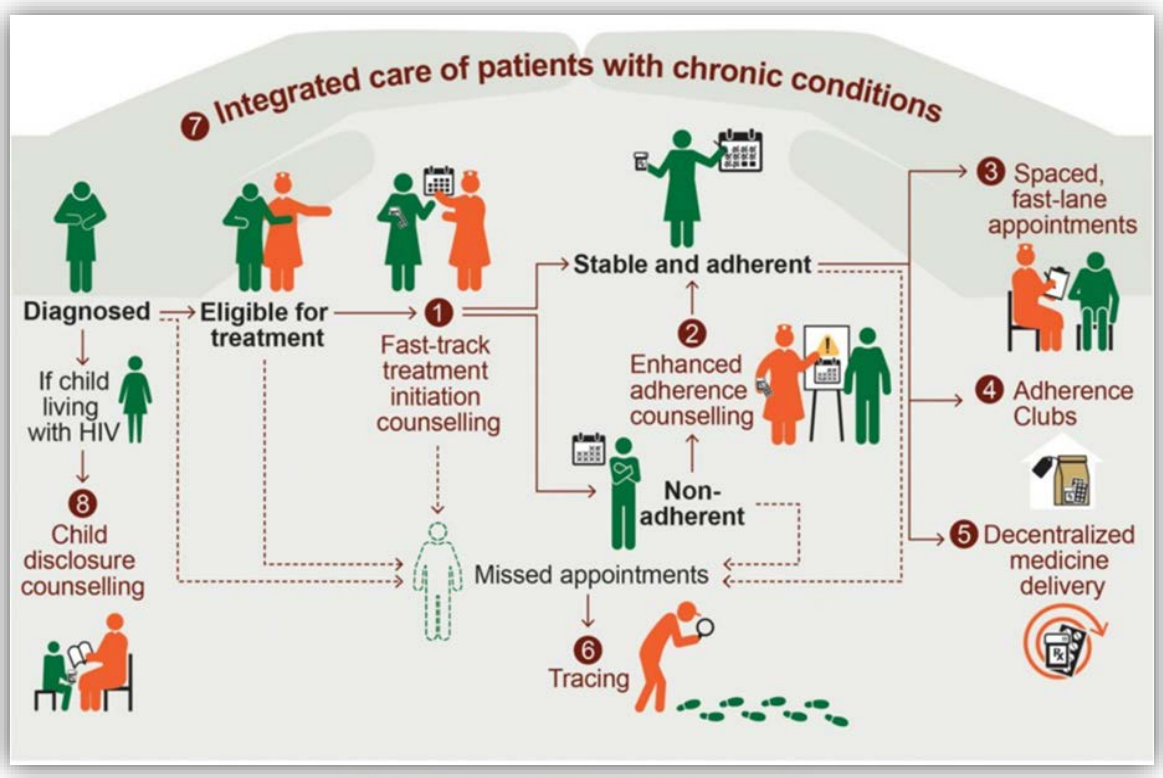

Figure 1.5: Proposed framework for the integration of patients with chronic conditions (Source: Department of Health [45])

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2. *Prevention and treatment integration*

For a better management of PLWHA, there should be an integration of HIV prevention and treatment services [46]. The argument behind the adoption of such a strategy is based on the fact that every new infection involves transmission from a person already living with HIV/AIDS, therefore, the integration of HIV prevention into HIV-care settings has the potential to prevent thousands of new infections as well as improve the lives of PLWHA [51]. HIV-treatment programmes should include the full array of sexual and reproductive health services, and HIV treatment should be an integral component of these programmes. A strategic approach to controlling the HIV epidemic, therefore, requires continued and comparable expansion and integration of care, treatment, and prevention programmes [51].

The recent drive towards treatment as prevention (TasP) – HIV prevention methods that use

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ART to decrease the risk of HIV transmission – fosters the strategy of integrating prevention and treatment programmes. Based on evidence from various biomedical studies, guidelines have been developed to ensure the safe use of ART for the prevention of HIV among people with perceived risk of contracting HIV. In September 2015, the WHO released new guidelines recommending pre-exposure prophylaxis (PrEP) to population groups at significant HIV risk [46]. According to these guidelines, PrEP is a highly effective, safe, biomedical option for HIV prevention, and can be incorporated into other combination prevention strategies in Southern Africa, given the high prevalence of HIV in the region [52].

There is evidence that the use of the PrEP strategy could be very effective in the prevention of HIV among at-risk groups such as MSM, HIV-serodiscordant couples, transgender persons, and drug addicts [53]. This strategy has implications for the reduction of the incidence of HIV in South Africa towards ending AIDS 2030 as work on developing an HIV vaccine continues. Questions remaining to be answered are whether HIV infections on PrEP cause ARV resistance and whether TasP leads to widespread resistance with poor adherence in healthy people? Also, whether the South African health system can afford to provide large populations on ARVs as PrEP or TasP?

Microbicide and HIV vaccine trials

Although there is mounting evidence supporting the effectiveness of ART as prevention, the South African health system is joining the international community in search of an effective prophylactic HIV vaccine. According to Anthony Fauci, the Director of the United States National Institute of Allergy and Infectious Diseases, “Even a moderately effective vaccine would significantly decrease the burden of HIV disease over time in countries and populations with high rates of HIV infection, such as South Africa” [54].

Thus far candidate HIV vaccines have been tested in three human efficacy (Phase 3) clinical trials [55]. Only the third trial conducted in Thailand showed potential protection against HIV, with 60% protection (post hoc analysis) from HIV infection one year after vaccination, and 31.2% at the end of 3.5 years [54, 55]. The lesson learnt from this trial is that a vaccine against the HIV infection is possible [56]. A suggestion is that if an HIV vaccine were found to work in South Africa, it could dramatically alter the course of the pandemic [56].

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Conclusions

Impressive progress in scientific discovery, resource mobilisation, political commitment and implementation has been made by the South African health system to create a favourable global HIV trajectory. Through the failures and successes of the South African national ART programme, many lessons have been learnt, which could be used to inform the way forward as the world moves toward ending the HIV epidemic by 2030. Nevertheless, achieving the goal of ending AIDS 2030 depends largely on the retention of PLWHA in care and adherence of patients to ART and dealing with underlying drivers such as stigma and social norms simultaneously. Consequently, various efforts (biomedical, socio-behavioural and implementation research, including innovations – vaccine and cure) are being employed by the South African health system towards ending AIDS in 2030. These efforts in particular focus on improving the retention of the increasing patient cohorts on ART. To this end, various differentiated care models are being considered based on evidence on their potential effectiveness.

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CHAPTER TWO

Critical Realism: Axiology, Ontology, Epistemology and Methodology framework

Introduction

Realism has gained traction in the last 40 years among social scientists as a foundational philosophy and as an applied approach to inquiry [1, 2]. As a foundational philosophy, realism refers to the external reality as "consisting of structures that are themselves sets of interrelated objects and of mechanisms through which these objects interact" [2]. The realist philosophy theory about the world (structures) focuses on human agency and the interaction between these two – structures and agency [3].

As an applied approach to inquiry, realism offers an alternative way of developing theories of causality – non-reductionist conception of theory – that avoids the shortcomings of the causality theories developed through positivism [4]. Realism lays the foundation to explain contingent causality in a way that allows for the generation, testing and refining of contextualised hypotheses. This is related to the fact that realism assumes a transcendental ontology – framework of emergence and validation of knowledge of being [5].

Realism, when considered in its broad sense, is based on the belief that there is an external 'reality' independent of human perception [6]. What the 'reality' consists of, is the notion that has brought about various schools of realism. The most prominent manifestation of realism in the social sciences is critical realism, a philosophy of science usually associated with the work of Roy Bhaskar [5, 7], which was further developed by Archer (1995) with contributions from other philosophers and methodologists [8].

Critical realism – Axiology

Critical realism is a philosophy that offers a transformational model of understanding social activity, whereby social structure and agency find a place. Critical realism accepts the existence of independent structures that influence the actions of actors in a particular setting, while acknowledging the role of the subjective knowledge of these actors. Critical realism, therefore, leverages elements of positivist and interpretivist paradigms to formulate a relatively new

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approach to knowledge development [9]. This implies that research conducted with the critical realist paradigm should provide greater detailed causal explanations on phenomena or events regarding the actors' interpretations, structures, and mechanisms that interact to produce the outcome of interest. Because of the qualities of critical realism to merge the assumptions of the positivist and interpretivist positions, it has been suggested that critical realism subsumes positivism and interpretivism [10], resolving the quantitative-qualitative dilemma [11].

Critical realism – Ontology

Ontologically, critical realism stratifies reality into three different domains, the real, actual and empirical phenomena [7]. The 'real' phenomenon refers to the relatively unchanging existence, which has structures (set of internally regulated objects and practices) and mechanisms (causal powers) that generate events or phenomena [12, 13] and is intransitive (exists independently of our understanding thereof). The 'real' relates to the existence of (usually) invisible mechanisms with generative power causing what is observed. This is in the sense that anything that can have real effects is real [14]. For instance, we know that culture is real because it has real effects. Similarly, the implication is that social constructs and institutions are real and have real effects [14].

The 'actual' phenomenon defines events (and non-events) independent of whether they are observed or not. This layer represents the portion of those events that take place in the 'real' that *may* or *may not* be experienced by the relevant actor [15, 16]. The 'actual' domain is, therefore, a subset of the 'real' and includes actual events generated by mechanisms [9]. These causal mechanisms cannot be seen operating directly, as they are not open to observation, but they can be inferred through a combination of empirical investigations and theory construction [13].

The third domain, the 'empirical', is a subset of the 'actual' and relates to the human perception and experiences of what actually happens – the day-to-day experience [17]. This phenomenon contains information that becomes known to human beings through direct and indirect experiences associated with the 'actual' domain. Through research endeavours, researchers can theorise about the 'real' by exploring the experiences and perceptions of the actors of the phenomenon [16]. The relationship between these three domains is illustrated in **Figure 2.1.** The 'real' is the greater domain encompassing the 'actual', which in turn, includes the 'empirical' [18].

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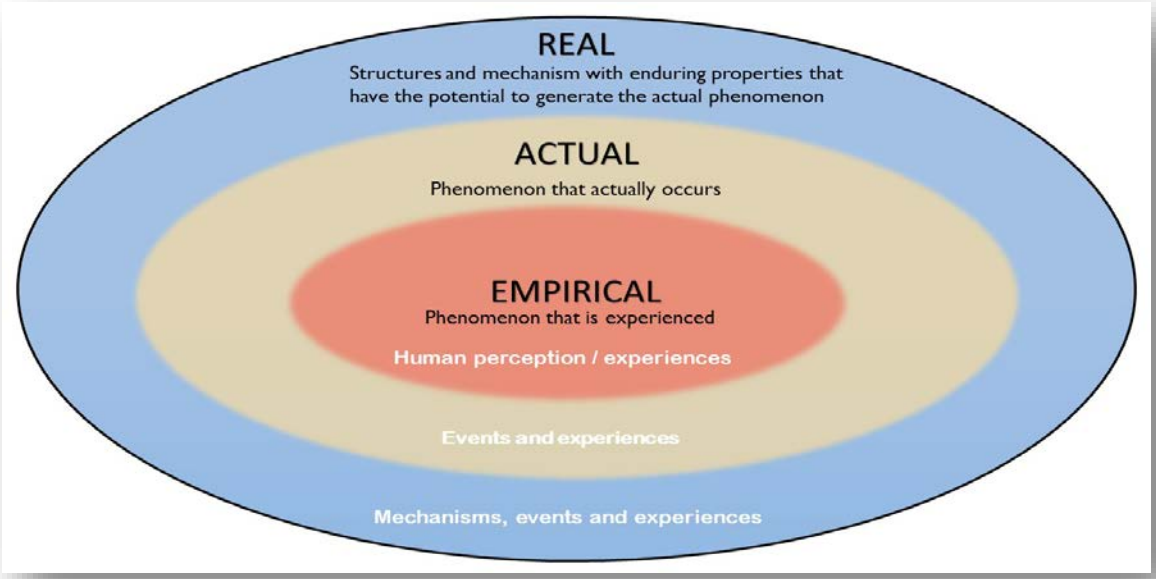

Figure 2.1: The stratified ontology of critical realism

Another important ontological assumption of critical realism is that reality is composed of different levels (multi-layered reality). By this, it is assumed that these different levels of reality exist in a hierarchy where lower levels create conditions for higher levels and vice versa. According to Eastwood et al. [17:2], "Each stratum is separate and distinct and may interact with the layer above or below to produce new mechanisms, objects and events." The authors suggest that such level-specific mechanisms constitute a level, thus, each level possesses its emergent properties, which is important when analysing a social phenomenon such as the effectiveness of a programme [3]. This assumption implies that complex social phenomena, such as seeking and using health programmes cannot only be explained regarding mechanisms or processes working at a particular level, be it an individual, health system or community level.

The two ontological assumptions described above; reality being intransitive (existing independently of humans) and being stratified to paint a picture of a complex interaction between dynamic, are open and stratified systems (both material and non-material). Following these attributes, it is understood that particular structures give rise to certain causal powers, tendencies, or ways of acting described as "generative mechanisms" [19]. According to Bhaskar [5], theorising about what happens in the 'real' could be achieved by identifying those generative mechanisms and underlying structures that combine to produce the phenomenon of interest.

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Critical realism – Epistemological assumptions

Epistemological assumptions relate to how one acquires and develops knowledge and it also relates to how one evaluates the truths and validity of claims made during knowledge generation and how these claims could be measured against existing knowledge [9]. Critical realism assumes that there is a logical relationship between ontology, epistemology, and methods and strategies [11]. The epistemological assumptions of critical realism are anchored on three tenets, i.e., the recognition that reality is independent of human perceptions, a generative view of causation, and a focus on explanations and methodological eclecticism [15].

In critical realism, an understanding of the world could be achieved through the analysis of the experiences observed and interpreted by an actor along with other data types. According to Wynn and Williams [9: 793], "The resulting knowledge claims are focused on specifying and describing those elements of reality which must exist in order for the events and the experiences under examination to have occurred." This suggests that realists give importance to meaning construction and communication among human actors, as a topic of investigation and as an essential medium of research and theorising [20].

Epistemologically, realism holds that "all enquiry and observation are shaped and filtered through the human brain and that there is, therefore, no such thing as 'final' truth or knowledge" [14: 4]. The researcher is value-aware and needs to triangulate any perceptions and opinions collected [2]. This is because the notion of triangulation assumes a single reality and that the use of different sources is meant to create a "family of answers" that would foster the understanding of the complexities of the reality. The implication of this is that it is possible to work towards a better understanding of the reality by obtaining information from various sources, but we can never reach final certainty or provide definitive 'proof'[14].

Because critical realism asserts that there are real underlying causes, structures, processes, and entities giving rise to the observations we make of the world, epistemologically, it is appropriate to form theories and hypotheses about the underlying causes to arrive at explanations of what we observe. This entails employing scientific methodologies to generate these theories. A prominent realist approach to methodology is the causal mechanisms theory. A good approach to a scientific explanation of an outcome or pattern is to discover what real mechanisms typically bring about events and outcomes caused by specific happenings and powers. This could be achieved by postulating hypothetical mechanism(s) or structure(s) that, if they existed, would generate the observed phenomenon – *retroduction*.

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Thus a causal explanation is generated with the realism philosophy which should include generative mechanism and outcome tendencies [10]. Pawson and Tilley [21] suggest that this explanation requires a contextual notion, as the circumstances within which the casual powers operate are important. Smith [10] added that such an explanation should include the structure that underlies the generative mechanisms, the outcome that these mechanisms tend to produce, and finally, the elements of context that trigger or inhibit the firing of these generative mechanisms. Therefore, causality philosophy offered by realism is useful in formulating a contextualised hypothesis that could be tested and refined [10].

Critical realism – Methodological principles (scientific realism)

Scientific research under critical realism strives to develop explanations for the way things work and how they are capable of doing so [9]. Critical realism requires a deep understanding of the social situation, which entails going beyond the observable and investigating the mechanisms underneath the events. Causality is considered generative, in the sense that actors and society have potential mechanisms of causation by their very nature [6]. This latent potential is actualised when the right context factors trigger these generative mechanisms. Generative mechanisms come about as the result of the interplay between actors and dynamic open systems, in which structures with a certain causal power emerge, and result in actual events. The causal mechanisms theory also suggests a different approach to data gathering and a different mode of reasoning from quantitative and comparative methods.

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Claims are made in critical realism by providing explanations of a set of events by mining the hypothesised existence of mechanisms which if identified and enacted could have produced the outcome. In other words, what must reality be like for an event of interest to occur? Therefore, the critical realist, while trying to explicate a phenomenon, identifies the mechanism that emerges from the components of a physical and social structure to produce the phenomenon. These mechanisms, nevertheless, are often neither observable directly nor measurable. Sometimes it is difficult to identify mechanisms because in most cases, there are multiple possible sets of mechanisms, which may have produced the outcome of interest. The possibility of multiple possible mechanisms that offer explanations justifies the need for evaluating and comparing alternative explanations. These ontological and epistemological tenets have implications for research (**Table 2.1**).

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Table 2.1: Methodological principles of critical realism (adapted from Wynn and Williams) [9]

Critical realist principle	Ontological and epistemological basis	Evaluation criteria
Explication of event Identify and abstract the events being studied, usually from experiences, as a foundation for understanding what really happened in the underlying phenomena.	- Stratified ontology - Mediated knowledge	- Thick description of case "story" including actions and outcomes - An abstracted sequence of events (including the experiences of participants and observers)
Explication of structure and context Identify components of the social and physical structure, contextual environment, along with relationships among them. (Critically re-described from actor's viewpoint into theoretical perspective.)	- Stratified ontology - Open-systems perspective - Mediated knowledge - Unobservability of mechanisms	- Description of the structural entities, constituent parts, and contextual conditions existing in the case - Identification of the relationships among the entities - Explication of changes to the structure - Description of the resulting emergent properties
Retroduction Identify and elaborate on powers/tendencies of structure that may have interacted to generate explicated events	- Emergence - Focus on explanation - Explanation via mechanisms - Multiple explanations - Unobservability of mechanisms	- Identification of a set of plausible candidate causal mechanisms - Logical and analytical support for the existence of proposed mechanisms linking the structure to events
Empirical corroboration Ensure that proposed mechanisms have causal power and that they have better explanatory power than alternatives.	- Independent reality - Stratified ontology - Unobservability of mechanisms - Multiple explanations	- Analytical validation of proposed mechanism based on case data - Assessment of explanatory power of each mechanism relative to alternative explanations - Selection of the mechanism(s) that offers the best explanation
Triangulation & multi-methods Employ multiple approaches to support causal analysis based on a variety of data types and sources, analytical methods, investigators, and theories.	- Independent reality - Mediated knowledge - Unobservability of mechanisms - Multiple explanations	- Multiple theoretical perspectives - Multiple analytical and methodological techniques - Variety of data sources and types - Multiple investigators

While critical realism does not ascribe to a particular research methodology, the case study approach has been identified as a favourable approach for developing and testing explanatory theories.

Implications for realist evaluation

In their seminal work entitled, "Realistic Evaluation" [23] and realist reviews [24]. Important tenets that realist evaluation draws from realism are that (1) realism accepts that both material and social worlds are 'real' in the sense that they have real effects; (2) Social systems are open; (3) Understanding causation is possible through identifying and hypothesising generative mechanisms; (4) Realism offers a specific way of thinking about context; (5) No final truth

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exists. – We base our interpretation of reality on the empirical, which is only based on what is observable to humans.

- Critical realism asserts that the material and social worlds are real and have real effects. Regarding programme evaluation, this implies that programmes are also real and can have real effects – positive or negative [14]. This also implies that social institutions and concepts such as gender, culture and religion will have real effects on whether and how programmes work.
- The critical realist conception of open and closed systems is about "(ir)regularities in the flux of events and states of affairs" [25]. Pawson and Tilley [21] suggested that because programmes cannot be fully isolated or kept constant owing to various unanticipated events such as political change, personnel moves, physical and technological shifts, inter- and intra-programme interactions, and practitioner learning, they are considered open social systems. Regarding realist programme evaluation, the open nature of programmes always impacts on the delivery of a programme, and this means that they are never quite implemented in the same way [21].
- Realist evaluation drawn from critical realism is that causality is generative in nature, which relates to the understanding that the things we observe or experience are caused by deeper usually unobservable processes – mechanism. While programmes are understood to provide resources, opportunity and/or constraint to programme users, "it is the interaction between what the programme offers (structure) and the reasoning of its intended users (agency) that causes the observed outcome" [14].
- While structures and agency both have the potential to generate an outcome, their ability to do so (or not) is triggered by various contextual elements. Realism utilises contextual thinking to address the issues of 'for whom' and 'in what circumstances' a programme will work. Therefore, it is assumed, while conducting a realist evaluation that programmes will be active only under particular circumstances, i.e., in different contexts. Therefore, identifying those contextual conditions, which favour or inhibit a programme from reaching its anticipated outcomes, is crucial to understanding a programme's theory.
- Critical realism assumes that there is a world and entities out there that we cannot fully perceive or experience. Therefore, knowledge acquisition cannot be reduced to understanding the experiences and perceptions of how humans understand phenomena. The fact that we do not have pure, unmediated access to the real world but that our

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knowledge must always be locally and historically relative, means that no 'final' truth or knowledge is to be found [14]. Therefore, while evaluating programmes in the realist paradigm, our beliefs, theories and concepts about programme implementation that constitute reality should constantly be revised and interpreted to be ontologically real [9].

In summary, realist evaluation is rooted in realism, a philosophical paradigm that favours the elicitation, testing and validation of theories based on mechanism-centred causality principles - *retroduction*. Realism holds that the role of the mechanism(s) is pertinent because they generate outcomes, and that context matters because it has the potential to change the process by which an intervention produces an outcome [26]. While conducting a realist evaluation, both mechanisms and contextual elements are systematically mined and configured along with the intervention modalities, the relevant actors and outcomes of the intervention implementation process to conceptualise a generative theory that could explain how, why, for whom and under what context the intervention works (or not).

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CHAPTER THREE

Paper 1

A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health care facilities in the metropolitan area of Western Cape Province, South Africa: a study protocol. BMJ Open. 2016;6:e009977. doi: 10.1136/bmjopen-2015009977

Abstract

Introduction: Sub-optimal retention in care and poor treatment adherence are key challenges to antiretroviral therapy (ART) in Sub-Saharan Africa. Community-based approaches to HIV service delivery are recommended to improve patient retention in care and ART adherence. The implementation of adherence clubs in the Western Cape province of South Africa was with variable success in terms of implementation and outcomes. The need for operational guidelines for its implementation has been identified. Therefore, understanding the contexts and mechanisms for successful implementation of adherence clubs is crucial to inform the rollout to the rest of South Africa. The protocol outlines an evaluation of adherence club intervention in selected primary health care facilities in the metropolitan area of the Western Cape Province, using the realist approach.

Methods and analysis: In the first phase, an exploratory study design will be followed. Document review and key informant interviews will be used to elicit the programme theory. In phase two, a multiple case study design will be used to describe the adherence clubs in five contrastive sites. Semi-structured interviews will be conducted with purposively selected programme implementers and members of the clubs to assess the context and mechanisms of the adherence clubs. For the programme's primary outcomes, a longitudinal retrospective cohort analysis will be conducted using routine patient data. Data analysis will involve classifying emerging themes using the context-mechanism-outcome (CMO) configuration; and refining the primary CMO configurations to conjectured CMO configurations. Finally, we will compare the conjectured CMO configurations from the cases to the initial programme theory. The final CMOs obtained will be translated into middle range theories.

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Ethics and Dissemination: The study will be conducted according to the principles of the declaration of Helsinki (1964). Ethics clearance was obtained from the University of the Western Cape. Dissemination will be done through publications and curation.

Editorial Request

Strength and Weaknesses of the study

1. Antiretroviral treatment adherence clubs, aiming at engaging patients and staff in a long-term relationship to improve adherence to treatment, have proven to be effective in pilot settings in South Africa.
2. Realist evaluation is a methodological approach that allows exploring how and in which conditions such adherence clubs can be scaled up.
3. This paper presents the research protocol of a realist research programme that will assess the implementation and effects of facility-based adherence clubs in the Metro area of the Western Cape Province (South Africa).
4. Through empirical research in five settings, we will develop a programme theory that explains how adherence clubs lead to higher retention in care and better treatment adherence of HIV patients.
5. Applying realist evaluation can be challenging, and this study will contribute to methodological development by operationalizing methods to use the Context Mechanism Outcome configuration in the analysis of multiple cases.

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Introduction

South Africa is home to the largest number (6.8 million) of people living with HIV/AIDS (PLWHA) in the world [1]. The South African government, consequently, embarked on the fight against the AIDS pandemic through various programmes. As a result, an estimated 3.1 million (32.2%) PLWHA in South Africa have been initiated on antiretroviral therapy (ART) as of April of 2015 [2], representing the largest ART programme in the world [3]. The challenge that the South African ART programme now faces is retaining these patients in care and ensuring that they continue to adhere to their ART medication. In early 2011, the adherence club model was adopted by the Department of Health of the Western Cape Province (WCP) for phased rollout initially in the Cape Town Metro to address issues of retention in care and adherence among stable patients on ART.

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Background

Adherence - starting, managing, and maintaining a given medication regimen at prescribed times, frequencies, and conditions - is acknowledged to play a crucial role in determining the success of HIV care and treatment programmes [4,5]. Although perfect adherence is recommended for patients using ART, sustained long-term adherence to ART is seldom achieved. According to Bangsberg, with a moderate adherence to potent regimens, virological suppression is still possible [6]. Nevertheless, achieving even moderate adherence in patients on ART remains challenging. A meta-analysis of adherence studies, with adherence to ART, defined as taking 95% or more of prescribed pills, shows that in Sub-Saharan Africa, the pooled patient adherence rate is 77% [7]. Viral suppression, reduced disease progression and mortality, improve with every increase in adherence level [6]. Strong evidence suggests that poor adherence to ART leads to potential viral non-suppression, which risks the immediate health of the patient, and could contribute to drug resistance [8]. Non-adherence is now considered a significant public health challenge, as it can promote the development and transmission of drug-resistant HIV viruses [9]. In addition to viral non-suppression, low adherence to treatment has been associated with higher hospitalisation rates, productivity loss, disease progression, low CD4 count recovery rate and death [10].

While adherence is crucial to obtaining good clinical outcomes for ART patients, achieving a sustained engagement of the ART patients to the care umbrella is equally critical [11]. The World Health Organization defines sustained engagement or retention in care as “the engagement in a comprehensive package of prevention, support and care services irrespective of the particular clinic site” [12]. For patients who are on ART, retention in care ensures on-going receipt of ART, assessment of possible medication toxicities, and tracking treatment failure when it occurs in order to take the necessary action [13]. Retention in care should also include access to adequate psychosocial support and providing the secondary prevention message that can guide the patient towards adapting their lifelong condition around their lifestyle. Failure to retain ART patients often leads to medication cessation or non-adherence, and immunological failure.

It is observed that non-adherence usually occurs in patients who are not successfully linked to care and treated following diagnosis and in patients who fail to incorporate their treatment into their daily lives [14]. A number of complex and sometimes interrelated factors are responsible for this. These factors are categorised as individual factors, socio-economic, medication-

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related, and health care system (structural) factors [15]. Individual factors include forgetfulness, substance abuse, adverse social events, perceived social support, health literacy, self-efficacy and mental health [16,17]. Socio-economic factors affecting adherence include poverty, food insecurity and stigma [18,19]. Medication-related barriers to adherence include side effects and dosing [20]. With regard to the health system, it is argued that the mainstream (average) clinic often presents challenging treatment circumstances ranging from transportation issues, staff shortages, long waiting times, negative experiences with clinic staff and medication stock outs [15,21,22]. These factors constitute barriers to returning to the healthcare facility for scheduled follow-up consultations and maintaining long-term ART adherence among patients.

Various strategies have been adopted to overcome some of the challenges sited above. While decentralising ART treatment and care services, and shifting aspects of the ART care programme to nurses and other non-clinical staff, including the patients themselves, seemed to work provisionally [23–25], it is anticipated by Luque-Fenandez and colleagues that these strategies are reaching their limits in the face of the foreseeable increase in the number of patients that are being initiated on ART [26]. To provide a more sustainable solution, new models of care for ensuring total adherence of patients to lifelong ART across the Sub-Saharan region have been developed. Prominent among these care models are group-based care models, which either operate by recruiting patients into groups, at the clinic (facility-based) or detached from it (out-of-clinic) [27]. The primary objective of these care models is to improve access to ART medication, offer psychological and emotional support to patients, which encourages long-term adherence to medication and retention in care [28].

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Group-based ART treatment care models seek to improve access to medication and retention in care rates, and they strive to achieve this through service decentralisation and task shifting, providing safe and simple ART regimens, and eliminating regulatory or logistical constraints on ART delivery. Therefore, they promise to provide long-term retention in care for ART patients by providing quick and patient-friendly access to treatment and care while decreasing the burden on over-stretched health care facilities [29]. While the fundamental principles of group-based models of care models are the same, they need to be adapted to their context to address the main issues plaguing different communities [28]. A review of literature on the effectiveness of these group-based ART services indicate that most of them contribute to reduced burdens for patients and the health system, increased retention in care and lower service provider costs [30–33].

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The adherence club intervention

Patients entering the treatment cascade, whether as an early, a delayed or a returning patient may need support to understand the ramifications of lifelong adherence to medication that can have varying side effects [27]. Once their health is stabilised and their immune status is improved, most patients no longer require intensive clinical care and frequent visits to a health facility. These are described as 'stable' patients [34]. The key elements of care packages for these stable patients are two-fold: clinical and operational. The clinical priorities of 'stable' patients include sexual and reproductive health, immunisation, nutritional support and TB screening, while their operational priorities include retention interventions, viral load monitoring, adherence support, and provision of ART [35,36]. The adherence club intervention operates by providing the operational services to the stable patients on the HIV treatment and care continuum (see **figure 1** below).

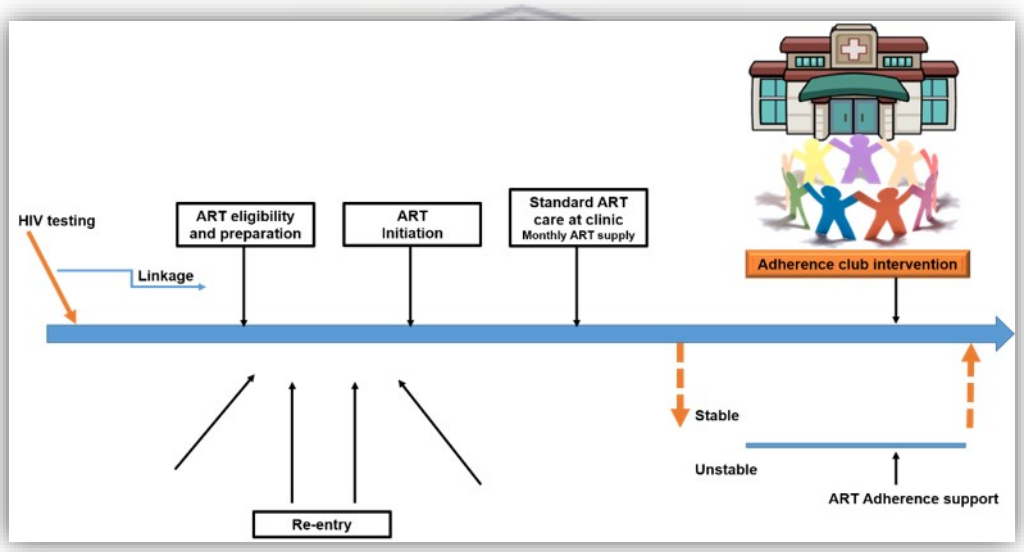

Figure 1: The intervention point of the adherence club intervention

The adherence club intervention could be thus viewed as an ancillary intervention to the standard clinic HIV treatment and care process as it focuses primarily on patients identified as 'stable'. Patients recruited into the adherence club must be 18 years or more, on the same ART regimen for at least 12 months with the two most recent consecutive viral loads of the patient undetectable, and has no medical condition requiring regular clinical consultations more than once a year. These patients are also expected to have a CD4 count value of 200 cells/cubic millimetres or more. When these conditions are met by the patient, programmatically, the

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patient is described as 'stable' and the consulting clinician takes the decision to recruit the patient into the next available adherence club.

An adherence club is limited to 25–30 patients, facilitated by a lay counsellor or community health worker and overseen by a professional nurse (club nurse) [32]. The club facilitator provides a quick clinical assessment of the patients, performs pill checks, provides emotional and psychosocial support, and where necessary, refers the patients to a clinician [27]. Adherence clubs have a number of specific attributes. It enables PLWHA, to access a continued ART supply. It also creates opportunity for establishing collaborations among the group members leading to peer support [37]. The adherence club also empowers PLWHA through self-management and provides community network for tracing patients not attending their club. It also ensures continued access to clinical care and support through a suitable referral mechanism, which leads to better care and, thus, improves retention in care and viral outcomes for the patients.

Various variations have been modified with the goal of taking the care of the patients closer to the homes of PLWHA, to improve service decentralisation. Adherence clubs, in the health systems' perspective have been shown to be beneficial in producing better retention in care than the standard care [26], reduce the burden that stable patients represent for the health facility [27], diminish the waiting time of patients in the clinic, and ease the workload of the health workers. Finally, it saves the health system and patients' invaluable time and money and improves the rate of identifying defaulters [37].

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Comparative studies between patients using the adherence clubs and those in the main clinic [26,38] showed better retention in care of the patients in the adherence clubs compared to those who remained in the mainstream clinic care. These studies demonstrated the potential effectiveness of the adherence clubs from a quantitative point of view. To enable how to scale-up the adherence clubs, however, a proper understanding of how it works, and why (mechanism) and under what circumstances (context) is crucial.

Aim of study

The current study aims to evaluate the implementation and effects of facility-based adherence clubs in the Metro area of the WCP using the realist evaluation approach. The aim is to develop an empirically tested middle range theory that explains the relationships between the dynamics

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triggered by the adherence club (mechanisms), within different clinical settings (context), and the observed outcomes (overall retention in care and individual adherence to antiretroviral treatment). More specifically, the study objectives are:

- To describe the adherence club intervention in three sites
- To assess the effectiveness (**outcomes**) of the adherence clubs in retaining patients in care and promoting individual ART adherence across five primary health care centres.
- To identify **contextual** factors that enable or prevent mechanisms to influence the outcomes of the adherence club within selected primary health care facilities
- To identify the **mechanisms** through which the adherence clubs achieve the observed outcomes.

Significance of the study

Evaluating the adherence club using the realist evaluation approach will identify the contextual factors, and the mechanisms underlying actors' practices required to generate the desired outcomes. This theoretical understanding is critical for understanding not only whether the adherence club intervention has been successful in a particular context, but also whether and under what context conditions it can be scaled up or replicated.

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Research Setting

The Cape Metropole (one of the six sub-districts of the Western Cape Province) is divided into four substructures and each substructure is dichotomised into sub-districts [39,40]. Each of the sub-districts has a comparative population. See **figure 2** below for the various sub-districts of the Cape Metropole district.

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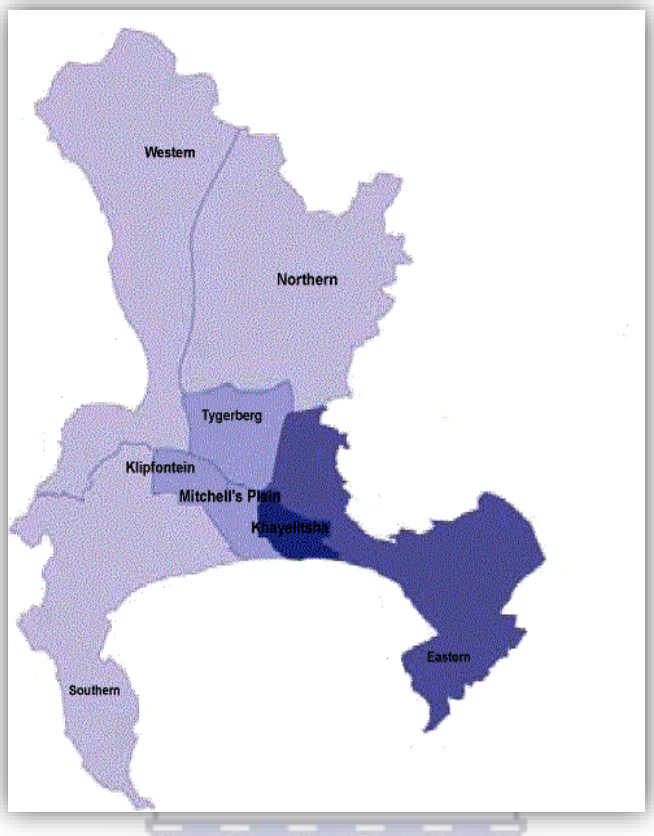

Figure 2: Health sub-districts of the Cape Metropole District [41]

Based on the HIV prevalence and ART uptake in the City of Cape Town as demonstrated on Table 1 below, we purposively selected Khayelitsha, Eastern, Mitchell's Plan, Klipfontein and the Tygerberg sub-districts to be included in the study.

Table 1: HIV prevalence and ART uptake in the City of Cape Town [40]

Sub-district	Estimated HIV+ Population TOTAL	Estimated HIV+ Population CD4<350	ART service points (Oct 2009)	On ART (Dec 2010)
Southern	18 654	9 327	8	5 298
Western	26 201	13 100	12	10 576
Northern	26 164	13 082	4	4 949
Tygerberg	18 532	9 266	4	6 005
Klipfontein	33 423	16 712	4	6 403
Mitchells Plain	20 557	10 278	4	9 574
Khayelitsha	44 772	22 386	11	17 659
Eastern	30 337	15 168	5	7 679
City of Cape Town	218 640	109 319	52	68 143

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Within the various sub-districts, we purposively selected five primary health care facilities. These five facilities are found within four of the eight health sub-structures of the Metro health district in the WCP. These primary health facilities include the Mitchell's Plain CHC and Heideveld CDC from the Mitchell's Plain Health sub-district; the Crossroads CHC from the Klipfontein health district; the Vanguard CHC from the Western district and the Ubuntu clinic from the Khayelitsha Health District. The Ubuntu clinic being the pilot facility for the adherence club intervention will allow examining how the facility has transitioned from the pilot phase into an implementation phase. It will give us an idea on how adherence clubs work during the pilot phase compared with the implementation phase. The other three facilities Mitchell's Plain CHC, Crossroads CDC and Heideveld CHC represent the typical facility in which the adherence club intervention was initially implemented. We wish to explore what other elements could be crucial in determining the success or failure of the adherence club intervention in these facilities. Finally, the Vanguard clinic that implemented the adherence club intervention in September 2014 was selected to allow us to understand the implementation process. Table 2 describes the location of the selected facilities within the various sub-structures and sub-districts and their characteristics.

Table 2: Study facilities within the different health substructures and sub-districts and their characteristics

Health Substructure	Southern-Western Substructure	Klipfontein-Mitchell's Plain substructure			Southern-Western Substructure
Health Sub-districts	Khayelitsha sub-district	Mitchell's Plain sub-district		Klipfontein sub-district	Southern sub-district
Facilities	Ubuntu Clinic	Crossroads CDC	Mitchell's Plain CHC	Heideveld CDC	Vanguard Clinic
Characteristics					
Adult patients on ARVs in August 2014	+/-8500	5267	2561	1486	1501
Number of ACs	231	42	39	20	2
Starting date of AC	2007	2012	2012	2012	2014
Number of patients in adherence club care	5900	1401	1309	480	35
Number of ART staff	30	15	11	08	09
Implementation context	Experimental	rollout	rollout	rollout	rollout
Predominant catchment population	Black	Black	Coloured	Coloured	Black

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Methodology: The methodological approach

This study will be guided by the realist evaluation inquiry. Realist evaluation belongs to the theory driven evaluation family [42,43]. Realist evaluation is an approach grounded in realism [44], a school of philosophy that asserts that both the material and the social worlds are 'real' and can have real effects, and that it is possible to work towards a closer understanding of what causes change.

Using the realist evaluation approach, we aim at collating empirical evidence from various sources to develop and test programme theories [45]. The realist approach assumes that programmes are "theories incarnate". That is, whenever a programme is implemented, it is testing a theory about what 'might cause a change', even though that theory may not be explicit. One of the tasks of a realist inquiry is, therefore, to make the theories of the actors within a programme explicit in the form of hypotheses or programme theories about how, and for whom, the programmes might 'work' (or not). Therefore, the product of each case of the study is thus a refined programme theory, which can be compared and reformulated as a middle range theory, explaining how the programme works (or not), for whom and in what b me impacts or the processes of programme implementation, but also about the specific aspects of programme context that might affect programme outcomes, and about the specific mechanisms that might be creating change. The unique nature of realist evaluation lies in its conceptualisation of the central components (context, mechanism and outcome) of a complex intervention.

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Realist evaluation uses the term 'outcome' to include short, medium and long-term changes, intended and unintended, resulting from an intervention. For the PLWHA, this change could be a change in the experiences of the patients in the programme and a change in their retention in care and adherence behaviour. For the health system, such changes could include changes in the workload of the health workers. Context relates to the circumstances in which the programme is implemented. In realist evaluation, context is considered as the features of the organisation, staffing, history, culture, beliefs, etc. that are necessary for the programme to 'fire' the mechanism or that prevent intended mechanisms from firing [47]. The context of the PLWHA is key to understanding the development of the 'generative mechanisms' and thus the programme theory behind the adherence club programme. With respect to the context, the investigators will look into those context conditions under which the adherence club could potentially achieve greater retention in care rates. Although mechanisms are said to exist independently of the context, a mechanism cannot fire in isolation. Only when mechanisms are

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activated in a particular context do they exercise their causal power [45]. What matters about context in realist evaluation is indeed that it influences the mechanisms to operate. In the realist evaluation perspective, programmes offer resources, opportunities, or constraints to the actors [48]. The observed outcomes come about because the required resources, opportunities and/or constraints influence the reasoning of the actors (mechanism) within a particular context. In the light of the study, the investigators will explore the various social or psychological drivers that cause the reasoning of both the programme implementers and the users, considering the various resources and opportunities that the adherence club intervention provides.

The relationship between the intervention, actors, context, mechanism and outcome is expressed as ICAMO configuration [49], which is a proposition that can be tested empirically to obtain a refined theory, which explains why an intervention works for some and not for others [50].

Methods

This study is designed around the realist evaluation cycle as illustrated in **figure 3** below. Realist evaluation is method neutral, so we have identified the suitable methods that will be applied in the evaluation process. Our data collection and analysis methods are chosen because they allow to describe outcome patterns and the context and identify the mechanisms embedded in the adherence club intervention. They will allow us to uncover the experiences, interpretations and responses of the programme implementers and users involved [51]. These methods are described in the section below.

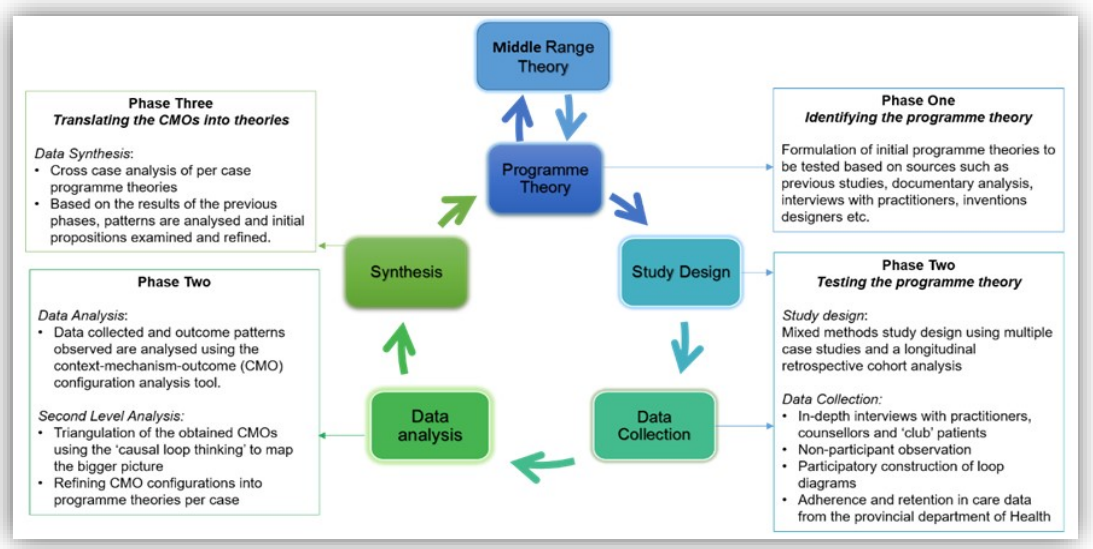

Figure 3: the realist evaluation process and the proposed phases of the study. [52]

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Phase One - Eliciting the programme theory

The first phase of the realist evaluation involves developing the initial programme theory. A programme theory is defined as "a set of explicit or implicit assumptions by stakeholders about what action is required to solve a social, educational or health problem and why the problem will respond to this action" [53]. As already mentioned, a programme theory represents a hypothesis that can be tested and further refined [54]. Therefore, realist evaluation starts and ends with a theory.

An exploratory qualitative study design will be used in this phase. This will offer us the opportunity to explore and describe the adherence club as conceived by the programmes designers and managers. Three data collection methods will be used in this phase: a document review of relevant documents on the adherence club; key informant interviews and a review of the evidence on the effectiveness of the adherence clubs.

Through a literature search of various databases and by contacting the Provincial Department of Health, documents will be identified for possible inclusion in the document review. The key informant interviews will be conducted with Médecins Sans Frontières representatives on the adherence club programme, Treatment Action Campaign members, the various HIV/AIDS/ STI and TB (HAST) unit medical officers (MOs) and adherence club managers; representing the facilities of interest will be included in the study. With regard to the review of available data assessing the effects of the adherence club programme, the investigators are aware of two peer review articles published on studies that evaluate the adherence club's effectiveness [26, 38].

The first set of data will be collected by the investigators through a document review process, based on their knowledge on the topic and the relevance of the document to the research aim. Documents such as the adherence club toolkit, reviews on the adherence club, policy documents, and implementation guidelines of the adherence club will be consulted. The second data set will be obtained through semi-structured interviews conducted by the investigators using interview guides. The interviews will focus on questions related to the design of the adherence clubs, the implementation strategies, why they think the adherence club will resolve issues around adherence and retention in care and the expected outcomes of the intervention. The interview will also seek answers to questions around the primary objective of the adherence club, the resources and dynamics around the interventions. A further review of empirical studies conducted to evaluate the effectiveness of the adherence club will also be performed.

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This second review will focus on studies that have been conducted to evaluate the effectiveness of the adherence club with regard to the outcomes of retention in care and adherence to medication.

The information from these three sources will be used to formulate the testable programme theories on the adherence club initiative using the Intervention-context-actor-mechanisms-outcomes (ICAMO) pattern configuration [55]. The resulting initial programme theory will be 'tested' in phase two.

Phase Two – Testing the programme theory

Study design

A multiple case study design will be used, in which each health care facility is considered a case. The case study design was selected because, first, it is methodologically complementary to realistic evaluation. Secondly, it allows for using multiple methods of data collection, and third, it recognises the importance of context. Within this study design, the convergent parallel mixed method approach of a retrospective cohort analysis and an explanatory qualitative design will be applied to the process of obtaining and analysing the data. While the retrospective cohort analysis will provide an insight into the outcomes (based on routine data captured in the club registers) of the patients receiving care in the adherence club model of care, the qualitative explanatory design will provide the evidence to strengthen every link in the implementation chain. The mixed-method research design will allow for quantitative indicators of the outcomes to be identified and the qualitative exploration of the context and mechanisms that contribute to the observed outcomes [43]. The quantitative data will allow the investigators to quantify the outcomes and some elements of the CMO configuration. The qualitative study will allow emergent outcomes and processes to be captured [56].

The selection of the study participants will take place at the facility-level. During the data collection period at each facility, the goal will be to include all the categories of staff directly involved with running (doctors, nurses, head of the adherence clubs, adherence counsellors) using (patients) the adherence club programme. At least one programme implementer per facility will be included, and at least five patient interviews will be conducted. The appropriate number of interviews will be determined by thematic saturation.

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The data collection process will be completed over an estimated period of 10-15 days per facility. The investigators could revisit any facility to explore issues that would need further exploration through either observation or interviews. The following data collection methods will be applied:

- Observation of the activities related to the adherence clubs. The observations and discussions will be recorded in field notes and / or audio recorded as appropriate.
- Semi-structured interviews with the adherence club implementers (clinicians and lay counsellors of their perspectives of the adherence club intervention and patient interviews about their experiences. Interview topic guides will be informed by the realist framework to elicit information on the following key elements: intervention, actors, outcomes, mechanism and context.
- A reflective journal will be kept at the end of every day to capture issues such as the reactions of the interviewees, and other interesting observations that cannot be captured by the audiotapes.
- Process tracing [57] of the operations of the causal mechanisms in each case will be done through participatory construction of flow loop diagrams during observations.

The data obtained from the above sources will be prepared for analysis accordingly. Field notes will be immediately developed after each interview to describe the context of the interview, the dynamic between interviewer and interviewee(s) and any other impressions of the investigators. The interview recordings will be transcribed professionally and then checked by the interviewer(s).

Data from the provincial Department of Health on the retention in care and adherence outcomes of the patients receiving care in adherence clubs at the selected facilities for the period 2012 – 2015 will be obtained and prepared for analysis. The focus at this stage will be obtaining data to describe the defaulting and retention in care behaviours of patients from the adherence club (referred back to the mainstream clinic, death or lost to follow-up - unknown outcomes). Data on the time to first viral rebound (<400 copies/ml) will also be collected based on the clinical attendance records.

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Data analysis

The data analysis is divided into three steps: thematic data analysis, identifying the CMO configurations and refining the programme theory.

Step 1*: Thematic data analysis*

The overall aim of the first-level analysis is to develop themes for classification of data into 'intervention', 'actor', 'context', mechanism' and 'outcomes'. The qualitative data collected from the multiple case study will be analysed using the 'thematic content analysis' technique for emerging themes as described by Miles and Huberman (1994).[58] A deductive analytical approach will be employed, which is suitable if the general aim is to test a previous theory in a different situation or to compare categories at different periods [59]. This process will be managed with the use of Atlas.ti version 7 [60]. A sample of the coding will be checked by the study supervisors to ensure that the mode of inquiry is as balanced as possible and appropriate. The analysis process will entail coding the interviews into themes in terms of intervention, actors, context, mechanisms and outcomes [61], with the aim of identifying the CMO configurations in the next step. The initial programme theory will provide the framework categories (prototype) and analysis will be focused on understanding the ways in which the proposed mechanisms are generated or not generated in practice, identifying alternative mechanisms and explanations. The qualitative data could also identify emergent outcomes and processes in the different contexts. Throughout the coding process, memos will record emerging conceptual links and other observations about the data.

Further information on the outcome of the adherence club programme as an intervention to improve retention in care and adherence will be obtained by conducting a survival analysis on adherence club data obtained from the provincial Department of Health. Kaplan-Meier methods will be used to describe the adherence and retention in care rates of patients in the adherence clubs.

Step 2*: Identifying CMO configurations*

The second-level analysis will start with seeking patterns that will contribute to identifying conjectured CMO configurations [62,63]. Configuration analysis will be used, based on the intervention-context-actor-mechanism-outcome (CMO) typology that was developed by Pawson and Tilley [42]. The second level analysis will be done by grouping the specific

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outcome, context and mechanism codes to form intermediate-level and high-level codes (conjectured CMO configurations). The context will be analysed in its capacity to enable the conjectured mechanisms to act, or not. This process is informed by the idea that realist evaluation seeks to uncover the underlying generative mechanisms and the context in which this happens to give rise to the observed outcomes [48].

Secondly, the conjectured CMO configurations will be 'tested' by confronting them with the data of each case (facility) to check their explanatory power. This will be achieved by representing the data in a tabular form for each higher-level outcome under consideration. The patterns (CMO matrices) will focus on what exactly in the programme creates the outcomes, and under what conditions. This is known as in-case analysis.

Step 3*: Refining CMO configurations into programme theory*

The CMO configurations will be refined in a process in which the CMO configurations obtained in step 2 across the cases are compared and their explanatory power across the cases is examined (cross-case analysis) [63]. This step involves putting the positive and negative cases in two separate categories. For each active mechanism identified as being associated with a positive outcome, other cases with a positive outcome will examined, looking for additional elements. In a similar manner, CMOs associated with 'failed outcomes' will be grouped together. To ensure the validity of the two final categories of CMO configurations obtained, the investigators will refer back to the detailed case studies and original transcripts for consistency. The final CMO configurations will be verified by employing 'causal loop thinking' to map the bigger picture of how the different components interact within the 'system' as a whole in order to influence outcomes in terms of retention in care and adherence within the adherence clubs.

Phase Three – Translating the refined programme theories into MRTs

In this phase, the CMO configurations will be compared with the initial programme theory. We will review and compare the results of the individual case studies to see how the initial programme theory can or needs to be modified. The process of moving from the specifics of individual cases to a theory that is more abstract is known as analytical generalisation and it is outlined in **Figure 4** below.

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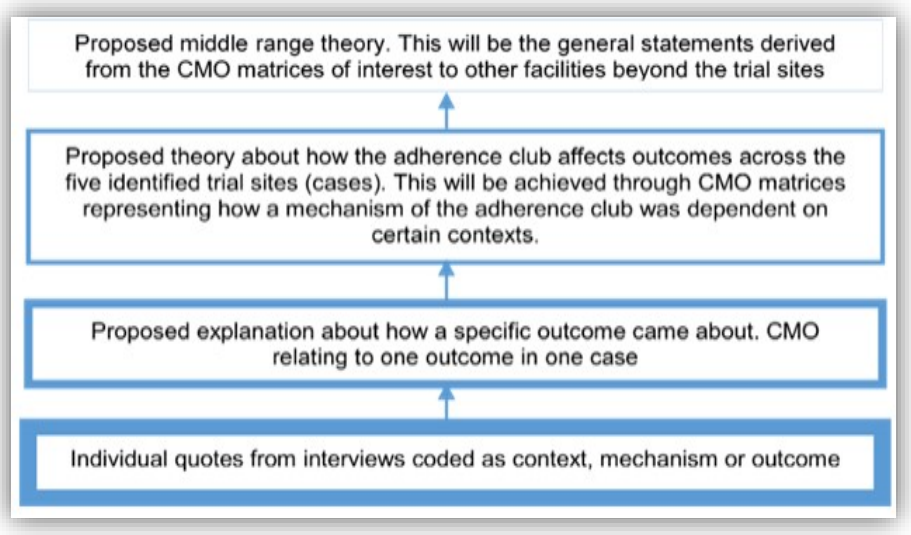

Figure 4: Analytical generalization [63]

Quality control

Prolonged engagement and persistent observation will be carried out to ensure that the investigators are familiarised with the content and context. Triangulation - using more than one method of data collection and using of a wide range of informants and data verification through peer review- will be employed. Credibility will also be ensured by holding debriefing sessions between investigators and superiors and also performing member checks of data collected, interpretations, and theories formed.

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Ethics statement

Clearance for the study was obtained the Higher Degree's committee of the University of the Western Cape. Authorisation to conduct the study will be sought from the Department of Heath of the Western Cape Province. At the level of the facilities, permission will be obtained from the various facility managers to access the various sites and finally, consents from the various participants at the sites (doctors, nurses, counsellors and patients) and the key informants (stakeholders) will be sought.

Discussion

Programmes are intended to create change. According to Pawson and Tilley, programmes are theory incarnate [42]. In order to create change, programmes make use of this implicit theory about how this change might occur. The task of an evaluator in evaluating a programme,

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therefore, is to test and understand the programme theory [47]. This paper describes the possible use of the realist evaluation methodology for the evaluation of the adherence club intervention that was piloted in 2007 and currently implemented since 2012 in over 400 primary health care facilities by 2014 in the metro health district of the Western Cape Province.

During the pilot phase of the adherence club intervention, an evaluation of the 20 facility based adherence clubs that were established was conducted using a retrospective observational evaluation [26]. The investigators compared loss to care and viral rebound in patients receiving the intervention with patients attending routine nurse-led care from November 2007 to February 2011. The study showed that 97% of club patients remained in care compared with 85% of other patients. Another evaluation describing the implementation of community-based adherence clubs at a large, public-sector facility in peri-urban community in Cape Town, South Africa revealed that after 12 months in the adherence club, 6% of patients were lost to follow-up and fewer than 2% of patients retained experienced viral rebound [38]. These studies provide an insight into the possible effectiveness of the adherence club model, they demonstrate little on the implementation process of the adherence clubs. Therefore, they lack analytical depth and do not present causal explanations.

Arguing for more serious theorising in connection with evaluation, Chen and Rossi [64] emphasise the importance of theoretical models in evaluating implementation processes. While 'black-box' evaluation methodologies focus on methodological rigour, thus aiming at controlling the contextual factors that might intervene in a study, realist evaluation on the contrary explores the role played by the various contexts on the effectiveness of an intervention or a programme [65,66]. Realist evaluation systematically tracks outcomes and the actual intervention and explores the contexts in which mechanisms are triggered [67]. Realist evaluation, thus, elucidates the nature of the programmes, the mechanisms that are likely to operate and the contexts in which they might operate to explain how the observed outcomes where attained [42]. For the above reasons, the investigators considered the realist evaluation approach as a suitable approach to evaluate the adherence club intervention implemented in the various primary health care centres. The selection of the realist evaluation approach was supported by three arguments. First, it provides a framework by which evaluators can systematically deconstruct an intervention into its components and reconstruct it with causal webs that can lead to the observed outcome [52]. Therefore, realist evaluation can provide a sound framework by which the context and mechanisms and how they influence the outcome

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of an intervention could be studied [52]. Secondly, realist evaluation is well suited for the investigation of complex systems (complex adaptive systems) such as health centres where the implementation of the adherence club intervention takes place [68]. Thirdly, realist evaluation offers evaluators the opportunity to develop an integrated outcome and process evaluation framework, which can lead to the sound decision making to improve the impact of interventions [69].

We recognise that there are some challenges associated with the use of the realist evaluation as various authors pointed out [50,70,71]. Marchal and colleagues found that many researchers using the realist evaluation approach have experienced challenges at various stages. These include debates about the nature of 'mechanism' and the challenge of differentiating between mechanism and essential context conditions [52]. While developing this protocol, the investigators were aware of these challenges. Efforts will be made to address them accordingly.

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SECTION II

ELICITING THE INITIAL PROGRAMME THEORY

Overview

Eliciting the initial programme theory of the adherence club intervention is the first phase of the realist evaluation. The initial programme theory serves as the hypothesis to be tested with the goal to provide refinement towards obtaining a middle-range theory of how, why, for whom and under what circumstances the adherence club intervention works. We adopted an elicitation research approach – an approach that employs any number of data collection techniques to gather knowledge. Eliciting the programme theory or theories of a programme in the realist sense entails identifying and making explicit the elements of the intervention, actors, mechanisms, outcomes, and contexts using the concept of generative causality. The process of eliciting the initial programme theory of the adherence club intervention represents Phase 1 of this study indicated by the circle. Refer to Figure II-I below.

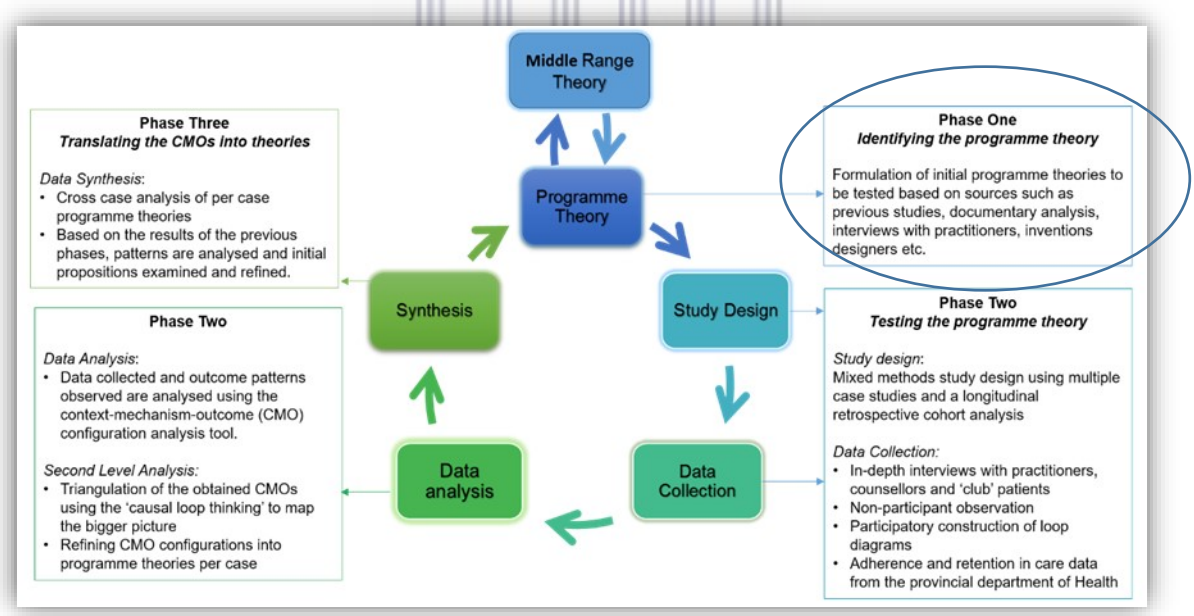

Figure II-I: Proposed evaluation cycle and processes

To elicit the initial programme theory of the adherence club intervention, we followed four steps.

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In the first step (**Chapter 4**), we conducted an exploratory qualitative study, employing two methods. A review of the design and implementation of the adherence club intervention documentation (policy documents, implementation reports, programme descriptions, etc.), and key informant interviews with purposively selected programme designers and managers. This chapter was published in PLoS One in 2016 **(Appendix 2.2)**.

In step 2 **(Chapter 5)**, we conducted a narrative synthesis of primary studies focusing on the mechanism(s) at work during the implementation of group-based interventions for adherence support among PLWHA on ART. This chapter was published in BMC Implementation Sciences in May 2017 **(Appendix 2.3)**.

In step 3 (**Chapter 6)**, we conducted a scoping review to identify generative mechanisms in studies of ART adherence that employed various social, behavioural and cognitive theories to explain or predict patients' adherence to ART. This chapter was published in BMC Public Health in March 2017 **(Appendix 2.4)**.

In step 4 **(Chapter 7)**, these elements are connected and aligned using the intervention-context-actor-mechanism-outcome heuristic configurational tool, following the generative model to obtain the programme theory (theories). This chapter is under review with BMC Medical Research Methodology.

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In the Figure II-II below, the various methods applied to obtain relevant information for the formation of the initial programme theory of the adherence club intervention is shown.

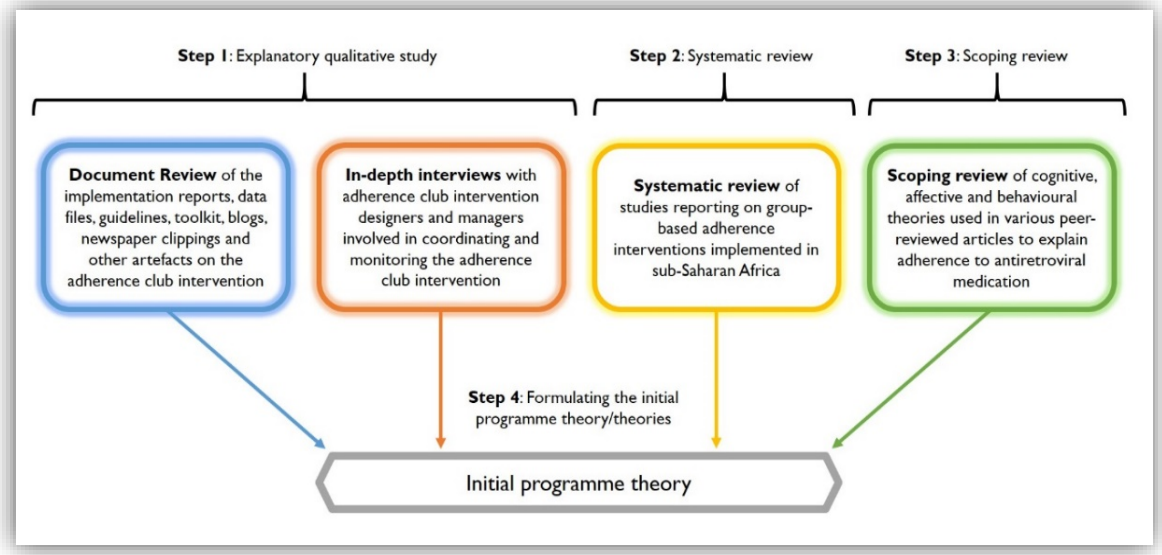

Figure II-II: Steps adopted towards formulating the initial programme theory

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CHAPTER FOUR

Paper 2

Towards Developing an Initial Programme Theory: Programme Designers and Managers Assumptions on the Antiretroviral Treatment Adherence Club Programme in Primary Health Care Facilities in the Metropolitan Area of Western Cape Province, South Africa. *PLoS ONE*. 2016; 11(8): e0161790. doi:10.1371/journal.pone.0161790

Abstract

Background: The antiretroviral adherence club intervention was rolled out in primary health care facilities in the Western Cape province of South Africa to relieve clinic congestion, and improve retention in care, and treatment adherence in the face of growing patient loads. We adopted the realist evaluation approach to evaluate what aspects of antiretroviral club intervention works, for what sections of the patient population, and under which community and health systems contexts, to inform guidelines for scaling up of the intervention. In this article, we report on a step towards the development of a programme theory - the assumptions of programme designers and health service managers with regard to how and why the adherence club intervention is expected to achieve its goals and perceptions on how it has done so (or not).

Methods: We adopted an exploratory qualitative research design. We conducted a document review of 12 documents on the design and implementation of the adherence club intervention, and key informant interviews with 12 purposively selected programme designers and managers. Thematic content analysis was used to identify themes attributed to the programme actors, context, mechanisms, and outcomes. Using the context-mechanism-outcome configurational tool, we provided an explanatory focus of how the adherence club intervention is roll-out and works guided by the realist perspective.

Results: We classified the assumptions of the adherence club designers and managers into the rollout, implementation, and utilisation of the adherence club programme, constructed around the providers, management/operational staff, and patients, respectively. Two rival theories were

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identified at the patient-perspective level. We used these perspectives to develop an initial programme theory of the adherence club intervention, which will be tested in a later phase.

Conclusion: The perspectives of the programme designers and managers provided an important step towards developing an initial programme theory, which will guide our realist evaluation of the adherence club programme in South Africa.

Keywords

Adherence, adherence club, antiretroviral therapy, realist evaluation, programme theory, retention in care, qualitative research

Background

Starting from a few isolated HIV cases in the late 1980s, South Africa had one of the fastest infection rates in the world, reaching the 7 million mark at the end of 2015 [1]. The South African Ministry of Health responded to the HIV epidemic by rolling out antiretroviral drugs at no direct financial cost to patients in 2004 and subsequently decentralising antiretroviral care and treatment to primary health care facilities nationwide [2]. Through this strategy, an estimated 3.1 million (32.2%) people living with HIV/AIDS (PLWHA) in South Africa have been initiated on antiretroviral treatment (ART) as of April 2015 [3].

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The success in enrolling patients on antiretroviral therapy (ART) has led to increasing numbers of patients in long-term care, which in turn contributes to clinic saturation [4]. As facilities became more congested, patient waiting times increased, patients received less individual attention, and the risk of staff burnout increased [5–9]. These circumstances have been associated with poor retention of patients and sub-optimal adherence to ART [10–12].

To address the issues of poor retention in care and sub-optimal adherence to medication, various community-based (group- and individual-based) approaches to improve HIV care and treatment have been implemented across sub-Saharan Africa. Group-based models of ART care and treatment work on the principle of grouping stable patients for decentralised care at lower levels (task-shifting), providing peer support among patients, reducing appointment frequency, separating the drug-delivery from clinical visits, making care simple and user-friendly, and creating a conducive environment for health education for group members [13–15]. One such

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group-based model for the treatment and care of ART patients is the "antiretroviral treatment adherence club, otherwise known as "adherence club" or "ART club", which was selected as the best practice model for retaining ART patients in care [16]. The antiretroviral adherence club intervention has been described as the adherence club or the ART club. When the intervention was originally conceived, it was called the 'Adherence Clubs' model of care, which was renamed 'ARV Chronic Clubs' model during the first phased rollout. To suit the requirements of the Western Cape Provincial Department of Health, the name of the intervention was changed from MSF's original *'Adherence Clubs'* to *`ARV Chronic Clubs'*. For consistency will refer to it here as adherence club.

The adherence club, a health system intervention, was conceived, designed, and implemented through a partnership between the Western Cape Provincial Department of Health (WC DoH), the Treatment Action Campaign (TAC), the Cape Town Municipality City Health department (CoCT DoH), Médecins Sans Frontières (MSF), and the Institute for Healthcare Improvement (IHI). MSF offered expertise, IHI provided quality improvement (QI) expertise and the WC DoH offered the political clout. A steering committee of senior managers was formed and all the groups identified above collaborated closely towards the project design and execution [4].

The adherence club intervention was designed to improve retention in care and adherence among 'stable patients' on ART in primary health care facilities in the Western Cape province [16]. Stable patients are defined as patients aged 18 years or more, on the same ART regimen for at least 12 months, with the two most recent consecutive viral loads of the patient undetectable, and having no medical condition requiring regular clinical consultations more than once a year. Between 2007 and 2011, pilot programmes of the adherence club model in selected primary health care facilities in the Western Cape Province demonstrated improved patient flow within the clinic, increased monthly enrolment of new patients, better adherence to medication, and decreased loss to follow-up rates [4,17,18].

In 2011, the adherence club intervention was officially rolled out for the first phase of implementation in selected public health care facilities within the metropolitan area of the Western Cape Province. During this phase, a sub-group comprising of 14 of the 25 large ART facilities were selected based on their size, willingness to participate, and the availability of a programme manager to support the facility during the project. By the end of 2014, adherence clubs were rolled out to an estimated 300 facilities in the province [18]. Although the routine HIV/AIDS registry indicated sustained retention in care and optimal adherence rates (viral

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suppression) amongst ART patients in adherence clubs, anecdotal reporting suggested implementation challenges in the start-up and day-to-day running of the adherence clubs in some facilities. This reflected in the variation of retention in care and adherence rates obtained from routine monitoring and evaluation data.

In consultation with the Western Cape Provincial Department of Health's HIV/AIDS, Sexually Transmitted Infections, and Tuberculosis (HAST) programme, an evaluation of the adherence club programme was undertaken. The realist evaluation approach was chosen because it holds potential to answer questions about what works, for whom, and under what contextual circumstances in a complex programme such as the adherence clubs [19].

Methodology

Theoretical framework

Realists seek to understand how and why a programme works, for whom, and in what circumstances [20]. The philosophical basis of realist evaluation is realism, which assumes that an external reality can be assessed through configurations of contexts, mechanisms and outcomes [21]. Therefore, realist evaluation, through its articulation of a configured intervention-context-actor-mechanism-outcome (ICAMO) in its findings, provides an explanatory focus which seeks to understand and interrogate "how, why and for whom a programme works?" in programme evaluation. It is generally acknowledged, therefore, that evaluation approaches such as realist evaluation can potentially open the "black box" of programme mechanism and provide greater insights on programme causality [22]. Typically, realist evaluations start with an initial programme theory (hypothesis) and end with a more refined theory.

A programme theory encompasses the assumptions and perspectives of the programme designers and implementers and is assumed to underlie a particular intervention [20]. Programme theories can be defined as the set of assumptions of programme designers (or other actors involved) that explain how they expect the intervention to achieve its objective(s) [23]. Describing the often implicit set of assumptions that steer the choice and design of a programme or intervention is useful because it allows investigators to understand what is being implemented and why. To elicit the programme theory, researchers unearth the models that the actors are implicitly using to describe and understand the intervention – what Pawson and Tilley [20] call

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‘folk theories’ – through individual interviews or group discussions [23]. Additional information may be derived from analysis of programme documents and/or policy documents. Finally, evidence and knowledge from other similar programmes may be used to build a complete programme theory. Testing the programme theory through empirical research entails identification of Context-Mechanism-Outcome (CMO) configurations, an analytic instrument, to help build the programme theory [24]. This leads to specification of the programme theory. At the end of a realist evaluation cycle, the evaluator obtains a refined programme theory, while at the end of multiple realist evaluation cycles of a particular type of intervention; the evaluator gradually builds up towards a middle range theory.

In summary, exploring what programme designers and managers think about how the adherence club intervention works means seeking an understanding of how these stakeholders understand the influence of various contextual elements, what mechanisms are in action, and how the adherence club would trigger these mechanisms in specific contextual conditions that contribute to the outcomes. The results of this exercise are then combined with the results of a systematic review to formulate the initial programme theory that will be tested in subsequent empirical studies of adherence clubs in the Western Cape Province.

The first step in conducting a realist evaluation is to elicit the programme theory that explains how the intervention is expected to work according to the programme designers and implementers [20]. An important step in eliciting the programme theory involves eliciting the assumptions and perspectives of the programme designers and managers with regard to how and why the adherence club intervention would work. In this article, we report on the assumptions of the adherence club programme designers and managers (implementers) regarding their understanding of the programme implementation process, how and why it would achieve the anticipated outcomes, and under what conditions. We also discuss how this informed our development of the initial programme theory of the adherence club intervention.

Methods

We used an exploratory qualitative study design. Two methods of data collection were adopted: a review of policy documents and other literature on the adherence club programme; and semi-structured in-depth interviews with programme designers and managers (implementers).

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A review of policy documents and other literature on adherence club programme

We obtained a variety of documents regarding the intervention (e.g. implementation reports, data files, and other written artefacts) from different sources with the purpose of collecting independently verifiable data and information about the ART adherence clubs [25]. The document review served two purposes. First, reviewing existing programme documents helped us to understand the history, evolution, and operation of the adherence club programme. Secondly, the information obtained from the documents served as pointers to the aspects that required more probing during the interview process with the key informants.

The first author searched various databases (PubMed, Google search, Google Scholar, and EBSCOhost) and relevant websites (Médecins Sans Frontières, the provincial Department of the Western Cape and Health E-news) for documents on the ART adherence club intervention. He used search terms such as “adherence club”, “ART adherence club”, “ART clubs”, “facility-based adherence club”, and “MSF innovation in ART management in South Africa”. This search process identified documents such as programme descriptions, implementation guidelines, and a toolkit on the adherence club. Policy documents for the rollout and implementation of the adherence clubs were obtained from the HAST Directorate of the Western Cape Province.

After the search process, we judged each document for relevance (are the claims made based on the relevant and appropriate information?) and utility (are the knowledge claims appropriate to our needs?) [26,27]. Twelve (12) documents were included in the document review. **Table 1** below shows the types and description of the documents included in the document review.

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Table 1: A description of the documents included in the document review

Title	Author/year	Document Type	Description
The adherence club toolkit	MSF/WCPG (2013)	Toolkit	This toolkit provides a detailed account on how to establish clubs, the ART club staff organogram, lessons learned through the Khayelitsha implementation experience and tools utilised in the ART club model.
Adherence club register	MSF/WCPG	Adherence Club register	This document is the adherence club register that the club facilitator fills in during every club meeting.
ART adherence clubs: A long-term retention strategy for clinically stable patients receiving antiretroviral therapy	Wilkinson LS (2013)	Journal Article	This article describes the adherence club programme (structure and function). It also elaborates on the implementation strategy that was employed and provides the experiences from the implementation of the adherence clubs in Khayelitsha.
Treating Millions for HIV — The Adherence Clubs of Khayelitsha	Champion EW (2015)	Journal Article	This article describes the experiences of the author as he investigated the functioning of a community-based adherence club in the home of a club member. He also reports on an interview that he had with the coordinator of the adherence club programme for MSF.
Out-of-clinic adherence club for delivery of ARVs shows better retention than standard of care	Odendal L (2012)	News Article	This article discusses the advantages of the adherence club programme over the standard clinic care with regard to retention in care and adherence. It elaborates on a comparative study that was conducted to investigate the effectiveness of the adherence club, the findings of the study and the implications.
Reaching closer to home: Progress implementing community-based and other adherence strategies supporting people on HIV treatment	SAMU & MSF (2013)	Report	This document describes the progress that has been made in implementing community-based models of ART care since the release of the report "Closer to Home" by UNAIDS and MSF in July 2012.
MSF again paves the way with ART	Bateman C (2013)	Journal Article	This article provides a general description of the adherence club, emphasising the superiority of the adherence club model of care over the standard clinic care. The article states some conditions that are necessary for the adherence club initiative to be successful. The article ends by providing a doctor's perspective on the adherence clubs.
Clubbing together for treatment	Health-e News (2012)	Health News Article	This article describes the adherence club intervention and its role in reducing patient loads (ART initiation). It discusses the effectiveness of the adherence club, and how this could be replicated in other areas.
Western Cape ART-Adherence Treatment Clubs and Preventative Therapy for New-borns	WCG (2014)	News Article	This news article was written on the inauguration of the World AIDS day on December 2014. It describes the progress that has been made on the retention in care of PLWHA since the inception of the adherence clubs. It also reports on the progress made in the implementation of the adherence club in the Western Cape Province.
Guidelines for ART clubs	Western Cape Government (2015)	Standard Operating Practice (SOP) of the adherence club	This document describes the standard operating practices of the adherence club. It starts by describing the aims and the objectives of the adherence club, outlines the requirements to establish the adherence club, the organisation and running, the pharmacy requirements for the scripting and dispensing medication to ART patients and finally, the scripting schedule of the ART medication.
Implementation scale up of the Adherence Club model of care to >30,000 stable ART patients in the Cape Metro, South Africa 2011- 2015	Wilkinson, L. et al. (2015)	Conference presentation and Journal article	This presentation focuses on the nature of the adherence club and its impact on the retention in care rates of PLWHA. It also describes the possible different types of adaptation of the programme.
Closer to home: Delivering antiretroviral treatment therapy in the community: Experiences from four countries in Southern Africa	MSF/UNAIDS (2012)	Report	This paper describes the implementation and the results of community-based methods of delivering ART in communities in four Southern African countries.

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The documents were analysed using the document analysis process described by Bowen [25]. We developed a data code manual a priori (**Table 2**), based on the realists' understanding of actors, context, mechanism and outcome. The data code manual was designed to guide the initial data analysis and extraction of information on the relevant actors, the context, the shifts in dispositions – thought process and decisions – of participants (mechanisms) during the implementation of the intervention, and the identified outcomes related to the intervention (immediate, intermediate and long-term).

Table 2: Data code manual

Category		Definition	Coding Rules
Actors		These are the individuals, groups, and institutions who play a role in the implementation and outcomes of an intervention	This was coded as the actions or actual practices of an individual, group or institution.
Context		Context refers to salient conditions that are likely to enable or constrain the activation of programme mechanisms.	Components of both the physical and the social environment that favour or disfavour the expected outcomes
Mechanisms		This refers to any underlying determinants or social behaviours generated in certain contexts	Any explanation or justification why a service or a resource was used by an actor to achieve an expected outcome, or considered as a constraint
Outcomes	Immediate outcome	Describes the immediate effect of the adherence club programme activities	Immediate outcome typically refers to changes in knowledge, skills or awareness, as these types of changes typically precede changes in behaviours or practices.
	Intermediate outcome	Intermediate outcomes refer to behavioural changes that follow the immediate knowledge and awareness changes.	Codes here define a move from direct outcomes to intermediate outcomes, identified through the indirect impact of the activity and accountability of the programme.
	Long-term outcome	Refer to change in the medium- and long-term, such as a patient's health status, and impact on community and health system	The codes here represent the further indirect impact of the activity demonstrating the lesser accountability of the programme.

Semi-structured in-depth interviews with designers and implementers

After the document review process, FCM and BVW conducted face-to-face semi-structured in-depth interviews with purposively selected key informants – persons who were involved in designing the adherence club intervention, and people working on the implementation or management of the adherence club programme and its rollout. According to Leeuw [28], managers, stakeholders, and workers involved in a programme have "cognitions" (or "mental maps") about the organisation and the environment of the programme. Realist evaluators can articulate the opinions and perspectives of the programme designers and managers through (a) general conversations and (b) interviews with a more limited and purposive selection of

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stakeholders [29]. Our goal was to further develop the theories from the document review, with both methods (document review and interviews) serving a 'conceptual refinement function' (theory gleaning) [21]. For this purpose, we explored the different perspectives of the key informants and identify the key similarities and differences in how they viewed the intervention and how they considered the intervention to achieve its objectives.

Twelve participants from different organisations working on various aspects of the adherence club at different levels of the implementation chain were purposively recruited in the study. We identified the positions of individuals whom we thought would be key informants. These participants were asked to recommend others whom they thought would be relevant key informants (snowballing). While conducting conventional qualitative studies, recruitment of study participants is continued until no new relevant knowledge is obtained (thematic saturation) [30].

The idea of standardizing saturation as a means of obtaining the appropriate sample size is challenged by O'Reilly and Parker [31]. Therefore, in this realist evaluation process, confirmation of the realist hypothesis was based on relevance and rigour rather than thematic saturation [24]. It should be noted that the health facility managers and operational staff involved in the actual execution of the programme were not included in this phase of the study.

An interview guide was developed for conducting the interviews (**additional file 1**). The interview guide included questions related to the design of the adherence clubs, the original idea behind the design, the goals and objectives, and the various components that make up the adherence club intervention. The interview questions also sought to obtain insights into the context required for the adherence club to have the expected impact, the dynamics that the adherence club brings to the treatment and care of people living with HIV/AIDS, and the possible mechanisms of change. Although English is not the native language of all the participants, they could understand and express themselves fluently for the interviews to be conducted.

We applied the 'realist interview technique' whereby theories are placed before the interviewees for them to comment with the view to provide refinement [20]. This method suggests that the interviewer teaches the interviewee the particular programme theory under consideration and then the respondent being the 'expert', in turn, is able to teach the interviewer about the components of the programme in an informed way (learner-teacher cycle) [32]. By this method,

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we presented tentative CMO configurations of the programme (developed from the document review process) and encouraged the respondents to explain their views about the tentative CMOs [33].

We also used trigger questions to obtain specific information. Feedback was later provided to the interviewees on the concepts and theories developed from their comments and contributions for validation. This process is described by Leeuw as the "elicitation cycle" [28]. The interview process was conducted between October 2015 and February 2016. **Table 3** below shows the various stakeholders who were included in the key informant interviews.

Table 3: List of key informants interviewed

Stakeholder	Number of participants	Number of interviews per group of participants
Médecins Sans Frontières	2	3
Treatment Action Campaign	1	1
Western Cape Provincial HAST directorate	1	2
Sub-structure HAST Managers	3	4
Sub-structure HAST MOs (Medical Officers)	3	4
The City of Cape Town	1	2
Institute for Health Care Improvement	1	1
Total	12	17

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Data management

For identification of the information source and anonymity, the key informant interviews are coded as KII_x where x represents an arbitrary number from 1-12. In a similar manner, information obtained from a document are coded as 'DR_x' for document review and 'X' for the document number.

Data analysis

We applied a realist philosophical 'lens' to the data analysis process, applying the CMO configurations as the analytical tool. The goal of the analysis process at this stage was to identify CMO configurations that represent the vision, goals and thought processes of the adherence club programme designers and managers (implementers). Information from both the document analysis and the semi-structured in-depth interviews were used to formulate CMO

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configurations that would inform the further development of the adherence club programme theory. This process was first applied to the document analysis for two purposes: (a) to identify gaps and (b) for the identification of themes and the construction of the tentative CMO configurations

During the final data analysis, information from both sources was pooled to formulate the CMOs. The analysis process was conducted in two phases: Phase 1 involved identifying the context, mechanisms and outcomes, as well as the actual interventions and the actors involved from the document review process and the in-depth interviews (thematic content analysis). Phase 2 entailed synthesising the empirical findings, which involved exploring how the context, mechanisms and outcomes are linked (generative explanation).

Phase 1: Theme identification

We employed the thematic content analysis method [34] for identifying, analysing, and reporting the CMO themes within data [35]. This approach fits in the realist analysis logic [36].

First, we transcribed the interviews verbatim. Both transcripts and documents were fed into the Atlas.ti version 7 software for a systematic management of the data. Secondly, we read the transcripts and documents repeatedly to familiarise ourselves with the contents. We applied the coding framework **(Table 2)** and coded the text. We specifically searched for instances where respondents talked about influential context, underlying actors' behaviour, possible mechanisms, and expected outcomes (initial, intermediate, and long-term). We sorted the segments of the texts and applied a process of data retrieval to organise the codes according to the different segments (context, mechanism, and outcomes).

Phase 2: Data synthesis - Context-Mechanism-Outcome (CMO) configurations

A realist approach of how an intervention is expected to work as anticipated by the programme designers and managers (expressed in 'folk theories') should explain how they believe the various components of the programme, the context, the actors and the mechanisms are linked and interacting to produce the expected outcome(s). Linsley, Howard, and Owen suggest that the explanation should consist of propositions about how the interplay between structure and agency in a social action constituted the regularity [37].

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The complexity of the programmes and the situations in which they are embedded often make it difficult to anticipate the ways in which change might be brought about by the multiple stakeholders and their myriad (potential) responses [38]. After we identified the themes related to actors, context, mechanism and outcomes of the adherence club intervention from the texts, following the recommendation of Wong et al. [39], we formulated preliminary explanations (causal inferences) of how the adherence club intervention could be successfully implemented, and how it could achieve the expected outcomes using the context, mechanism, and outcome components. The data analysis process is illustrated in **figure 1.**

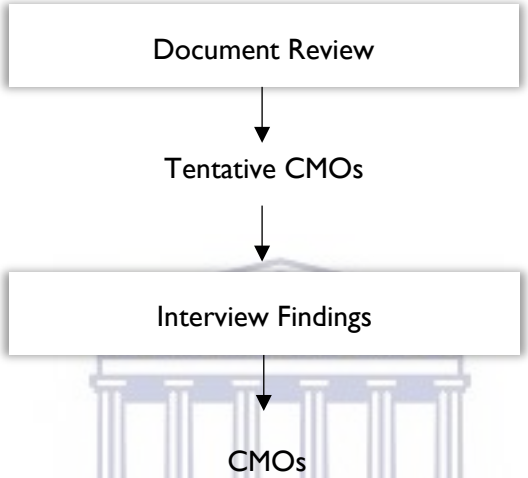

Figure 1. Data analysis protocol.

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We grouped the explanatory ingredients (context, mechanism, and outcomes) in the form of CMO configurations [20], the analytic centrepiece of realist evaluation [40]. After formulating the preliminary CMO configurations, we applied an iterative consultative process with five of the previously interviewed key informants to understand how the actors, mechanism, and context are expected to link to each other to produce the outcome(s). The emphasis at this stage was to obtain plausible causal explanations in the form of CMOs [41].

Ethical considerations

This study is part of a larger project "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health care facilities in the metropolitan area of Western Cape Province, South Africa" which has received ethics clearance from the University of the Western Cape Research Ethics Committee (UWC REC) (Registration No: 15/6/28). The

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University's research ethics committees are registered with the National Health Research Ethics Committee in South Africa. We explained the study aim and objectives to the potential participants and asked them to sign a consent form before their participation in the interview sessions. We also used codes to report the findings of the study and safely stored the data to ensure that the informants were kept anonymous and their information confidential. While conducting the document review, we followed the relevant standards of utility, usefulness, feasibility, propriety, accuracy, and accountability as outlined by Pawson et al. [42]. The study findings will be shared with the HAST Directorate in a feedback meeting.

Findings

In this section, we present the findings of the realist evaluation interviews with the key informant interviews combined with information from the document review. We first present the main findings in terms of Outcomes, Context, and Mechanism, and in a second part show how we proceeded to identify the CMO configurations.

Outcomes

We classified outcome themes under immediate, intermediate and long-term (**Table 4**).

Table 4: Classification of outcomes

Immediate Outcomes	Intermediate Outcomes	Long-term Outcomes
Decreased workload for operational staff	Decongestion of clinic	Programme standardisation
Decreased patient opportunity cost	Improved patient self-management	Retention in care and adherence to medication
		Healthier communities

Immediate outcome

Decreased workload for operational staff

One of the immediate outcomes of the adherence club intervention identified as a theme from the data is related to the decrease in the workload of the operational staff (clinicians and pharmacists). This point is explained in the adherence club toolkit and by two informants:

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> [The adherence club intervention] reduces [the] patient load in mainstream care, increases available capacity for clinicians to initiate new patients on ART, and manage clinically unstable patients and patients at risk of failing ART. It can also reduce the pharmacy load by utilising the central dispensing service for pre-packing. [DR_1]

> Therefore, it helped two things. One, for systems to be improved in clinics regarding Triage, and, secondly, getting these patients out faster and reducing waiting times, number one, and number two reducing, hmm the burden on Pharmacy. [KII_3]

> Clinicians are going to see fewer patients, there is going to be less disruption, they are going to know who is coming in, and they are going to know what their [patients] specific needs are… [KII_5]

Decrease in opportunity cost

Opportunity cost – the loss of other alternatives when one is chosen – in this context relates to patients missing either their work opportunities or family responsibilities when they spend long hours at the clinic for medication collection and routine check-up. This opportunity cost is reduced when they can collect their medication and consult quickly so that they can catch up with other activities. For the patients in the ART clubs, decreased opportunity cost was identified as an immediate outcome. The adherence club intervention is aimed at reducing the number of clinic appointments for patients. This reduces the time patients spend at the clinic as well as the frequency of the clinic attendance of the patients and, thus reduces the opportunity cost on the part of the patients. This is explained in the following excerpts:

> The adherence club only takes 45 minutes and then it is done. People can still go to work and go on with their lives. Before the adherence club, you can go to the clinic at seven in the morning, and when you leave, it is time for dinner. [DR_7]

> So, from the patient's side, it cuts down on opportunity cost, the time spent in the clinic where you are not working, you are not caring for your kids, you are not doing the things that you need to do to produce an income and look after your family. [KII_1]

The two excerpts above explain the cost and time-saving benefits to the patients. According to the participants, the adherence club intervention also offers cost and time benefits to the health system. This is echoed in the excerpt below:

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> Not only does the project [adherence club intervention] reduce the patient load in mainstream care, enabling clinicians to better concentrate on new and relapsed patients, it also saves the health system and patients' invaluable time and money. [DR_3]

Decongestion of the clinic

The intermediate outcomes of the adherence club intervention that were identified by the respondents include clinic decongestion and self-management of patients. To some of the study participants, decongesting the clinic is the primary goal of the adherence club intervention. These are the words of one of the informants: "*Decongest. That was number one... Firstly, to decongest the clinic because clinics are really full. We have got very many patients that are on ARV's and that need follow-up*." [KII_5] This outcome was perceived as one of the main objectives and used as a selling point to the managers. One of the programme managers reported that they would say to the facility managers and clinicians, "*Look, our intention is to decongest your facility and allow more people to come in*." [KII_4] Other informants echoed this point:

> So, usually when you go to a clinic and get buy-in from the staff, you focus on the benefit of the staff, which is the decongestion and the less work, but when I sell it to patients, then I am selling what helps the patients. [KII_1]

> So, on the other side, the benefit and health department is that they remove or decongest their clinics of these stable patients so that their resources are better utilised for new patients and patients that are struggling or unstable. [KII_8]

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Improved patient self-management

A second intermediate outcome of the adherence club intervention that was identified is the facilitation of self-management in the patients. This is explained in a document as follows: "*Community-based ART helps build patient self-efficacy and the social networks that encourage patient autonomy within a supportive environment*." [DR_{12}] An informant further explained how this comes about:

> Normally, the clinic manages the patient. If the patient fails to attend his/her clinic appointment, they are contacted and are educated on how to manage their condition as well as navigate the health facility for the easy management of their disease. While in clubs, and especially in community clubs, the patients self-manage their disease because there are no

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clinicians to give instructions. Thus, the patients can tell when they are well and to continue taking their medication and when they are unwell to go to the clinic. [KII_8]

Long-term outcome

Programme standardisation

The adherence club intervention offers a standardised ART treatment protocol. This is an important outcome for the overall ART programme. A respondent revealed what happened before the standardisation process and describes the outcomes related to the standardisation brought by the adherence club intervention.

> We know they are stable patients, but some were getting one month, some were getting two months, some were even getting more. Some were getting, maybe against what the rules were. When I say 'rules', I am talking about pharmacy practice and maybe clinical practice, but there were no guidelines. So in this way, I felt it [Adherence club] was a formalised process whereby facilities were being given guidance on how to manage these stable patients by letting go a little bit, by giving two months' supply, but also still hanging onto that ART programme that was quite very tight… by calling them back to the clubs. [KII_4]

Two key informants indicated the advantages of the standardisation outcome when they described how the adherence club programme offers a structured care delivery process:

> So, it [adherence club] is structured, and the rest of them. So, I'm managing the Clubs, but the other staff can comfortably know that there are 30 or 60 patients less that they are going to have to see because they are in a different setup, they have got a support group or whatever." [KII_5]

> Then, in terms of adherence from the clinical aspect, I think what, what the club offers is structure. So, everybody's scripts are aligned, everybody's blood visit is aligned, and everybody's annual clinic visit is aligned. So, by having that structure, we are able to offer a better or more routine, or the routine clinical component and so, patients do not fall through the cracks. Because we know that that does happen where they due for a test, they come to the clinic, 'someone does not review their file correctly. [KII_{12}]

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Retention in care and adherence to medication

Retention in care and adherence to medication are considered the main long-term outcomes of the adherence club intervention. This is captured in these phrases:

> So, for the patients, it was about having them being adherent, not only to their medication but to their appointments. [KII_5]

> To be honest, I think for me, the main benefit is that we know that a patient came, and he has his medication. [KII_{11}]

Healthier communities

Some of the study participants suggested that the adherence club intervention could ultimately lead to healthier communities.

> And the other aspect around community awareness is I think it has had an impact to an extent because when we go out in the community as we generally try to engage that community as well - we would like to actually go to a community meeting and present that we would like to begin offering community clubs in this area. [KII_2]

> I absolutely believe that it can for all the reasons that I have stated the benefits for *all* the parties involved. I think that it is a great way that we can keep, that we can work towards keeping our communities healthier. [KII_{11}]

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Context

Three themes attributed by the respondents to the context of the adherence club intervention emerged from the analysis. These context components could be categorised under local (micro), organisational (meso), and distal (macro) context components (**Table 5**).

Table 5: Classification of Context

Local (Micro) Context	Organisational (Meso) Context	Distal (Macro) Context
Availability of conducive space	Sustained hierarchical pressure	Monitoring and evaluation
Programme champions	Human resources (staffing dynamics)	Higher level support
Oppressive Surveillance	Implementation methodology	Stakeholder collaboration

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Local (micro) context

Availability of conducive space

Themes identified from the interviews suggested that the availability of a conducive space for conducting the adherence club activities is an important contextual element. According to the adherence club Toolkit document, "*The adherence club space varies from facility to facility depending on available infrastructure space*." Some of the informants identified the lack of space for the club activities as a challenge.

> So, at one of our very big facilities which has very many patients, they have been going off site. They have been in the position that they have an NPO [Non-profit Organisation] working with them that is paying the rental for this off-site space. We have in the meantime tried to get it free, and we were on the verge of a breakthrough when the manager just said 'no'. So, now, we are looking for a different place. They found one. They have not moved yet, but that is - so, so the adherence clubs are about space. [KII_4]

Programme champions

Another contextual component identified from the data that could influence the mechanisms of the adherence club intervention is 'programme championship', whereby an individual is identified to 'champion' or 'lead' of the project. An informant reported "*they* [facility managers] *identify mentors from the facility to drive or champion the process [adherence club intervention]*." [KII_4] Another informant explains further that "*Often times, the Unit manager is somebody that is really invested and would want that* [implementation of the clubs], *so that is an easy person to get things going, but the Family Physician is also an important person*." [KII_5] Informants described the importance and attributes of a champion in the adherence club programme.

> I think it is important, very important to have someone driving it, to have someone having the oversight over, to ensure that all the bits take place. You know the Clubs Manager or the Clubs champion does not have to be doing everything. In fact, they should not be doing everything. They should be able to support or capacitate the team to actually do it. And it is necessary because we are finding that, as our programme grows more, more and more patients are joining clubs, and facilities have to do a significant amount of planning and coordinating in order to implement clubs well, and to make sure they do not fall off the bandwagon because of the size. [KII_8]

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> Well, it is critical because that is the person who swings it. And I mean, we have example after example of any of the facilities that have done fantastically, you can name a person. Sometimes, you are actually very lucky, and it could even be two people or one person who was replaced by another person who carried it on. You know, we have also seen a key person leave, and this amazing programme falls apart. So, that champion is critical. [KII_{12}]

Oppressive surveillance

A perception of oppressive surveillance in the form of external pressure and control was identified from the interviews as one of the aspects that influence the mechanisms that drive retention in care and adherence to medication within the adherence club programme. This denotes the practice of patients being visited at their home to ensure that they are living in supportive conditions. Oppressive surveillance is also perceived in the frequent adherence monitoring through pill counting to ascertain their adherence to medication. This also includes the increase in the number of times that they have to see the clinicians for their clinical visits

> So when they, when clinicians enrol patients in the clubs we make sure they are assessed at specific levels before they allowed…and then the other issue is that they have to then see clinicians six monthly not annually because its seen as the need would be six monthly. So those patients will have extra visits. [KII_8]

> So I would really love to see whether it is [home visits] adding any value because it is another huge administrative and supervisory intervention which I do not feel the facilities are really able to do and the NPO's do not seem to be doing a great job on that either. [KII_{10}]

Organisational (meso) context

Sustained hierarchical pressure

While most participants suggested that the higher structures provided a supportive environment for the implementation of the adherence club, others thought the supervisors at the sub-structures were exerting pressure, especially on the facilities. This pressure was perceived through the close monitoring of the programme.

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> I think because we are watching it so closely on all levels, it is watched closely. So, if we see that [the number of clubs] are not increasing, we kind of need to, we do jump in, and we do something. [KII_5]

> Hmm, then from 2014, so two years ago was the first time I started to realise, but by then, I had already done some analysis. The data was not as good, but I had done some analysis and worked out that actually, we were not decongesting. We were just [ameliorating] the growth. So, the growth was going to be slower in the clinics, but actually, we had not managed to decongest. So, I then set targets, enrolment targets to say 'if you enrol this many persons a month into clubs then you will be in a steady state and if you enrol more than you will decongest. And that made quite a difference. [KII_{12}]

According to the adherence club toolkit, *"where a sub-district rolls out clubs as part of their ART service, it should set a target for the number of its total ART cohort that it aims to enrol in the club model. It will require two indicators to track the achievement of this target and the quality of the model: (a) number of patients enrolled in clubs in the facility (b) number of patients retained in the facility clubs."* Some participants suggested that, because they are given targets to meet in terms of the number of patients to be admitted into the clubs, the number of clubs to be created within a period, and the percentage of ART patients to be in clubs, they were being pressured:

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> So, I then set targets, enrolment targets to say 'if you enrol this many persons a month into clubs, then you will be in a steady state and if you enrol more, then you will decongest." And that made quite a difference. We had this flurry of interest because it was the first time anyone had been given any kind of target of where they should be trying to go. The first six months, we had an *amazing* response and then for the next year or so, we had quite a few facilities that were really struggling with that rapid growth and then, you know, they were really just struggling with the logistics of clubs. [KII_{12}]

Staffing dynamics

Respondents identified human resource availability and other staffing dynamics as important contextual components that affect the implementation of the adherence club intervention. According to the adherence club toolkit document, five (cadres of) staff are needed to successfully run the intervention in a facility – a club manager, club nurse, clinician, counsellor, and pharmacist or assistant pharmacist. A document describing the adherence club intervention

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states that the intervention "*requires sufficient human resources to support and run the clubs and cannot [should not] drain current facility staffing as the clubs expand.*" [DR_3]

An informant suggested that when the facility does not have all the required cadre for running the adherence club, some level of flexibility should be considered. This idea of adaptability is explained by two informants:

> So, the facility did not have all those cadres of workers available. Sometimes, the same nurse had to be the club manager and also had to be the club PN [Professional Nurse] and also had to do different roles, but with one person… So, in that way, although the outline of how a club should run had all the definitions of what these people should be doing and who they should be, we kind of still, kind of tailored it to the context. [KII_4]

> We try to encourage all the nurses in facilities to actually be a Club nurse. So, you could rotate through that role and because then you see the value that all those patients, even though they not in your waiting room anymore, they are still your patients you know. [KII_9]

The various staff adaptations provide different staffing contexts for the implementation of the adherence club intervention within different facilities.

Organisational (meso) context: implementation methodology

Some of the participants identified that the use of a particular method for the implementation of the adherence club intervention within the facilities had an influence on the results that they obtained. This identified the implementation methodology as an important organisational contextual factor for the successful implementation of the adherence club intervention

> It is a breakthrough series collaborative model. If you work collaboratively over time, which is a series thing, and it is quite structured, then you will get breakthrough results. First, it is very important that it has a very clear aim and that aim has to do with, generally with patient outcomes. So, it has to be something that is, people feel it is worth doing. So, even though we might have said our aim was to spread the clubs to you know all the ARV clinics in the City we all knew that that aim was, actually, to improve retention in care and to improve initiation, early initiation across the City *by*, our change was the clubs, by spreading the clubs but we all had in mind that this was going to have great patient outcomes, that was the intention. So to spread the clubs and get worse patient outcomes would not have been a desirable outcome. [KII_4]

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> Yes, that strategy [breakthrough series collaborative model] was very effective. We are actually using it with Province in another model now where we identify high burdened facilities. We ask them to identify their club teams, they come for a training; we do a training; the Mentors that we have identified to offer support during implementation; they are there for support; follow them for 6 months; we return again; we check in how it is going; we address any key challenges; we set new goals and we go. [KII_7]

Distal (macro) context: emphasis on monitoring and evaluation

Other contextual factors that respondents reported as important for the successful implementation of the intervention were monitoring and evaluation services in the programme:

> So, monitoring and evaluation become a big thing for you in clubs, because it is pointless you are putting patients there [in the adherence club], but you cannot determine if you are retaining them in care. And what I also would like to point out is that besides these patients remaining in care, they have one clinical visit per year. Only one that have contact with the clinician. [KII_8]

> It [implementing adherence clubs] does require planning and support and monitoring and evaluation, all of those bits are important. And so, when you see other provinces trying to do it, you do actually want to say "you have got to have some structures in place. [KII_2]

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> So, there is a monthly meeting where they look at the ARV data. And when I set those targets, the sub-district manager jumped on them and put it into the programme for implementation… [KII_{12}]

Distal (macro) context

Higher-level support

Another theme that emanated from the data relating to the context is the support provided to facilities from higher structures or departments. We found that during the implementation phase, the steering committee provided most of the support. This support is explained by a participant:

> We train them on the model, and they would come up with a plan for how they were going to roll it out. And they would then be allocated a club mentor, which was either one of the HAST MOs [Medical officers] or somebody else… And so, that means that that person,

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> once they have been trained and went back, you would pop into the facility and answer questions and support where they were struggling, etcetera, for a given amount of time. And then, six months later, we [steering committee] would have another learning session where all those teams would come back and report on where they were [with club implementation], what they were struggling with, etcetera and get input. And then, we did that another time. So, it was over three sessions. And those mentors for the facilities were supposed to kind of, once the facilities were up and running, step back and then move to another facility. They did that in some places, in some places they still provide some mentorship. That is the one set of training that took place. [KII_{10}]

The importance of on-going support is expressed by another participant:

> So, I think the advantage also is District's presence …. District support … I think that's important. …So, the advantage of that was to get buy-in from everybody, and we did, it was actually a success… [KII_3]

One other informant made the comparison between facilities that received support for the running of their adherence clubs, to those that did not, thus highlighting the important role that on-going support plays in propagating better retention in care and adherence outcomes.

> So, that is why Ubuntu was one of the most successful. Like I say, they received support from MSF, you know, during the implementation of these clubs. It was successful … So, it is about what support MSF gave a clinic initially. [KII_8]

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Stakeholder collaboration

Stakeholder collaboration was identified as an important contextual theme for the implementation of the adherence club intervention. For instance, the programme's steering committee, consisting of the various stakeholders and the Western Cape HAST Directorate, provided the political clout for the implementation of the adherence club intervention within the Cape Metropole. Three informants highlight the role and importance of stakeholder collaboration:

> At the provincial level, we [MSF] still sit as a technical partner on the steering committee, and that is where I sit with a member of Institute for Care Improvement and others and HAST MOs [Medical Officers], etcetera and Pharmacists and data capture clerks, all of

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> that. And that steering committee, I think, is vital to be able to continue to engage with the change in dynamics of implementing the programme. [KII_{12}]

> So, that is me and the HAST managers, the HAST MOs [Medical Officers], the leader of the HAST team at Province, the Pharmacist. We all meet once every two months and go through problems or things that we are changing in the club system or, for instance, when we finalised the SOP or now as we want to roll out family clubs. We all sit together and make a plan. [KII_1]

This collaboration between stakeholders can lead to interactions and possible programme buy-in. The role of collaboration is expressed in these excerpts.

> Okay, and that is the model that we used in that project. And because I had done that project, and it was done with the municipality with City Health, and the Head of the City HAST had been working for … at the time, and it was a collaboration, so they were also involved in our project, and she then moved across to the City. [KII_4]

> Well, the [HAST] Directorate gave us the space to be able to make that collaborative effort to work in those clinics and so both the City and the Province had to work together and both of them had to agree that we could do this collaboratively. [KII_2]

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Mechanisms

We identified the following potential mechanisms during our analysis. We classified the mechanisms according to those operating at the management/provider level and the mechanisms at the patient level (**Table 6**).

Table 6: Classification of Mechanisms of action

Provider/Management Level	Patient-level
Buy-in	Motivation
Interaction	Group dynamics - Social/Peer support
Motivation	Nudging
Problem-solving	Encouragement
	Trust
	Bonding
	Learning
	Fear

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Providers/managers mechanism

Buy-in

Buy-in from stakeholders such as facility managers, operational staff, and patients is central to the successful rollout, implementation, and execution of the adherence club intervention. The adherence club toolkit emphasises the importance of buy-in from the facility managers and suggests that the facility managers take 'ownership' of the intervention. According to a document reviewed, if the facility manager and the clinicians buy into the intervention, then they could "*maintain good long-term adherence in patients on ART treatment by creating an environment within the health facility for more convenient clinical visits that is conducive to the patients' lifestyle needs*." [DR_9]

> Most of the participants identified buy-in as an important driver of the possible success of the adherence club intervention. This is expressed in the words of these key informants:
> I realised to get this programme working right; you need everybody's buy-in from the beginning… [KII_{11}]
>
> So, I think at times it is the degree, I guess, I call it of buy-in from the Facility Manager, the knowledge of the Facility Manager around ARV's and the needs of the various people in the facility, whether it is the staff, the patients, or whoever. [KII_1]

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Interaction

The concept of interaction as a mechanism of action for implementation of the adherence clubs flows from the collaborations that exist between the various stakeholders. According to a document written by MSF, "*The extent to which patient groups engage in mutual support will probably be context- specific and should be community/patient driven. As a minimum, community stakeholders should be involved in planning and implement community-based models.*" An excerpt from the interviews affirms this point of view:

> So, because of the earlier work we had done, we all had relationships, we all had, a lot of people in the ARV [ART programme], because it was ARV [the ART programme], so a lot of people in both Province and in the City had an experience of this methodology [Breakthrough Series Collaborative Model] and we had won a Mpumelelo award with it so we were all confident that it was good methodology. We had fantastic results, we all enjoyed working like that. It was very collaborative; very creative. [KII_8]

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Motivation

Motivation on the side of the clinicians and counsellors working with PLWHA on ART was identified from the data as an important mechanism of action. It is related to the fact that the adherence club intervention offers a structured and somewhat predictable work schedule so that they can anticipate their workload. An informant explained this in detail:

> You can plan for it [preparations for the club meetings] proactively, "these are my clubs. These are the dates when they are going to come through the year. Let me see that my scripts have gone in two weeks before. Let me see that I have got the medicine pre-packed the day before. Let me see that the patients that didn't come, have been contacted. [KII_{10}]

> So, it is structured, and the rest of them, so I am managing the clubs, but the other staff can comfortably know that that's 30 or 60 patients less that I am going to have to see because they in a different setup, they have got a support group or whatever. So it had benefits for both parties. [KII_2]

Problem-solving

These interactions can also lead to effective problem-solving, which in turn increases self-efficacy and trust among the different stakeholders

> There still is a need for the steering committee' because that committee is basically doing the technical work and basically a lot of the focus is now on innovation because we have rolled out clubs in a particular way… MSF did it in a particular way, in a very well-resourced way, but, you know, the reality out there is that we don't have all those cadres. [KII_7]

Patient level mechanism:

Motivation

Motivation is one of the concepts identified as a possible mechanism through which the adherence club intervention works. Motivation in itself is achieved in more than one way. First, the motivation of patients on ART could be achieved through the trusting relationship between the club facilitators and the patients. This trusting relationship would inspire the patients to take to heart what they have learned in the peer education, counselling or consultative sessions. This

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is reflected by an informant who explained the importance of the counsellors acquiring the skills to develop trust relationships with their patients:

> Is there basic information that we can translate to a lay worker to say 'this is what you do to make someone feel comfortable, this is how you build trust, this is how you do not build trust.' I think that are key skills that they need [without which], I don't think the adherence clubs are going to work. [KII_{10}]

Another source of motivation and positive enforcement that may influence the patients to be retained in care is provided through the continuity of care that the patients get from the Club Facilitators and the clinicians that see them on a regular basis. This point is explained by an informant:

> Some of the patients value the other patients being there, but some of them value the actual facilitator who is someone that they get to know. At least, they see the same person every time, whereas, normally, if they go to the clinic, they will see a different clinician every time. [KII_1]

Continuity of care offers the patients the chance to familiarise themselves with the same Club Facilitator and Club Nurse. This is supposed to instil trust in the patients, which motivates them to attend their club appointments, especially when the Club facilitators get to know the patients personally and call them by name. This is believed to motivate the patients to be retained in care and adhere to their medication.

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Group dynamics - social/peer support

Grouping patients together for their ART treatment is not only about providing them with easy access to medication but about the relationships formed between the group members. Most of the interview participants identified some interaction among the group members to have a positive impact on retention in care and adherence. It is suggested in a document "*the relationship between providing social support and improved adherence to treatment is well established*." [DR_{12}] The concept of group dynamics emerged in the document analysis:

> Club members establish a positive group dynamic over time, which renders much-needed peer support for adherence to lifelong treatment. [DR_2]

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> [The adherence club] creates [an] opportunity for establishing group dynamic and peer support. [DR_1]

These two quotes identify peer support as a product of the group dynamics within ART clubs. The clubs are thought to offer social support that could foster retention in care among the group members and ultimately, medication adherence "*The relationship between providing social support and improved adherence to treatment is well established*." [DR_{12}] This theme of positive group dynamics also emerged from the interviews. One of the informants reported that when the group members convene from time to time, they familiarise themselves with each other, which creates a positive atmosphere for better relationships and sharing:

> See the same people every two months. They get to know each other a little bit, which also helps build a little bit of *camaraderie* and understanding that there are other people in the same situation, and they allow sharing between people. [KII_1]

Medical anthropologists describe this concept as 'biosociality'- a relationship formed when patients collectively share meanings of the extreme experiences of illness and stigmatisation causing a sense of bonding among the patients [43]. Two participants explained further that:

> It is about being in a group of patients who have similar challenges that I have. Number one, we are all HIV positive, and we all need to be put on treatment. So that just kind of breeds some loyalty, and so it also gives you an idea as to what the health status is having this 'dreaded disease' as people called it back in the day. [KII_5]

> The adherence club model gives a bit of social fabric where people come together in a group, in a support group structure and actually get to engage with other people just like them, maybe not from the same exact suburb but certainly the same community of people living with HIV. [KII_7]

Another participant explained that being managed as a group brings about a shared identity which leads to a peer supportive environment: "*It is about gaining the sort of peer support environment where we do not feel as alienated as being the only person with HIV and able to talk through things and to get your treatments quickly.*" [KII_1] Key informant 5 explains in detail how the group identity develops:

> But you look around you, and you can see "But this person, you know, has the same thing as I, but he or she is looking, is healthier than I", and so you can converse and, "What is

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> happening? How come you look like this and I look like that, and we have the same issues?" Hmm, you know it is kind of…" They share their lives with each other and you know there is an old saying that says "a burden shared is a burden halved. [KII_5]

Nudging

Another salient mechanism that was identified by interviewees is nudging - helping people to make the right choices by setting default options in a specific way. The standards of practice of the adherence club have clauses that oblige patients to attend club activities. A method applied by the operational staff is to 'nudge' the patients by reminding them that if they do not adhere to the club activities and collect their medication within the 5-day grace period, they would be returned to the main clinic care (which has the challenges of long waiting times to see a clinician and to collect medication at the clinic pharmacy). This is captured in the following excerpts:

> Patients can be removed from club care and returned to mainstream care where more intensive clinical or adherence follow-up is required. A patient exits the club when he/she misses a mandatory club session and fails to attend the clinic within five days. Patients determined by the club nurse to require more regular follow-up and those with elevated viral loads are also returned to mainstream care. [KII_8]

> We decide our grace period, but we are also going to be stricter with our club patients to stop them coming each time after the club session. They will need to see the Clubs Manager when they are late. [KII_1]

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Encouragement

According to the study participants, treating patients in a group is considered to foster collaborations and 'friendship' among the group members. In the group-based setting, the members tend to encourage and motivate one another towards adhering to their medication and attending their clinic appointments. This concept is further explored by another key informant:

> So, for me, it [adherence club intervention] would be a means of making that connection with the people in your group, and you see each other every two months. You are going to see each other every two months and so you would want to see the person. You would want to know, you know, 'They were looking so badly, I wonder what is happening' and hopefully, they connected and swapped numbers and kind of messaged each other as a form of encouragement. [KII_{10}]

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Trust

Trust was also identified as an important mechanism through which the adherence club intervention would achieve its objectives. One of the interviewees explained that patients could trust the system if the clinic or operational staff could deliver the services as promised to the patients:

> So, I think that in a sense, when you have given what you said you are going to give is an incentive, and we have definitely seen in facilities that struggle to have this system in place that the patients are far less willing to be on time or come on their club day. So, I think that does have an, have an impact. [KII_{12}]

Bonding

Bonding among the patients grouped together was identified as another mechanism of action to promote retention in care and adherence to medication among patients on ART. According to the Standard operating practice document,

> The Club environment needs to provide a space that is conducive for people in the club to chat to each other, as part of the aim of the club system is to *foster bonding* between patients so that they can support each other in the ongoing need for adherence. [DR_9]

A participant explained that bonding can also be achieved in the group when patients come together in the club session:

> But you know, from my observations, people enjoy coming and meeting others. They build relationships maybe with unlikely people that they would otherwise not have met. And I have definitely seen some club members who disclosed, you know, social or personal issues in that space because they feel like they can trust this space. [KII_7]

Mutual learning

Another mechanism that was identified to be activated in the context of the adherence club implementation is mutual learning. According to some of the interviewees, patients learn from one another while in the group, and this can help them to self-manage their disease easily.

> So, you learn from each other within the group. You learn about, you know, the adherence to medication. You are encouraged to come to your appointments. You are encouraged to disclose, you encouraged to live your life a little bit, you know, with positivity and not with negativity and think that you know 'I am dying tomorrow.' So, there is a lot to be gained

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> from being in an adherence club, because for me, an adherence club is a form of a support group you know. You see the same people every two months, you visit, and you can chat, and you hear what their life is all about and you can, you can kind of do the same thing as it were. [KII_9]

Fear (of losing the benefits of the club)

Fear was identified from the data as one of the driving forces behind their faithful attendance of the club activities. This fear is mostly associated with losing the benefits the patients feel that the club has over the standard clinic care.

> You know, patients do not want to leave the club because, if you have a job, you know, they come get their medicine, in and out but if you just have to go home to do the washing, whatever, and you got a little bit more time then you will lose the interaction, I think. So it depends on where you are in your life, I think. [KII_{10}]

Discussion

Identified CMO configurations

Using the configurational analysis approach, our goal at the second stage of analysis was to consider the possible interactions between each of the specific components and identification of context, mechanism, and outcome. We applied Berman's policy implementation model to illustrate how various ICAMOs occur at each level [44]. According to Berman's model, policy implementation follows the following processes: (1) translation of the policy to a programme; (2) programme adoption by managers; (3) programme implementation by providers, and (4) programme uptake by patients. Our discussions here focus on the last three processes. We identified CMO configurations for three groups of actors: the providers, the managers, and the patients.

Provider perspective

Providers will likely adopt and implement the adherence club programme if the policy environment is conducive and if it suits their interest. The political clout of the programme contributes to its spread and implementation. The informants suggest that this is achieved through the steering committee, district health support, collaborations between the facilities and

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the government health organisations. This results in buy-in from the facility's managers and providers, and the feeling of soft coercion by the facility managers. The stakeholder collaboration also provides an atmosphere of effective problem-solving and empowerment, consequently contributing to the successful adoption and implementation of the programme. Support in the form of training and guidance provided by the steering committee to facilities also facilitates uptake by providers. These mechanisms are assumed to promote the successful rollout to the adherence club intervention in various primary health care facilities. The contingent causality explanation of this perspective is represented in **figure 1** below.

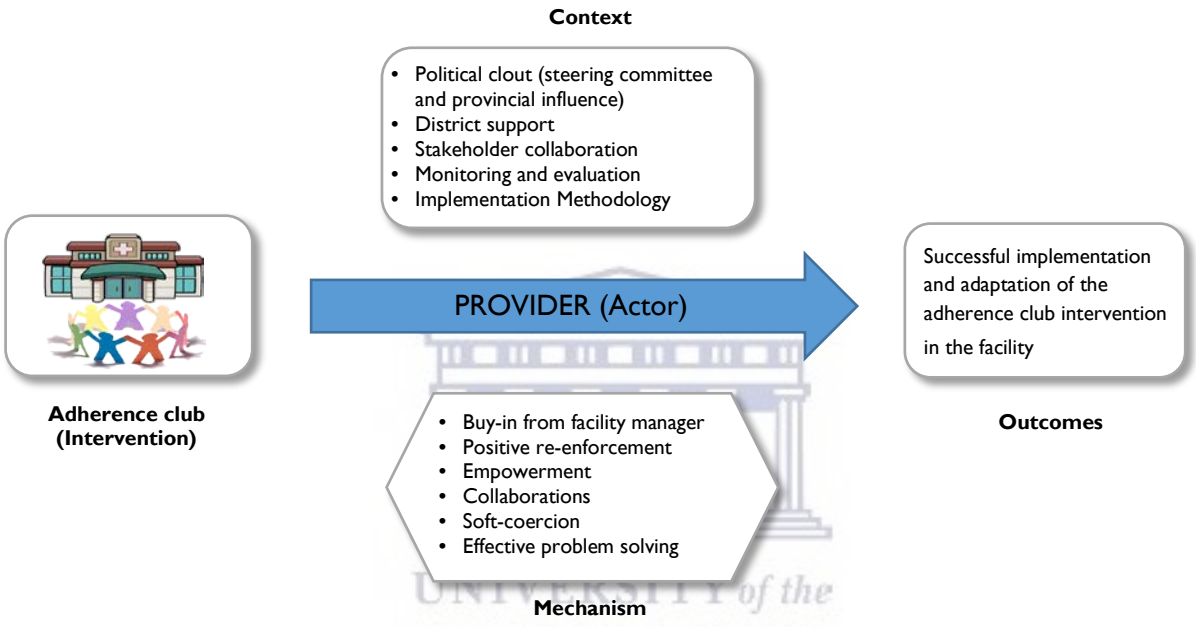

Figure 3. ICAMO configuration for providers.

Management perspective

The ICAMO for the managers focuses on how the programme is supposed to work at the level of the clinical management. Clinic managers are more likely to adopt and implement the strategy if their buy-in and motivation are achieved through support from the district level, collaborations with non-governmental organisations and the central drug-dispensing unit. Their motivation may be increased by the prospect that the programme would decongest the facility and lighten the load of the operational staff. They can be coerced to adopt the programme through hierarchical pressure and standard setting. If the right balance is struck, successful implementation and adaptation of the intervention become more likely, and its potential to standardise the ART programme, decrease the workload and decongest the clinic higher. **Figure 3** describes the CMO configuration at this level.

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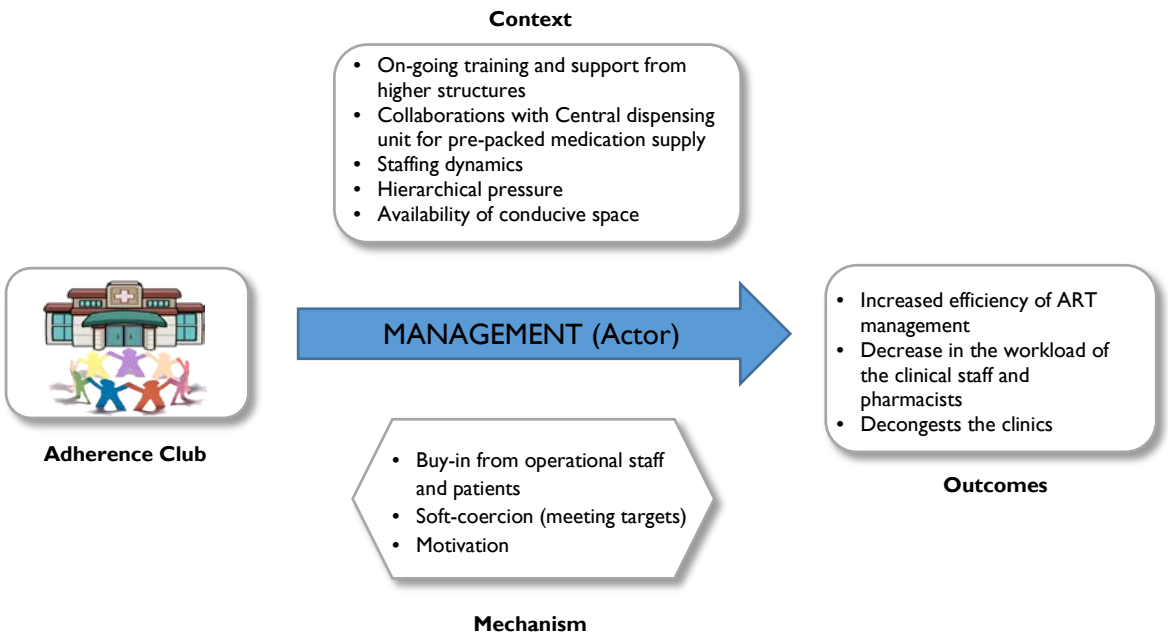

Figure 3. ICAMO configurations for managers.

Patient perspective

Two CMO configurations emerged related to the patient perspective, suggesting different pathways through which the outcomes could be achieved. The first CMO, illustrated in **Figure 4,** represents the most popular view of the designers and managers. Patients are assumed to regularly attend the adherence club and to take their drugs if the mechanisms of patient empowerment, positive group dynamics (biosociality), learning, trust, motivation, and social support are triggered. This requires the buy-in from the facility manager and operational staff, the availability of resources such as operational staff, patient selection criteria, a conducive meeting space, and the contributions of other organisations towards running the adherence club programme as context factors (context). When the ART club is tailored to its 'target' group of patients and its context and as such triggers the mechanisms, it is assumed to encourage patients to self-manage their disease, be retained in care, and adhere to their medication.

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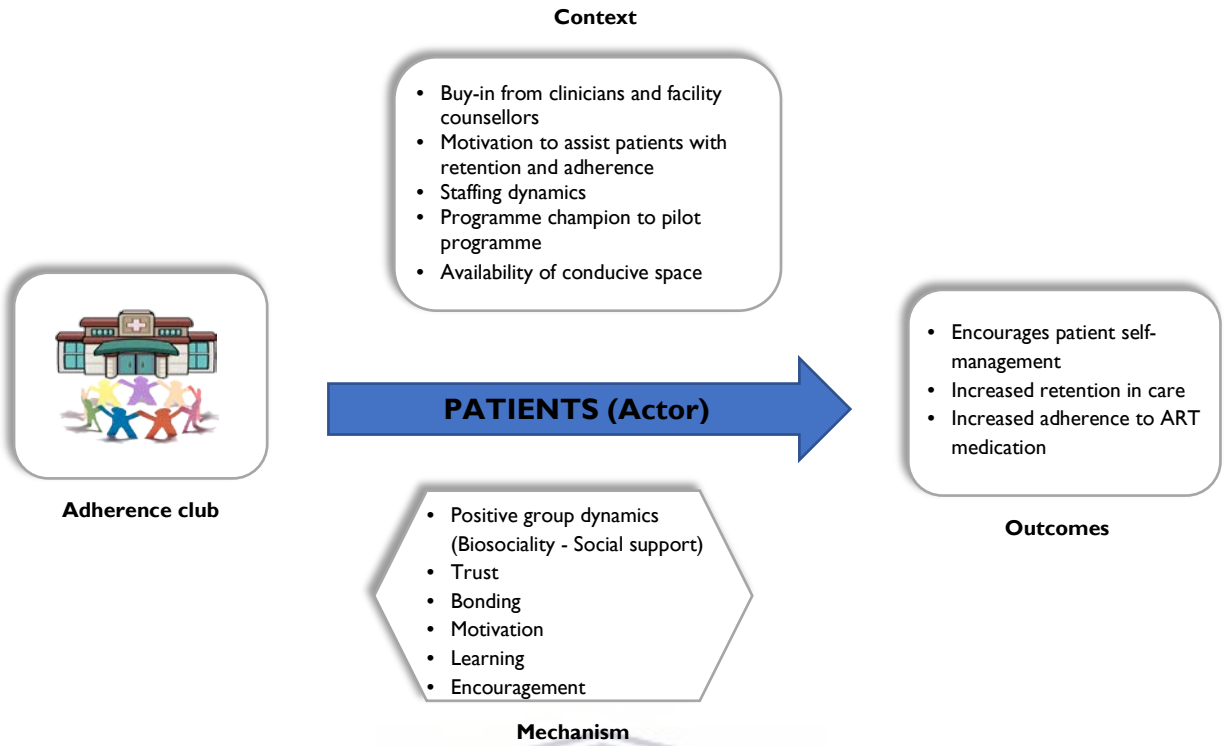

Figure 4. ICAMO for configurations for patients (**proposition 1**).

An alternative CMO indicates that patients may attend the adherence club out of fear to have to go back to the main clinic care if they fail to attend their club sessions (**Figure 5**). Within different contexts, different mechanisms are activated, for instance, patients either may feel motivated by the contextual conditions or be nudged. Mechanisms that were identified to be triggered by the context of this situation included fear of returning to the main clinic and losing the benefits of the clubs, feeling nudged by the patient surveillance activities (attendance registration, pill counting for adherence monitoring), and being coerced by club rules and processes. These could plausibly contribute to behaviours of increased retention in care and adherence to medication among the patients.

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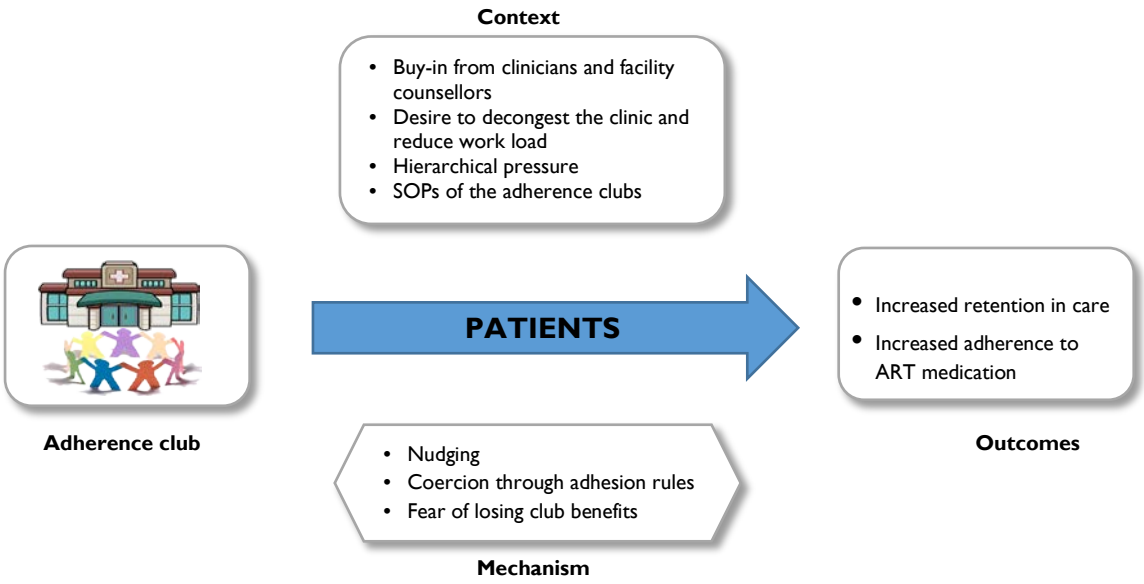

Figure 5. ICAMO configurations for patients (Proposition 2).

Framing the ICAMOs in existing theory

There are many approaches to initiating change in health behaviour, from external pressure and control to the use of incentives or rewards. The first patient-related ICAMO configuration typifies the use of incentives and rewards and identifies motivation as an important mechanism of action which prompts patients to attend the adherence club sessions, based on what the adherence club promises to offer. With motivation as a central ingredient, this ICAMO could be linked to the self-determination theory, according to which motivation – "the inherent tendency to seek out novelty and challenges, to extend and exercise one's capacities, to explore, and to learn" [45] plays a central role in determining the actions of the individual (in this case retention in care and adherence to ART medication). According to Ryan and Deci [45], motivation highlights the use of evolved inner resources for personality development and behavioural self-regulation. Thus, treatment environments that afford autonomy and support confidence are likely to enhance retention in care, adherence and consequently, positive health outcomes [45].

The second patient-related ICAMO configuration suggests that the patients are being nudged, pressured, or controlled to attend club activities. In other words, an external force prompts the patients to attend the club activities. Nudging theory suggests that humans are prone to making bad decisions because they are easily tempted to, and that they should be helped to make better choices. According to Thaler and Sustein, gently helping people to make better choices by

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"setting default options, and other similar seemingly trivial menu-changing strategies, can have huge effects on outcomes" [46]. The effects of well-chosen default options provide just one illustration of the gentle power of nudges. The choice architects (clinicians) are supposed to rearrange the physical and social environment in order to make people change behaviour to make better choices [46]. Nudging could also be implemented through the threats of losing the benefits of the adherence club benefits when the patients fail to attend the adherence club activities.

Elements of an initial programme theory of the adherence club programme

The implementation of the adherence club intervention occurs in a policy environment driven by goals of decongesting the health system and achieving better retention in care and adherence rates among patients on ART. The HAST Directorate at the provincial level oversees the implementation and running of the programme. This is done in part by a steering committee with representatives from HAST, MSF, TAC, and the City of Cape Town. The role of the steering committee is to monitor the implementation of the intervention and engage with the changes in the dynamics of implementing the programme to come up with solutions to address surging challenges. From the steering committee, decisions on how to improve the roll-out and implementation of the adherence club intervention at the facility level are taken and shared with the sub-district HAST offices that micromanage the implementation process at the various primary health care facilities. The decisions are then adopted by the ART unit of the facility, and the clubs are run accordingly. Monitoring and evaluation of the performance of the adherence club intervention at the facility levels inform the decisions taken at the level of the steering committee.

The different provisional ICAMO configurations for different actors at various levels show how each level is related to the others and how the effective adoption and implementation needs to be secured at the different levels of the health system, from the central policymaking and programme level, through the district and sub-district to the facility-level. Combining the provider's perspective, the management's perspective and the patient's perspective of how the adherence club programme works, indeed, provides an initial overarching programme theory of the adherence club programme (**Figure 6**).

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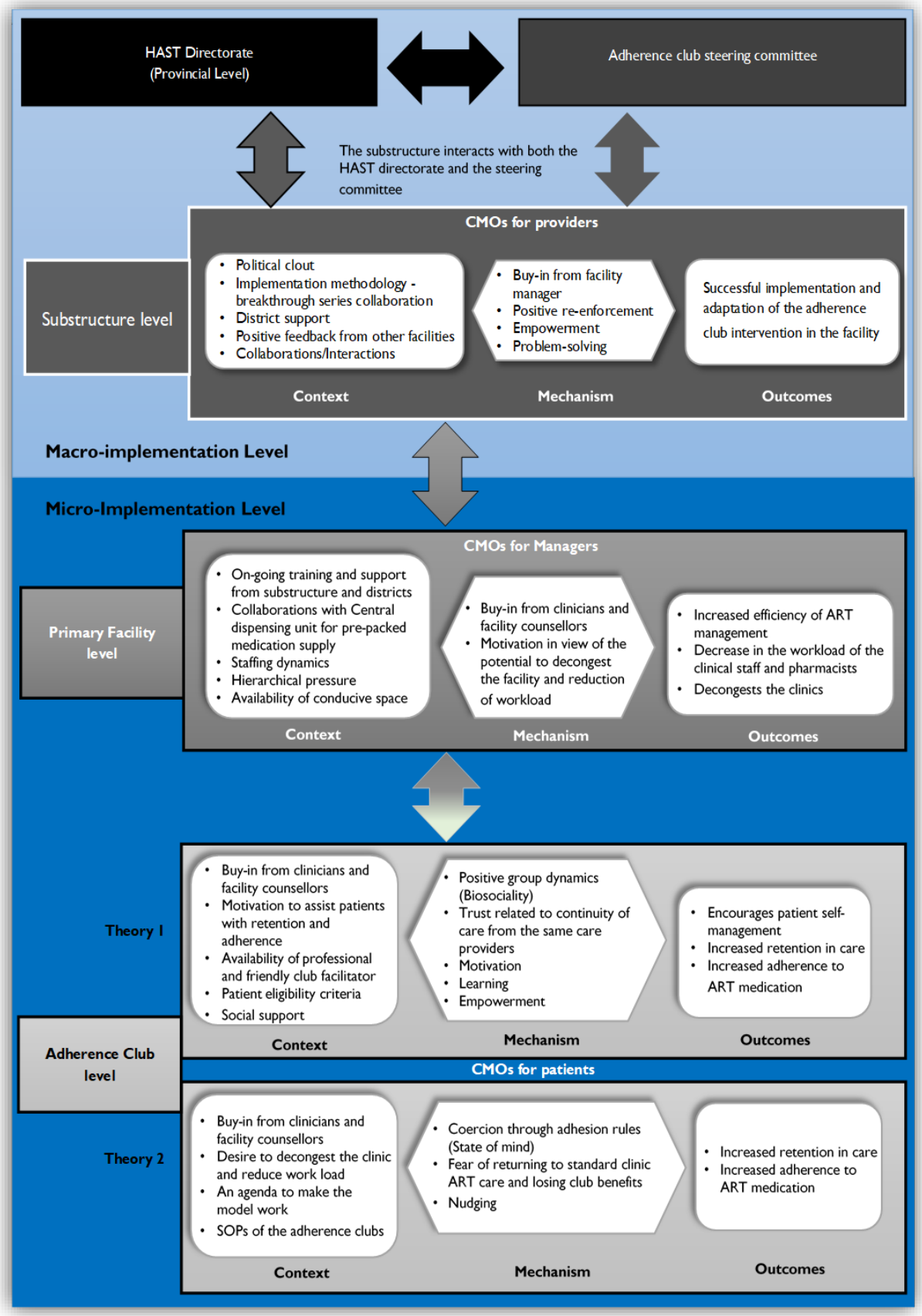

Figure 6. An initial conceptual framework of the adherence club programme

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From a realist perspective, in a multilevel system such as the health system, the outcome patterns (proximal, distal, negative, intended and unintended) of one level may constitute the proximal context in the next level of the system [47]. For instance, decisions made on the number of adherence clubs to be implemented within a timeframe at the sub-district level might become a contextual component within which it is implemented at the facility management level and consequently the execution of the programme. In a similar manner, the outcomes at the ART unit and facility management could form part of a distal context within which the programme is being implemented. Understanding how actors and their decisions operating at these different levels interact and influence each other can provide a more comprehensive understanding of the adherence club intervention at the final level of implementation and execution.

Rigour and trustworthiness

The rigour and trustworthiness of the study findings were improved by applying the following principles. We conducted a pilot of the interview guide, which helped us to assess the type of information that the questions we asked were likely to produce. We applied the processes of method and source triangulation. The document analysis allowed us to triangulate the information from the interviews. In addition, a wide range of stakeholders was recruited as study participants. We conducted iterative questioning in data collection dialogues with the study participants. We conducted member checks with the study participants of the theories that were formulated if they reflected their views. In conventional qualitative studies, researchers are required to apply the principle of bracketing (neutral territory) during the entire study by which we acknowledged and side-lined our preconceptions before engaging in the study [48], on the contrary, conducting a realist interview requires the investigators to engage with the respondents [21]. Conducting a document review provided us with relevant concepts and theories to engage with the study participants. In this process, we took neither an insider nor an outsider perspective about the programme [21]. Trustworthiness was enforced by actively searching for disconfirming evidence through negative case analysis [49] or deviant case analysis [26] and by keeping an audit trail. Finally, we followed the relevant aspects of the Criteria for Reporting Qualitative Research (COREQ) outlined by Tong, Sainsbury, and Craig [50].

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Study limitations

We applied the process of iterative consultation with the stakeholders during the configurational analysis process. We do acknowledge that this process has the potential to introduce confirmation bias, whereby, with subsequent consultations, the stakeholders tend to agree with whatever the evaluators have presented. We limited this bias by asking the stakeholders to think differently or in a way to improve the theories. Another limitation of the study is related to the fact that while obtaining the assumptions of the programme designers and managers, we did not include stakeholders such as facility managers, the operational staff and patients. Consequently, the programme users' perspectives were obtained based on interviews with managers and providers rather than the programme users.

Conclusion

Based on the interviews with the adherence club programme designers and managers and a document review, three perspectives of how the adherence club intervention is expected to be successfully implemented and achieve the goals of patient retention in care, adherence, and clinic decongestion were identified. This represents the first step towards developing programme theories that explain how the adherence club intervention is expected to work, for whom and under what circumstance. The next step is to assess the evidence on the various mechanisms of action working in other group-based adherence interventions and review the literature on theories that have been explored to explain retention in care and adherence to ART. This will allow us to formulate a programme theory that represents a hypothesis of how the adherence club works which we will subsequently test in empirical studies.

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CHAPTER FIVE

Paper 3

An Exploration of Group-based HIV/AIDS Treatment and Care Models in Sub-Saharan Africa Using a Realist Evaluation (Intervention-Context-Actor-Mechanism-Outcome) Heuristic Tool: A Systematic Review. *Implementation Science* (2017) 12:107. doi 10.1186/s13012-017-0638-0

Abstract

Introduction: It is increasingly acknowledged that differentiated care models hold potential to manage large volumes of patients on antiretroviral therapy (ART). Various group-based models of ART service delivery aimed at decongesting local health facilities, encouraging patient retention in care and enhancing adherence to medication have been implemented across sub-Saharan Africa. Evidence from the literature suggests that these models of ART service delivery are more effective than corresponding facility-based care, and superior to individual-based models. Nevertheless, there is little understanding of how these care models work to achieve their intended outcomes. The aim of this study was to review the theories explicating *how* and *why* group-based ART models work using a realist evaluation framework.

Methods: A systematic review of the literature on group-based ART support models in sub-Saharan Africa was conducted. We searched the Google Scholar and PubMed databases and supplemented these with a reference chase of the identified articles. We applied a theory-driven approach – narrative synthesis – to synthesise the data. Data were analysed using the thematic content analysis method and synthesised according to aspects of the Intervention-Context-Actor-Mechanism-Outcome heuristic-analytic tool – a realist evaluation theory-building tool.

Results: Twelve articles reporting primary studies on group-based models of ART service delivery were included in the review. The Six studies that employed a quantitative study design failed to identify aspects of the context and mechanisms that work to trigger the outcomes of group-based models. While the other four studies that applied a qualitative and the two mixed methods design identified some of the aspects of the context and mechanisms that could trigger the outcomes of group-based ART models, did not explain the relationship(s) between these elements and how they interact to produce the outcome(s).

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Conclusion: Although we could distil various components of the Intervention-Context-Actor-Mechanism-Outcome analytic tool, from various studies of the group-based programmes identified, we could not, however, identify a salient programme theory based on the Intervention-Context-Actor-Mechanism-Outcome heuristic analysis. The scientific community, policymakers and programme implementers would benefit more if explanatory findings of how, why for whom and in what circumstances programmes work are presented rather than just reporting on the outcomes.

Five Keywords: Adherence, group-based ART model, antiretroviral therapy, narrative synthesis, retention in care, realist evaluation, theory-driven review.

Background

Sub-Saharan Africa (SSA) remains the most severely affected region by the HIV and AIDS pandemic, accounting for nearly 71% of the people living with HIV (PLWHA) worldwide [1]. In response to the hyper-epidemics in various countries in this region, and with support from major Global Health Initiatives, HIV treatment programmes – following evidence of the effectiveness of ART – were rapidly expanded from 2005 [2]. Currently, there is evidence that HIV treatment and care can be used to foster the 'test, treat, suppress, and prevent' approach to controlling the HIV pandemic, an approach believed to potentially end AIDS by 2030.

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Antiretroviral treatment (ART) is a 'holistic' treatment approach, whereby taking antiretroviral drugs in compliance with the treatment protocol, eating healthy, and receiving psychosocial support and palliative care is provided as a package [3]. Patients who follow most or all the components of ART have shown improvement in their viral load readings (<400copies/mL), an increase in the CD4 count (>200 cells/mm^3), a lower incidence of opportunistic infections, and an overall improvement in health [4]. For PLWHA to benefit from all aspects of ART, they must be retained within the care umbrella – that is patients need to be tested for HIV, initiated on treatment, retained in care, and reach and maintain viral suppression. Ensuring that patients are retained in care is, therefore, crucial for reaching and maintaining viral suppression and by extension, a successful ART programme [5]. The concept of patient-focused care that has received support for clinic patient management in recent times has promoted individual-focused ART adherence. Nevertheless, it is argued by Haberer et al. that successful population-level

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ART adherence is pivotal to realising the clinical and prevention benefits of antiretroviral scale-up and consequently ending AIDS by 2030 [6].

As HIV treatment and care programmes mature and extend over the years, the need to ensure long-term retention in care for patients receiving ART while continuing timely initiation of new patients into treatment presents an on-going challenge to healthcare providers and policymakers [7]. Although the mainstream treatment scheme (facility-based ART services) has gone a long way towards providing the necessary clinical care that patients on ART need to achieve and sustain viral suppression [8], increasing numbers of patients initiated on ART decrease quality care delivery, making it difficult to maintain population-level adherence. It is estimated that in SSA, on average, only 64% of patients are retained in care after two years on ART [9]. Such sub-optimal retention in care rates have implications for the new three-part HIV treatment labelled "90-90-90" by 2020, and for the vision to end AIDS by 2030 [10].

Evidence from various studies reveals that task-shifting, where specialist clinical care is delegated to primary health care facilities, make efficient use of resources without compromising patient outcomes [11,12]. Nevertheless, this strategy has a limited capacity to provide long-term resolutions to the challenges of patient retention in care if clinics are overcrowded and waiting times are long, as is often the case in South Africa. Consequently, a continuum of strategies ranging from health service-driven to client-driven options has been developed and implemented to optimise ART delivery in various countries in SSA [13–15].

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Alternative antiretroviral treatment models of care

In responding to the need of scaling up treatment for millions of PLWHA while retaining those already in HIV treatment and care, various differentiated care models have been developed. Differentiated care is defined as 'a client-centred approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of people living with HIV while reducing unnecessary burdens on the health system'[16].

The standard facility-based care model usually involves patients visiting the health care facility on a monthly basis, to be seen by a clinician for routine consultation and then by a lay counsellor for their drug accountability assessment and counselling. The patient is then provided with one month's supply of medication from the pharmacy. Differentiated care models on the other hand usually integrate most of the services provided by the standard care model and offer it as a

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tailored package to the suit the needs of different types of patients (patient groups). For instance, patients can be provided with their medication, education and counselling and monitoring services when they are part of a differentiated care model. Differentiated care models are different from mainstream ART service delivery in that they streamline ART services by adapting the care components to the needs of differentiated groups of patients.

Differentiated models usually cover the core activities for providing ART while addressing some of the challenges that patients who use the mainstream clinical care face such as long waiting times, poor access to medication and long distances to the clinic. These differentiated models usually provide minimal clinical screening; quick antiretroviral medication refills; adherence support and defaulter tracing; strict monitoring of attendance and problem solving; and encouraging self-efficacy and mutual support [17]. Therefore, differentiated models of ART service delivery usually adopt a multifaceted approach towards achieving better adherence and retention in care rates. They increase the capacity and efficiency of ART service delivery by tailoring services according to the needs of different patient groups, reducing clinic contact and relying on community-based services for those who are stable on ART.

Most differentiated care models were developed and implemented by organisations such as Médecins Sans Frontières (MSF) and the AIDS Support Organization (TASO) in collaboration with various local governments in SSA [13]. Following their implementation success in pilot projects, differentiated models are increasingly recognised as an essential approach to managing patients on ART [18]. According to Campion, for these alternative treatment models to be successful, they should ensure that drug delivery is patient-centred, they should fit into the lives of the patients, require minimal time, and they should not be linked to clinical consultations [19].

The new WHO guidelines (2015) highlight the need for differentiated care frameworks with variations in service frequency, health worker cadre, service location and service intensity across countries and populations [18]. Duncombe and colleagues designed a framework for HIV treatment services which identifies variations in the intensity of the core programme components that are tailored to the specific needs of different groups of individuals across the cascade of HIV services [20]. This framework focuses on service intensity of four delivery components: type of services delivered; the location of service delivery; the cadres of health service providers involved; and frequency of visits to health [17]. **Figure 1** displays this framework.

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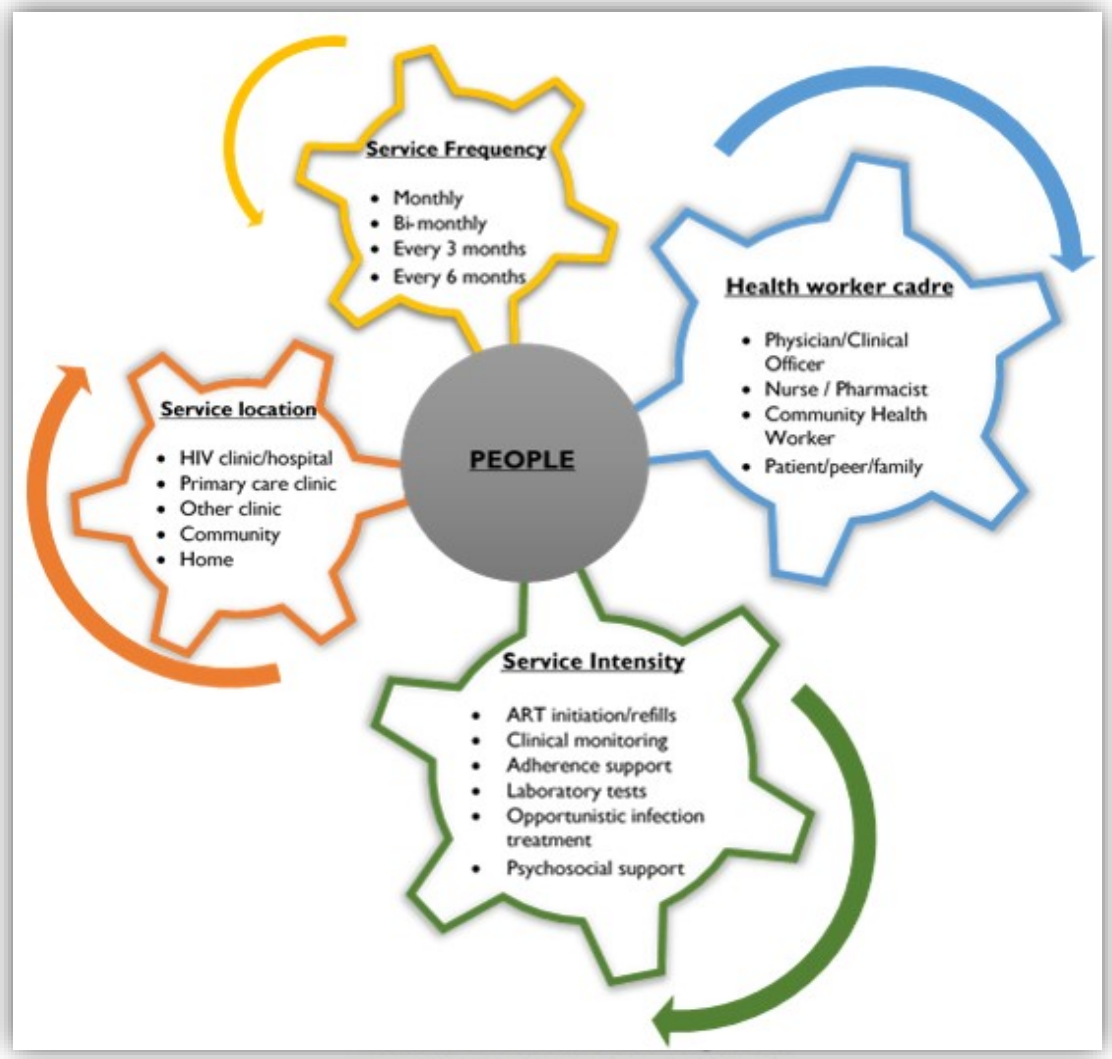

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Figure 1: A framework for differentiated models of ART services (Adapted from Duncombe et al. [17]).

Differentiated care can either be health care worker managed groups or client (patient) managed groups and can either facility-based individual model or out-of-facility individual model [16]. Most individual-focused models of ART service delivery focus on providing psychological support, adherence monitoring and equally address household dynamics potentially impacting on patient adherence [12,14]. The effects of adherence-enhancing interventions targeting individuals are usually small to modest. Because individual-focused models are usually resource-intensive, they tend to fade over time [21]. While group-based care models offer psychological support and ensure easy access to medication and adherence monitoring, they also create a conducive atmosphere for peer-support among the group members. Individual-

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focused models such as home-based care [22,23] and 'accompagnateur' (adherence supporter) [24–26] do not have this aspect of care, except in situations where two or more family members are receiving ART.

Group-based ART delivery models operate on the notion that patients on ART have a mutual self-interest to receive convenient and quality ART services in a conducive and supportive environment, free of stigma and discrimination. To improve the aspect of convenience, most group-based models of ART and HIV care are out-of-clinic care models – brought close to patients. Examples of the abovementioned include Community ART distribution, Community ART groups, and Community–based ART adherence clubs. **Table 1** below presents alternative models for the delivery of long-term ART.

Table 1: Summary of strategies for differentiated models for delivery of long-term ART [13,20]

Key objective		ART Adherence Clubs		Community ART Distribution Point (CADP)	Community ART groups (CAG)	Community Home-Based ART care (CHBC)
		Facility-based club	Community-based club			
Patient Perspective	Reduce cost (time + transport)	• Reduction of clinical visit • Less time spent at clinic for drug refill	• Reduction of clinical visit • Less time spent a clinic for drug refill	• Reduction of clinical visit • Less time spent at clinic for drug refill	• Reduction of clinical visit • Less time spent at clinic for drug refill	• Reduction of clinical visit • Less time spent at clinic for drug refill
	Increase peer support	At club in health facility and potentially beyond into community	At club in community and beyond	At distribution points by expert patients	At CAG meetings in community and beyond	At HBC meetings by the CHWs
	Enhance community participation	No	Potentially	Potentially	Potentially	Potentially
Healthcare service perspective	Reduce workload • Nurse • Pharmacist • Counsellor/CHW Expert patient	Yes No No (facilitation by club)	Yes No No (facilitation by club)	Yes Yes No (Distribution and monitoring)	Yes Yes No (formation, training and supervision of CAGs)	Yes Yes No (formation, training and supervision of HBC)
	Maintain/improve health outcomes • Adherence • Retention	Yes Yes	Yes Yes	Unknown Yes	Unknown Yes	Unknown Yes
	Improve self-management of patient	Adherence support	Adherence support and tracing	Organisation of service for drug refill, adherence support, tracing and testing	Drug refill, adherence support, tracing and testing	Adherence support and tracing
	Decongest facility	No	Yes	Yes	Yes	Yes

CADP = Community ART Distribution Point; CAG = Community ART groups; CHBC = Community Home-Based Care

The effectiveness of group-based ART models in retaining ART patients in care and improving adherence to medication has been assessed in different studies in SSA. Studies on the community ART group (CAG) model in Tete, Mozambique have shown better retention in care rates and lower mortality among ART patients enrolled in the CAG model compared to patients in standard facility-based clinical care [27,28]. Studies on both the facility-based and

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community-based ART adherence club models in the Western Cape Province of South Africa have shown better retention in care and adherence to medication rates among patients compared to those patients in standard ART care [29,30]. Also, based on the findings of a systematic review to assess the effectiveness of group-based adherence models of care, it was concluded that community support programmes could be an effective strategy to improve the effectiveness of ART treatment and care in SSA and elsewhere [31].

It is argued by Chen [32] that theory-driven approaches to programme development improves implementation. The theoretical understanding of how and why individual-focused interventions work have been explored previously using various health behaviour theories [33]. On the other hand, because group-based ART interventions models are complex – typically multi-component and context-dependent – they are challenging to replicate and evaluate [34]. In most instances, not even the programme theories – an explicit theory or model of how an intervention contributes to a set of specific outcomes [35] – of group-based ART interventions models are described. Therefore, our understanding of *how* and *why* group-based ART models achieve better adherence and retention in care rates within their context is limited. To this end, we aimed to review primary studies systematically and develop a narrative synthesis of the mechanism(s) at work during the implementation of group-based interventions for ART adherence support. Identifying the causal mechanisms of group-based ART models is the precursor step in developing programme theories that explain *how* and *why* group-based ART treatment and care models work, for which ART population group and under what circumstances.

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There are three steps in eliciting a programme theory in realist evaluation [36]. Step 1 entails conducting an exploratory qualitative study to identify the assumptions of the programme designers and health service managers on how and why the adherence club intervention is expected to achieve its goals and perceptions on how it has done so. These assumptions are also called “folk theories” [37]. In the second step, we reviewed theories on ART adherence to identify candidate/potential mechanisms provided by ART interventions [38]. The third step, which is the focus of this paper, involves assessing the evidence on how and why group-based ART adherence interventions work by examining their underlining theories using the context-mechanism-outcome (CMO) heuristic – a realist evaluation analytic tool.

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Review questions

Three research questions guided the review:

1. What are the key mechanisms that drive the outcomes of group-based ART adherence interventions?
2. What are the contextual factors that influence the triggering of mechanisms, the implementation and the outcomes of group-based ART adherence interventions?
3. Are there identifiable pathways to the outcomes? If so, how do the key mechanisms and contexts interact to produce these outcomes?

Realist evaluation and generative mechanisms

Realist evaluation is underpinned by a 'generative' model of causality [38]. Identifying the 'generative mechanism' is at the core of eliciting the programme theory. Generative mechanisms describe the causal forces, powers, processes or interactions that generate change within an intervention – including the choices, reasoning and decisions that people make because of the resources provided by the programme. Therefore, the key explanatory element in realist evaluation is the generative mechanism, which elucidates the reasoning in light of the resources, opportunities and/or restraints that lead to action. Following that differentiated models encompass more than a single strategy to enhance adherence and retention in care attributed to resources, opportunities and constraints, a generative mechanism in realist logic is thus mathematically represented as:

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Intervention modalities (Resources, opportunities, constraints) + Actor reasoning = Mechanism.

The same mechanism can produce different results in different contexts (**Figure 2**). This suggests that while the same intervention might instigate the same mechanism(s), the differences in the outcome(s) of an intervention in different settings could be largely associated with the differences in the context within which the intervention is implemented. For instance, if 'motivation' (mechanism) is stimulated by adherence counselling and educational talks (intervention), to improve ART adherence (outcome) among PLWHA (actors), then possible context variations could include the pre-existing group dynamics within the adherence club, the local socio-economic conditions, the local cultural norms, the geographical accessibility of the club, etc. The educational level of patients, the meaning they attach to their disease, and the way

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they cope with it are examples of other patient-related factors that are likely to vary substantially. The level of adherence to medication and retention in care in the different contexts represented by different health care facilities depends on how much the motivation is triggered by the intervention and modified by the various context conditions.

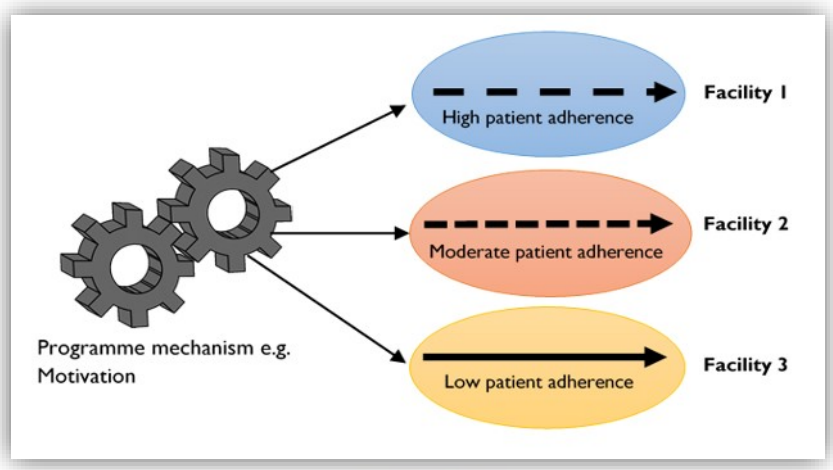

Figure 2: The same mechanism is postulated as generating contrasting outcomes.

Formulating an initial programme theory in realist evaluation involves adopting a 'generative' approach to causation. Pawson and Tilley [37] identified Context, Mechanisms and Outcomes as the three tenets to explaining how and why programmes work or not with the notion that an outcome (O) is generated by a mechanism (M) being triggered in context (C). Considering that intervention work through actors, generative *mechanisms* (M) are used to explain how the *intervention* (I) (or aspects of the intervention) unfolds in a particular *context* (C) and in relation to the various *actors* (A) to produce the observed *outcomes* (O). Representing the intervention modalities (I) and the relevant actors (A) provide a comprehensive representation of how, why for whom and under what circumstances a programme works (or not) [40]. Following this causality conceptualisation, we considered an intervention-context-actor-mechanism-outcome (ICAMO) configuration to provide a comprehensive analytical tool to account for (or explain) aspects of the intervention that provide the mechanisms and the actors through whom the intervention works. In this article, we adopted the ICAMO heuristic tool for the analysis purpose.

To explore potential generative mechanisms that group-based ART models could provide through their various modalities, we carried out a narrative review of the literature, a theory-based review approach, which allows us to explore components of the intervention

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implementation to identify their underlining theory or theories. This study was conducted as part of larger research project "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health care facilities in the metropolitan area of Western Cape Province, South Africa" [41]. The first phase of this project involves eliciting the initial programme theory of the adherence club intervention – what aspects of antiretroviral club intervention work, for what sections of the patient population, and under which community and health systems contexts. An important part of eliciting the initial programme theory is reviewing the literature on how similar interventions that have been implemented are postulated to work, why they work, for whom they work and under what circumstances [42], and this paper presents the findings of that step.

Methods

Study design

We used narrative synthesis (NS) – an approach used to systematically review and synthesise findings from multiple studies. It relies primarily on the use of narratives to summarise and explain the findings of a synthesis [43]. NS is applied when statistical meta-analysis (for quantitative studies) or meta-ethnography (for qualitative analysis) is not possible and when the existing literature includes a wide range of interventions and studies with different (study) designs, which because of the heterogeneity cannot be pooled for analysis [43,44]. Pawson and colleagues [45] suggested that theory-driven reviews are more fruitful approaches to reviewing evidence when evaluating competing interventions addressing the same problem.

NS fits with the logic of realist evaluation – NS requires the reviewer(s) to develop a theory of how the intervention in question works, why and for whom [43]. NS is recommended for reviews addressing questions on the effects of interventions, particularly, the implementation of interventions that are proven to be effective in experimental settings [46]. NS suits the study because most group-based ART interventions have been shown to be effective in pilot studies a recommendation for its use [43,46]. Finally, the heterogeneity of the literature on group-based ART interventions warrants the use of narrative reviews.

NS also fits in with the formulation of the initial programme theory as conceived by realists. The guidance on NS in Systematic Reviews focuses on the effects of interventions ('outcomes') and the factors influencing intervention implementation (which aligns with the notions of

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‘mechanism’ and ‘context’). This approach is thus well matched with the realist logic. According to Arai and colleagues [46], the ‘theory of change’ identified in the first step of a NS provides a way for abstracting the mechanisms into propositions at the end of the synthesis process. Finally, NS is aligned with the epistemological position of realist evaluation.

Identification and selection of studies

The search process proceeded in two phases. First, we conducted an exploratory search to enable us to make an initial judgement on the availability of evidence to answer the review questions. Second, after confirming that there is adequate literature, we searched for primary research studies for possible inclusion in the review. We applied two methods to search for literature: electronic database searching (PubMed and Google Scholar) using keywords and snowballing of citations from the reference list of other authors. The goal was to find primary studies that shed light on the explanatory model of how the group-based ART models work.

The following search MeSH terms were used for the search of the electronic databases: ‘Community-based antiretroviral therapy programme’, ‘Group-based antiretroviral therapy’, ‘Interventions to improve adherence to antiretroviral therapy and retention in care’, ‘Implementation of community-based antiretroviral therapy programmes’, ‘Effectiveness of antiretroviral treatment and care interventions’, ‘Differentiated antiretroviral treatment models’, ‘Alternative antiretroviral therapy interventions’, ‘Group-based adherence intervention to antiretroviral therapy’, ‘Qualitative evaluation of group-based models’ AND ‘in sub-Saharan Africa’. **Figure 3** presents the search process.

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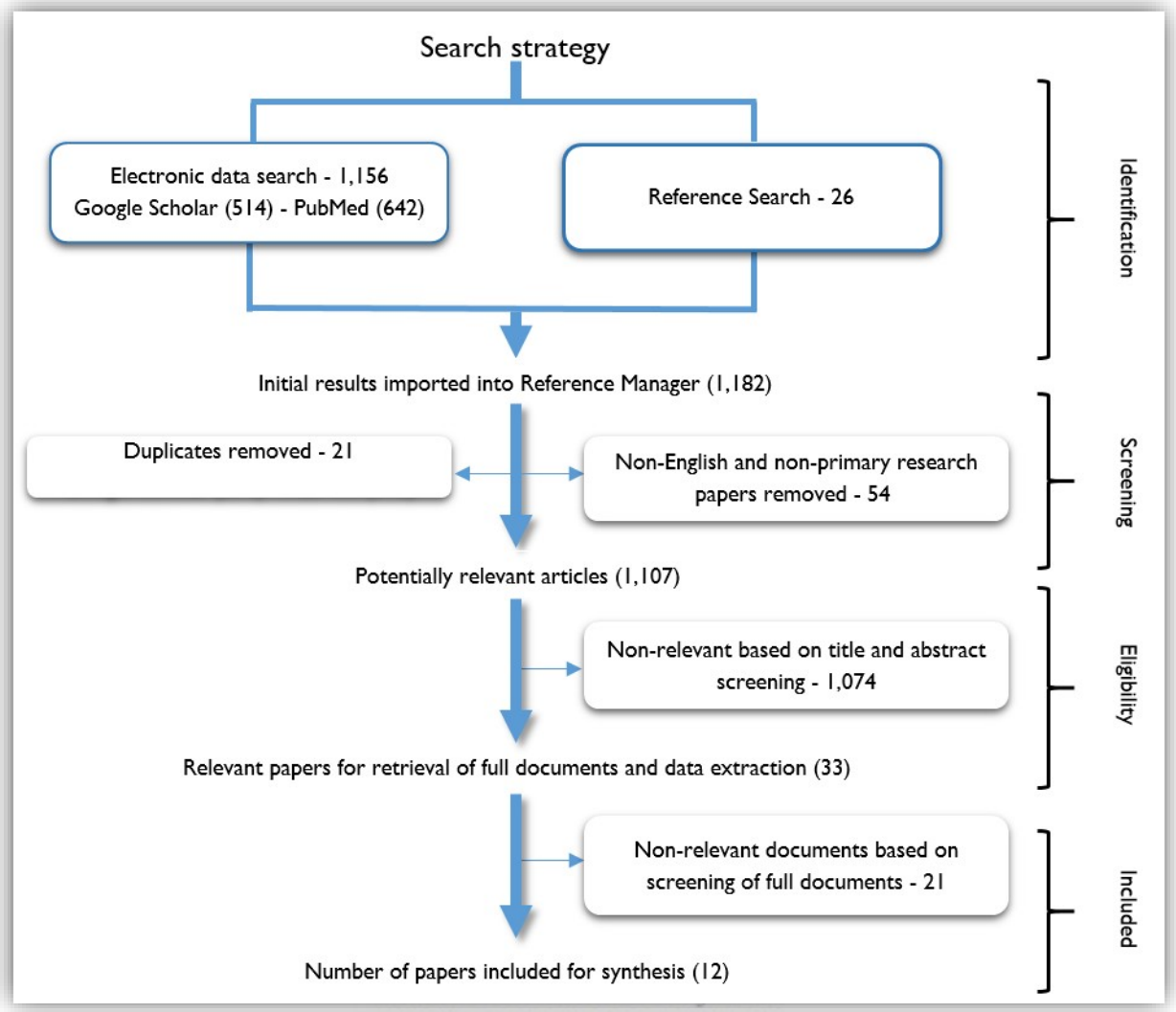

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Figure 3: Article screening process based on the PRISMA protocol

Inclusion criteria

We defined the inclusion criteria for the study selection of the review using the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) mnemonics for qualitative reviews [47].

- ***Sample***: Stable adult (18+ years) patients on ART
- ***Phenomenon** of **Interest***: Retention in care and adherence to antiretroviral medication
- ***Design***: Quantitative, qualitative and mixed-methods studies
- ***Exposure***: Facility-based and community-based group-ART models in SSA
- ***Research type***: Primary research articles on group-based ART models

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Exclusion criteria

- All articles that did not deal with a group-based ART model of treatment and care such as home-based care models.
- Non-English papers
- Papers reporting non-primary research

We used the ReadCube® Reference Management system to screen and manage the retrieval of the studies. The search was conducted in February 2016 and updated in April 2017. The date limit set on the records to search was 2005 – 2016 because group-based ART management models only emerged in the early 2000s.

Ethical considerations

This study is part of a larger project "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health care facilities in the metropolitan area of Western Cape Province, South Africa" which has received ethics clearance from the Higher Degree's committee of the University of the Western Cape [41]. In addition, we followed the relevant standards of utility, usefulness, feasibility, propriety, accuracy and accountability while conduction the review [48].

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Data analysis – analysing the papers for the narrative synthesis

Conducting a NS involves four distinct but interrelated steps [43]:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in the data
- Assessing the robustness of the synthesis

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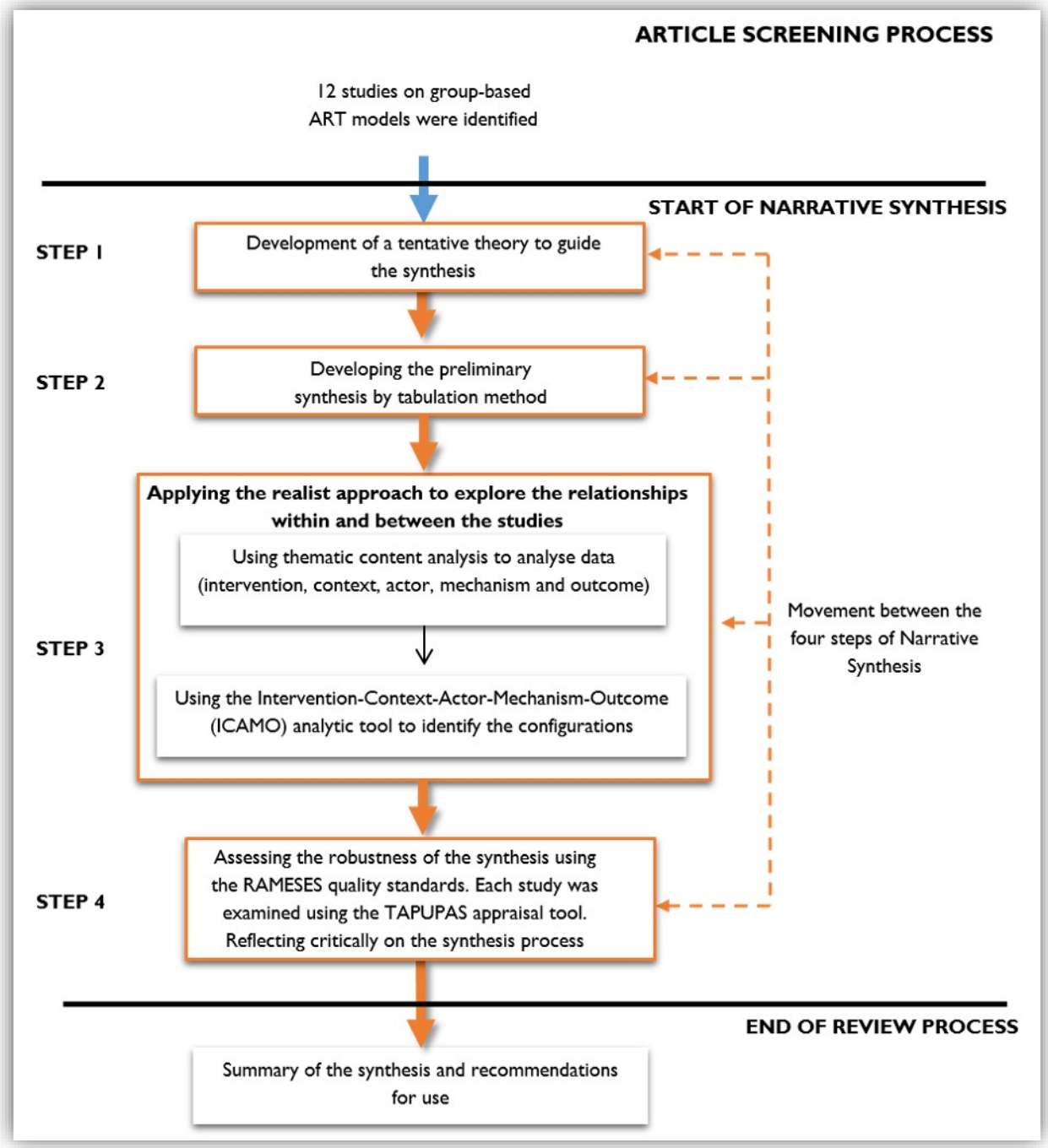

Figure 4: The analytical process of this narrative synthesis

Step 1. Developing a theory of how the intervention works, why and for whom

We developed a theory on how the intervention under investigation works, why and for whom. This tentative theory is meant to guide the synthesis process and is to be refined at the end of the synthesis. We formulated an initial theory guiding this synthesis (**Figure 5**) based on the

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principles of group-based ART models as outlined in the standards of practice of some of these group-based models [20,49] and the folk theories that we formulated from the consultation with the adherence club programme designers and managers [50]. Group-based models of ART services have some basic principles guiding their implementation:

- Task-shifting of services to the lowest level of care provider, from nurses offering ART services to community health workers and in some instances to PLWHA (expert patients).
- Adherence is improved by decreasing the burden placed on patients (time, cost, pills) and by increasing the user-friendliness of care and treatment services.
- Having patients receive their care together to increase peer support among the patients and creating an enabling treatment and care environment.
- By separating the drug-delivery and clinical care and reducing the intensity of the services, the care process is simplified for the providers and made much user-friendly.

We associated the generic components of group-based ART intervention (intervention modalities, actors, context, mechanisms and outcomes) to formulate the initial theory (**Figure 5**). The primary outcomes are adherence to medication and retention in care. The mechanisms were derived from underlying determinants or social behaviours identified in the folk theories and include motivation, trust, encouragement, social support, self-efficacy and buy-in. These mechanisms are expected to be triggered by the various programme components within the immediate (*micro*), organisational (*meso*) and distal contexts (*macro*) [51]. The contextual factors include human resources (staffing dynamics), stakeholder collaboration, availability of conducive physical space and support from the higher level of the organisation. The dashed lines in **Figure 5** indicate that the context goes beyond the immediate environment where the intervention is being implemented, including the organisational and the distal context.

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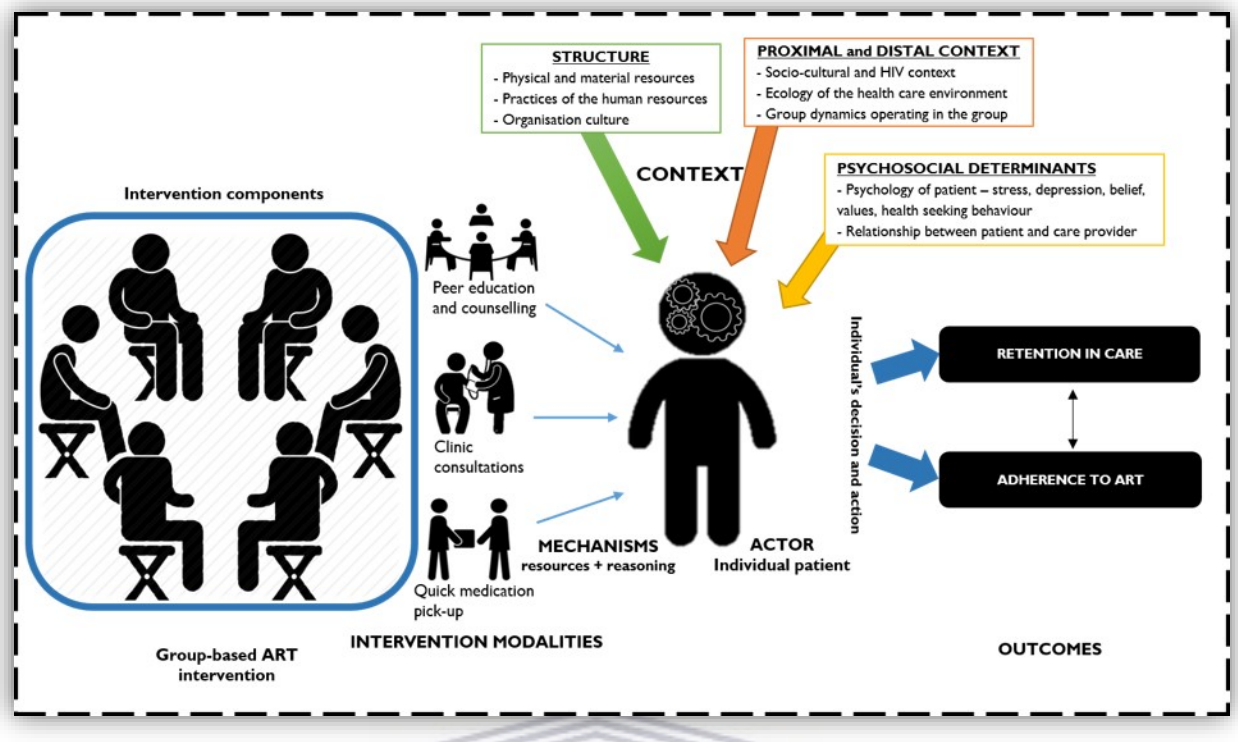

Figure 5: Representation of the initial theory of how group-based ART models work

Data analysis/synthesis

Step 2. Developing a preliminary synthesis - *Extracting data from the included studies*

In the second step, we extracted the data according to the following categories were used: (1) publication citation, (2) study country, (3) participants and setting where the study was conducted, (4) study design, (5) implementation setting, and (6) description of the outcome.

Table 2: Summary of the studies reviewed

Study	Intervention type Country	Description of sample Sample size	Study Design	Detailed Description of Outcomes
Decroo et al. (2011)	Community ART group - Alternative ART collection by a group member in Tete Mozambique.	Stable patients on ART (February 2008 - May 2010) N=1384	Cohort study	1269 (97.5%) were retained in care, 83 (6%) were transferred out, 30 (2%) had died, and 2 (0.2%) were lost to follow-up.
Decroo et al. (2014)	Community ART group - Alternative ART collection by a group member in Tete Mozambique.	Stable patients on ART (February 2008 - December 2012) N= 5729	Retrospective cohort	Mortality and LTFU rates among 5729 CAG members were, respectively, 2.1 and 0.1 per 100 person-years. Retention was 97.7% at 12 months, 96.0% at 24 months, 93.4% at 36 months and 91.8% at 48 months.

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Dudhai & Kagee (2015)	Facility-based adherence clubs - Cape Town, South Africa	Adult 'stable' patients are forming groups of 15-30. N=13 6 patients, 7 Health care workers	Descriptive Qualitative Design	1) The adherence club reduces the time ART users spent at the clinic. 2) Logistical problems associated with the timely and correct delivery of drugs. 3) Sense of belonging and cohesion among club patients 4) Patients become active participants in care rather than passive receivers of health care The adherence club helps to decongest the facility
Grimsrud et al. (2015)	Community-based adherence clubs - Cape Town, South Africa	Stable patients are forming groups of 25-30. Down referred to an adherence club from May 2012 -December 2013. N=2133	Observational cohort	Over an 18-month period, 2113 patients were decentralised to one of 74 CACs (decongestion). LTFU among CAC patients was 2.6%, 3.9% and 6.2% at months 6, 9 and 12, respectively. Kaplan-Meier estimates of viral rebound were 1.4% at six months and1.7% at 12 months. Overall retention on ART was 97.2% at six months and 93.5% at 12 months.
Khabala et al. (2015)	Medication Adherence Club - Nairobi, Kenya	Mixed groups of 25–35 stable hypertension, diabetes mellitus and HIV patients. August 2013 - August 2014. N=1432	Retrospective descriptive study	From a total of 2208 consultations, for both HIV and hypertension/diabetes patients, adherence appears to be high with blood pressure checked in 99%, weight checked by 98% and blood tests ordered correctly in 98–99% of patients. 2208 consultations, 43 (2%) were referred to the regular clinic. The overall loss to follow-up was 3.5% (30).
Luque-Fernandez et al. (2013)	Facility-based adherence clubs - Cape Town, South Africa	Adult 'stable' patients are forming groups of 15-30. November 2007 - February 2011. N=502	Retrospective Observational cohort	97% of Club patients remained in care compared with 85% of other patients. Club participation reduced loss-to-care by 57% and a viral rebound in patients who were initially suppressed by 67%.
Rasschaert et al. 2014	Community ART group - Alternative ART collection by a group member in Tete Mozambique.	October 2011 - May 2012 CAG patients and Stakeholders. 16 FGDs and 24 IDIs	Grounded theory	The CAG model provides cost and time savings for the patients, the certainty of ART access and mutual peer support resulting in better adherence to treatment. Patients also take more active role in their health care (self-management). Group members combine, share and develop their knowledge, experience and personal skills. At the community level, it has strengthened community action, empowered patients.
Rasschaert et al. (2014)	Community ART group - Alternative ART collection by a group member in Tete, Mozambique.	October 2011 - May 2012 CAG patients and Stakeholders. 16 FGDs and 24 IDIs	Exploratory Qualitative	(1) The CAG model was designed to overcome patients' barriers to ART and was built on a concept of self-management and patient empowerment to reach effective results. (2) The daily management of the model is still strongly dependent on external resources, especially the need for a regulatory cadre to form and monitor the groups. 3) The model is strongly embedded in the community, with patients taking a more active role in their healthcare and that of their peers. (4) There is a growing enabling environment with political will and general acceptance to support the CAG model. (5) Contextual factors, such as poverty, illiteracy and the weak health system, influence the community-based model and need to be addressed.

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Rasschaert et al. (2014)	Community ART group (CAG) - Alternative ART collection by a group member in Tete, Mozambique.	October 2011 - May 2012 CAG Stakeholders. Quant data: February 2008 - December 2012 Qualitative data: 16 FGDs and 24 IDIs N=105	Mixed-Methods Design	The counsellors were considered key to form and monitor the groups. The main modifications found were the progressive adaptations of the daily CAG functioning and the eligibility criteria according to the patients' needs. The CAG leads to cost and time-saving benefits and improved treatment outcomes. The model offered a mutual adherence support and protective environment to the members. The active patient involvement in several health activities in the clinics and the community resulted in a better HIV awareness, decreased stigma, improved health seeking behaviour and better quality of care.
Rich et al. (2012)	Community-based ART treatment. Group enrolment and patient support group in Rwanda.	HIV-positive adults starting community-based ART treatment between June 2005 - April 2006 N=1041	Retrospective medical record review.	Among 1041 patients who initiated community-based ART, 961 (92.3%) were retained in care, 52 (5%) died and 28 (2.7%) were lost to follow-up. Median CD4 T-cell count increase was 336 cells/mL from median190 cells/mL at initiation.
Vandendyck et al. (2015)	Community ART group (CAG) - Alternative ART collection by a group member in Lesotho	Six- Eight Stable patients on ART January 2007 December 2010 Qualitative Sample: 8 FGDs and 40 IDIs N=67 Quantitative Sample: N=199	Mixed-Methods Design	One-year retention of among patients in CAG 98.7% and those not in CAG, 90.2%. The CAG members commented that their CAG membership 1) Reduced time, effort, and money spent to get a monthly ART refill. 2) Induce peer support, which enhanced adherence, socio-economic support and empowered members to deal with stigma; and 3) Resulted in the feeling of relief and comfort. 4) Village health workers confirmed increase openness about HIV in their community 5) Clinicians reported a workload reduction 6) Community-led indicated that CAG members promoted health seeking behaviour to the community members.
Venables et al. (2016)	Medication Adherence Club - Nairobi, Kenya	N=106 10 FGDs 19 IDIs with HIV-positive patients and patients with NCDs 15 sessions of observations	Qualitative design	1) MACs reduce stigma for HIV-positive patients 2) MACs reduce waiting times and prevented unnecessary queues

Notes 1: FGD = Focus Group Discussion; IDI = In-depth Interview; N = Sample Size; LTFU = Lost to follow-up

Twelve articles representing six studies were identified. Seven of the studies were on the Community ART Group (CAG) intervention. Five of the studies' settings were Tete, Mozambique [27,52–55], one was in Lesotho [56] and the other one was in Rwanda [57]. Three of the studies examined an ART adherence club intervention implemented in South Africa [29,30,58]. Two studies in Kenya focused on the Medication Adherence Club implemented in Nairobi, Kenya [59,60].

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Results

Step 3. Exploring relationships in the data and between studies: a realist perspective

We applied a two-phase process guided by Realist Evaluation principles (represented by the green boxes in the synthesis process in **Figure 4**).

First, we applied the thematic content analysis approach to systematically identify recurrent or salient themes across the selected studies. This was guided by core elements of the initial programme theory (see **Additional file 1** for coding framework).

Table 3 - Identification of recurrent or salient themes across the selected studies based on the realist logic

Study	Intervention modalities	Actors	Context	Mechanism	Outcome
Decroo et al. (2011)	- A group representative visits the nearest health facility to collect medicines for the group. - Group members could still visit the health centre at any other time - A group meeting is held in the community before each clinic visit, and the designated group leader counts each members' pills - The group representative meets with a clinician who prescribes ART and prophylactic drugs for each group member.	- Stable patients on ART - Adherence counsellor or clinician	- Poverty among ART patients - Perceived stigmatisation of patients when they attend clinics - Treatments guidelines allow for one clinical consultation every six months and monthly supplies of medication.	- Building and reinforcing social networks and peer support - Encouraging greater patient responsibility	- Decrease the financial and economic/social costs of their treatment - Greater responsibility for the management of their own health
Decroo et al. (2014)	- Community ART groups (CAG) - Peer support groups involved in community ART distribution - Mutual psychosocial support	- Stable patients on ART - Group of CAG members	- Difference psycho-social and biomedical characteristics than patients - Difference in adherence profile of patients in the CAG model	None identified*	- Mortality and loss to follow-up rates where better for patients in the CAG group than the clinic cohort - Retention in care rates with time was also improved.
Dudhai & Kagee [50]	- Facility-based antiretroviral adherence club	- Stable patients on ART	- Consistent and timely delivery of medication (failure) - Management of logistics by the host facility - Communication challenges between the host facility and the Chronic Dispensing Unit Staffing dynamics - need for more staff to run more clubs	- Cohesion among club members - ART users view themselves as active rather than passive participants in their care.	- Decongest the clinics so we have more time to spend with the sick patients or the new patients. - Shorter waiting time - Avoids financial loss on the part of the patient

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Grimsrud et al. (2015)	- Community-based antiretroviral adherence club intervention - Support ART maintenance for groups of stable patients in a community health worker-facilitated model with peer-support and increased patient self-management - Shifting the service away from health facilities to be community-based - Most CACs met five times per year	- Stable ART patients - Groups of 25-30 - Community health worker - A professional nurse was assigned as the CAC nurse rotating on a monthly basis.	- Limited resources within the community venue and distance to CHC for supplies - Policies regarding dispensing and distribution - Ensuring access to a clean and appropriate community-based facility - Limited resources within the community venue and distance to CHC for supplies	None Identified*	- Better retention in care - Fewer people lost to follow-up and less attrition from the care programme
Khabala et al. (2015)	- Medication Adherence Clubs - MACs are nurse-facilitated groups of 25–35 stable hypertension, diabetes mellitus and HIV patients who meet quarterly to (i) confirm their clinical stability, (ii) have a short health talk and (iii) receive pre-packed medications. - Routine patient follow-up with clinical officers occurs yearly when a patient develops complications or no longer meets the inclusion criteria.	- HIV and non-communicable disease patients - Professional nurse	None Identified*	- Patient satisfaction	- An efficacious method of reducing clinicians' workload - It also demonstrates a low loss to follow-up
Luque-Fernandez et al. (2013)	Facility-based antiretroviral adherence club - Facilitated by non-clinical staff (counsellors) - Groups of 15 to 30 patients are formed and convene at the clinic during quiet times - Medicines are pre-packaged for each participant and brought to the group by a counsellor who weighs the patients and administers a symptom-based general health assessment. - Any patients reporting symptoms suggestive of illness, adverse drug effects or who have weight loss are referred to the clinic to be assessed by a nurse. - The counsellor or experienced patients lead short group discussions on health issues - A draw blood for viral load and CD4 count testing.	- Stable patients on ART - Non-clinical staff (counsellors) - Professional Nurse	None Identified*	- Group dynamic itself may be an important contributor as was historically motivated	- Administrative efficiency and decongestion of services are key aspects of the model - Improved retention in care might result due to the removal of these and other structural barriers to care - Virologic rebound was lower in the club model
Rasschaert et al. (2014a)	- Community ART groups (CAG)	- Stable patients on ART	- Progressive ministry of health involvement and	- Self-management and patient empowerment	- Decreased workload and better monitoring of patients

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	- Based on the principles of self-management. - Patients rotate to pick up medication supplies for the rest of the group on a monthly basis - Each group elects a group leader, who functions as a spokesperson for the group. - The group members meet regularly in the community, perform monthly pill counts and offer mutual adherence support. - Lay counsellors, assist in forming and monitoring the groups in health facilities and the community	- Group of CAG members - Involvement of other organisations likes MSF - Involvement of the Ministry of health - Lay counsellors	integration of activities in existing health services - Flexibility to adapt to changing patients' needs over time - Community participation - CAG model is well accepted by all stakeholders - Changed mindset of all stakeholders concerning the new healthcare approach - Continuous supervision, training and coaching sessions for patients and health staff - Low educational levels of most patients - Chronic shortage of staff	- Mutual adherence support - Increased assurance of timely access to ART - Motivation of care staff - Strong social links and networks between members	- Better general well-being - Less loss to follow-up and deaths - Improved adherence to treatment - Increased HIV awareness - Increased uptake of HIV testing, and a reduction of stigma
Rasschaert et al. (2014b)	- Counsellor key role in forming and monitoring groups - GAC members participate in HIV-related activities in clinics and community - Group established CAG entry requirements - Flexible application of medical CAG eligibility criteria	- MSF employed counsellors - Stable patients on ART - Group of CAG members	- Permanent presence of counsellors in clinics - Resources for training and meetings - Consistent drug supply - Buy-in from the Ministry of Health - Problems with group formation, rotation system and relationships in groups	- Empowerment of patients - Mutual adherence support - Social control through 'Code of Conduct.' - Bonding between CAG members - Trust relationship - Patients are actively involved in their health decision making - Problem-solving skills	- Better HIV awareness - Improved quality of care provided as supervision is in place - Decreased stigma - Improvement in the quality of health for patients - Better access to drug refills contributed to improved retention on ART.
Rasschaert et al. (2014c)	- Groups comprise up to six stable patients on ART - Monthly, a group member is appointed to collect the drugs on behalf of the group and reports on and receives medical consultations for the group members. - Counsellors, sensitise patients to join groups and monitor the group activities.	- Stable patients on ART - Group of CAG members - MSF employed counsellors	- Weak healthcare system - Shortage in health staff - Lack of infrastructure - Discrimination and social exclusion when monthly attending the clinic. - Cultural beliefs that HIV is caused by spiritual spells and can only be managed by traditional healers - CAG intervention widely accepted among stakeholders	- Patients' active role in healthcare - Social control and group rules - Psycho-social support - Understand the importance of taking medication - Very strong bond and network between the members.	- Reduced workload and improved quality of care in clinics - Better health outcomes - New identity of CAG members in group, clinic and community - The less frequent clinic visits per individual patient reduce the time and cost investment significantly - Better adherence to medication
Rich et al. (2012)	- Patients qualifying for ART were given the option of entering a group of 12–24 persons for ongoing patient education and support.	- Patients qualifying for ART - Trained community health workers, also known as an "accompagnateurs,"	- Targeted support provided to health centres to ensure adequate staffing and retention of trained nurses, plus weekly	None Identified*	- Good retention in care rates is retaining people in care at two years with very low rates of loss to follow-up and death.

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	- Group enrollment consisted of a 3-hour educational session and four individual visits before the initiation of ART. - After ART initiation, groups would attend routinely scheduled visits on the same day and meet for ongoing patient education and social support. - Routine visits occurred monthly for the first ten months and then bi-monthly afterwards		physician supervision visits. - Trained CHWs, also known as an "accompagnateurs," performed daily home visits. - Each patient received a monthly food package valued at the US $30 - Housing assistance, employment training, and school fee support for patients and families in grave socioeconomic circumstances.		
Vandendyck et al. (2015)	**Community Adherence Group** - PLWHA stable on ART was invited to constitute a CAG - CAG members meet monthly in the community. - During the meeting, they verify each other's pill count (adherence) and choose a representative to go to the health facility. - At the health facility, the group representative has a consultation on behalf of the rest of the group members. - Then the representative returns to the community to distribute ART to the fellow group members	- PLWHA stable on ART - Community health workers	- Support from the village head - Separation of monthly ART refills from clinical assessments - Need for a reliable drug supply system to ensure access to ART - Availability of appropriate number of community health workers and lay counsellors to support the formation, training and monitoring of CAGs - Need for clear mechanisms to trigger support or referral back to clinic care to ensure patients and groups in need receive appropriate care - Availability of a simplified monitoring system to avoid increased administrative workload	- Being together, living in the same situation, bring the CAG to form a network of peers - Patients were empowered to take responsibility and to support each other. - Induced peer support, which enhanced adherence - Socio-economic support and empowered members to deal with stigma - Feeling of relief and comfort - Empowerment resulted from a new role for patients	- Village health workers confirmed increased openness about HIV in their community - Community leaders added that CAG members promoted health seeking behaviour to community members - Clinicians reported a workload reduction. - Better retention in care within the first year of CAG membership. - Reduced time, effort and money spent to get a monthly ART refill
Venables et al. (2016)	- Medication Adherence Clubs provide a medication refill system for stable HIV, Diabetes and Hypertensive patients. - Medications are pre-packed and labelled by the pharmacy - MACs are made of 10–30 stable hypertension, diabetes mellitus and HIV patients who meet quarterly to (i) confirm their clinical stability, (ii) have a short health talk	- Stable HIV, Diabetes and Hypertensive patients - Non-medical health educators	- High prevalence of HIV, Diabetes and Hypertension - Support from a non-government organisation - Population living in informal settlements	- Patient satisfaction - social support (mutual adherence support) - acceptability related to advantages, - Empowerment	- MACs reduce waiting times and prevented unnecessary queues - MACs reduce stigma for HIV-positive patients

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	and (iii) receive pre-packed medications. - Fast-tract appointments - Routine patient follow-up with clinical officers occurs yearly when a patient develops complications or no longer meets the inclusion criteria.	

MAC = Medication Adherence Club; CAG = Community ART groups; CHW = Community Health Worker

*No phrase corresponded to the definition of a mechanism as outlined in the coding framework

Following the thematic analysis, we explored the theoretical propositions assumed to represent the functioning of group-based ART models within each paper. First, we searched for the components of intervention, actors, context, mechanism and outcome within each article as they describe the group-based intervention in question. We found that the studies included for the review adequately described the intervention(s) under evaluation and their modalities. Similarly, the actors in the various studies were clearly identified in terms of the patient profiles, and the outcomes were well identified. Concerning the context, however, we observed that some studies provide more information than others but generally, there was a minimal structured discussion. Finally, virtually no paper presented a clear discussion on the generative mechanisms underlying the intervention under investigation. Indeed, we observed that all studies that only applied a quantitative research approach either failed to identify possible mechanisms or only identified a few [29,30,52,53,57,60]. Very few studies identified some contextual factors around the implementation of group-based adherence models [54,59,60].

Because the studies that applied a quantitative design provided little or no information on the possible mechanisms and context conditions that explain the outcomes of the intervention, they provide little information that could help to theorise how group-based interventions work. The qualitative studies [27,55,58,59] and the mix-method studies [54,56] on the other hand, offered more information on the context, mechanism(s) and outcomes. Nevertheless, most of the information from the qualitative studies was produced by three studies conducted by the same group of authors evaluating a singular intervention (Community adherence group) from different perspectives and another group of authors evaluating the Medication Adherence Clubs. These qualitative studies identified potential mechanisms and aspects of the context that could help explain the outcomes of group-based. Mechanisms identified from the selected studies include [perceived] social support (mutual adherence support), acceptability related to perceived advantages, empowerment, patient satisfaction, bonding among group members (trusting

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relationship), motivation, and increased assurance. However, none of the studies explored or demonstrated a relational association between the intervention, context, mechanism and outcomes nor did the studies show a causal explanation of how, why, for whom and under what circumstances do the interventions under investigation work (or not).

In summary, different studies identified different components of the ICAMO heuristic-analytic tool. Most of the studies did not identify all the components of the ICAMO tool. It was especially common with the studies that adopted the quantitative study approach. While some of the qualitative and mixed-methods studies identified most or all of the components of the ICAMO tool, none of the studies provided a conceptualised causal link of these components to explain how and why the interventions work in the context in which they are implemented.

Rigour and trustworthiness

Step 4. Assessing the robustness of the synthesis

The inclusion of articles for the review process was based on two criteria: relevance and rigour. The RAMESES quality standards guided the quality assessment of the articles with regard to relevance [29], while the rigour was judged using a tool designed by the Centre for Reviews and Dissemination for Systematic Reviews in the Social Sciences [54].

We employed the TAPUPAS appraisal tool developed by Pawson and colleagues [41] to judge the relevance of the studies included in the review. This tool has the merit of not restricting itself to validity but also including other pertinent issues related to rigour such as ethics and accessibility [61]. The seven questions in the TAPUPAS appraisal tool embody statements of good principles in research and its reporting. The attributes of the TAPUPAS appraisal tool include [48]:

- Transparency: is the process of knowledge generation open to outside scrutiny?
- Accuracy: are the claims made based on relevant and appropriate information?
- Purposive: are the methods used fit for purpose?
- Utility: are the knowledge claims appropriate to the needs of the reviewer?
- Propriety: has the research been conducted ethically and legally?
- Accessibility: is the research presented in a style that is accessible to the reviewer?
- Specificity: does the knowledge generated reach source-specific standards?

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Overall, the studies that were included in the review met all the criteria stipulated in the TAPUPAS appraisal tool. The studies that were considered relevant for the review were then scrutinised for rigour: each study was assessed in terms of quality. Different evaluation tools were used for different studies based on the study designs. The screening was done using an adapted extraction/critical appraisal form to guide data extraction of studies in a systematic review of the health and social sciences [62]. (**Additional file 2**).

Based on this assessment process, we concluded that the findings obtained based on these studies could provide valuable and credible information on which sound conclusions could be drawn. In addition, the study is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (**Additional file 3**).

Discussion

This study is part of a large research project that applies the realist evaluation approach to study whether, how and why the adherence club intervention for the management stable patients on ART works. In realist research, the first step is to develop the initial programme theory. To do this, we first elicited the opinions and assumptions of the programme designers and managers (also called the folk theories). Based on these assumptions, we formulated tentative programme theories of the adherence club programme. In this paper, we sought to explore if the tentative programme theories that we formulated are compatible with research evidence (both applied research and basic research). We, therefore, conducted a narrative synthesis to identify and examine publications on group-based adherence models, looking at how those programmes were designed (especially their programme theory) and their effectiveness. We then assessed whether and how the studies produced evidence that could inform and refine our folk theories.

We found, not entirely unexpectedly, that the quantitative studies we identified did not provide sufficient information on the context and mechanisms that come into play to trigger the outcome. Although the four qualitative studies and the two mixed-method studies we found identified and described some of these elements, the association between these components and the explanation this may provide to account for the outcomes was not explored nor demonstrated. In other words, none of the studies provided evidence regarding the potential interplay between the aspects of the intervention, relevant context, significant actors, generative mechanisms and the outcomes of interest (causal explanation). This was identified by examining each of the identified studies through the ICAMO analytic tool. Consequently, they do not inform in an

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explicit manner how, why, for whom and in what circumstances that the evaluated group-based interventions work (or not).

Granting that the kind of studies we identified are useful in that they aim at assessing effectiveness, it would benefit the scientific community, policymakers and programme implementers more if details on the context and mechanisms of interventions designed to change behaviours were provided and if the evaluators would identify the causal processes underlying the observed results. This recommendation is echoed by calls made by implementation scientists to increase the use of theory to build knowledge about what works, where, and why' [63]. Van Belle et al. also proposed that theory-driven approaches such as the realist evaluation approach have the potential to demonstrate the complex interplay between the components of a programme (or an intervention), relevant context conditions, actors involved, causal mechanisms and expected outcomes [64].

Strengths and limitations

Using the NS allowed us to preserve the integrity of the findings of the different types of studies that are reviewed, as the method does not seek to quantify findings that are narrative or qualitative in nature, nor does it attempt to describe the qualities present in numeric data [65]. Also, the use of categorical codes allowed for mediating between two forms of data which helped us to move from reported findings to higher levels of abstraction [65]. However, applying this method required us to rely on the descriptions of interventions supplied by the authors, and this could be a potential limitation of this approach.

Other limitations are related to the use of only two databases for the search of the studies for inclusion in the review. This introduces the possibility of missing out other studies that could be relevant to the review objective fitting the inclusion criteria. This potential loss was compensated to a certain extent by conducting snowballing of references along with the database search.

Conclusion

The types of studies identified in this review present a wide range in their evaluation approaches. Most of the quantitative-based approaches, unsurprisingly, provide little if any information on context and mechanisms. The qualitative studies somehow described context and mechanisms

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but did not go beyond description and conjecture. Because these studies did not identify nor demonstrate causal relationships, they did not provide information to guide the development of the initial programme theories underlying the ART adherence club interventions. In light of this challenges, we suggest that a way forward towards understanding how the adherence club intervention and other group-based adherence models work is to review the literature of other disciplines for possible theories on adherence to ART and/or chronic medications.

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CHAPTER SIX

Paper 4

Exploring "generative mechanisms" of the antiretroviral adherence club intervention using the realist approach: a scoping review of research-based antiretroviral treatment adherence theories. BMC Public Health. 2017;17:385. doi: 10.1186/s12889-017-4322-8

Abstract

Background: Poor retention in care and non-adherence to antiretroviral therapy (ART) continue to undermine the success of HIV treatment and care programmes across the world. There is a growing recognition that multifaceted interventions – application of two or more adherence-enhancing strategies – may be useful to improve ART adherence and retention in care among people living with HIV/AIDS. Empirical evidence shows that multifaceted interventions produce better results than interventions based on a singular perspective. Nevertheless, the bundle of mechanisms by which multifaceted interventions promote ART adherence are poorly understood. In this paper, we reviewed theories on ART adherence to identify candidate/potential mechanisms by which the adherence club intervention works.

Methods: We searched five electronic databases (PubMed, EBSCOhost, CINAHL, PsycARTICLES and Google Scholar) using Medical Subject Headings (MeSH) terms. A manual search of citations from the reference list of the studies identified from the electronic databases was also done. Twenty-six articles that adopted a theory-guided inquiry of antiretroviral adherence behaviour were included for the review. Eleven cognitive and behavioural theories underpinning these studies were explored. We examined each theory for possible 'generative causality' using the realist evaluation heuristic (Context-Mechanism-Outcome) configuration, then, we selected candidate mechanisms thematically.

Results: We identified three major sets of theories: Information-Motivation-Behaviour, Social Action Theory and Health Behaviour Model, which explain ART adherence. Although they show potential expaning adherence behaviours, they fall short in explaining exactly why and

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how the various factors they outline combine to explain positive or negative outcomes. Candidate mechanisms indentified were motivation, self-efficacy, perceived social support, empowerment, perceived threat, perceived benefits and perceived barriers. Although these candidate mechanisms have been distilled from theories employed to explore adherence to ART in various studies, the theories by themselves do not provide an explanatory model of adherence based on the realist logic.

Conclusions: The identified theories and candidate mechanisms offer possible generative mechanisms to explain how and why patients adhere (or not) to antiretroviral therapy. The study provides crucial insights to understanding how and why multifaceted adherence-enhancing interventions work (or not). This has implications for eliciting programme theories of group-based adherence interventions such as the adherence club intervention.

Introduction

HIV/AIDS remains a major problem in many regions of the world, especially in Sub-Saharan Africa (SSA). Since its inception in the early 1980s, major progress was made towards fighting the epidemic. Through the rapid rollout of antiretroviral therapy (ART), at least 15 million people were accessing ART by 2015 globally [1]. However, most health systems in SSA face numerous new challenges emanating from scaling-up ART for people living with HIV/AIDS (PLWHA). Prominent among these challenges are sub-optimal adherence to ART, poor retention in care, and congestion of the primary health care (PHC) facilities [2].

Some solutions to addressing these challenges have been provided through the design and implementation of various HIV treatment and care models. In most cases, these models are designed to operate parallel from mainstream ART care delivery, thus known as differentiated models. These differentiated models streamline ART treatment and care and adapt the care components to the needs of the targeted group. Results from evaluation studies show that models of differentiated care have the potential to address the issues of sub-optimal adherence to ART medication, poor retention in care and to decongest the PHC facilities [3]. Therefore, differentiated HIV treatment and care is increasingly acknowledged as an essential approach to improving ART programmes and service delivery.

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Background

Increased universal access and improved effectiveness of antiretroviral drugs have re-defined the HIV epidemic from a deadly infectious disease to a chronic disease [4]. Thus, the health care needs of ART patients resemble those of people with chronic non-communicable diseases [5]. As a result, the treatment and management of HIV conform to the management of chronic diseases, which focuses principally on adherence to medication, retention in care and management of co-morbidities. Consequently, HIV treatment and care are faced with similar challenges of poor retention in care and suboptimal adherence to medication.

Optimal long-term adherence (>95%) is seldom achieved, although perfect adherence (100%) is recommended for patients on ART. It is observed that most PLWHA show periods of high-level adherence followed by periods of low-level adherence [6]. Moreover, adherence rates tend to decrease as patients' time on ART increases [7]. Although earlier studies suggested that a 95% or more adherence rate to HIV medication was required to achieve medication effectiveness, with the advent of more potent regimens, a moderate adherence (75%) can still produce the required viral suppression without producing drug-resistant mutations [8]. Nevertheless, some patients still fail to maintain moderate adherence to ART for various reasons.

Adherence to ART is complex and dynamic [9]. Adherence (with regard to ART) entails following the treatment plan, taking medications as prescribed (times and frequencies), and following instructions regarding food and other medications [10, 11]. The focus of this definition is on medication use and it highlights the notion of patients conforming to the recommendations of the care providers [4]. To achieve sustained use of ART and therapeutic goals, the patient is required to adopt an effective self-management strategy, maintain contact with the health system to ensure continued, uninterrupted drug supply, and use other important monitoring services such as CD4 count and viral load measurement.

Achieving a sustained engagement under the care umbrella is key to obtaining good clinical outcomes for patients on ART [10]. The concept of sustained engagement or retention in care relates to the ability of patients to adhere to critical aspects of care, such as attending regular follow-up appointments, doing scheduled lab tests, and other monitoring activities [11]. The World Health Organization [12] defines retention in care as "the engagement in a comprehensive package of prevention, support and care services irrespective of the particular

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clinic site." For patients who are on ART, therefore, remaining in care offers patients the opportunity to receive their ARV medication without interruption, of being assessed for possible medication toxicities, of being managed of side effects and detect treatment failure as soon as it occurs to take the necessary action [13]. In addition, being retained in care should provide patients with access to psychosocial support and secondary prevention messages that can guide the patients towards optimising self-management of their lifelong condition.

Poor retention in HIV care and adherence behaviours pose major challenges to the effectiveness of ART. Adhering to medication and remaining in care has the potential to improve the quality of life of patients and prevent further spread of the HIV infection. Various studies have explored the barriers and facilitators to adherence and retention in care for patients on ART [14–16]. As **Table 1** illustrates, a large number of factors have been identified.

Table 1: Barriers/facilitators to adherence and retention in ART care in Sub-Saharan Africa

Category	Barriers	Facilitators
Individual-Related Factors	• Age (being younger) • Depression (Mental health) • Forgetfulness • Substance abuse • Poor self-efficacy • Low Health literacy • Perceived wellness	• Age (being older) • Good self-efficacy • Good health literacy • Constructive Health beliefs
Medication-Related Factors	• Medication side effects • Medication dosing (Complex regimen) • Treatment fatigue	• Simple drug regimen • Simple dosing • Use of mechanical devices and technologies
Health System Factors	• Access to ART (Medication stock outs) • Relationship with health care providers • Staff shortages • Long waiting times • Poor services delivery	• Adequate availability of human resources • Adequate availability of resources • Good relationship with health care providers
Socio-economic Factors	• Poverty • Lack of family support • Food insecurity • Stigma and discrimination • Transportation challenges	• Short distances and reduced transport fees • Financial viability
Socio-cultural Factors	• Alternative treatment • Male dominance and gender-based violence • Religious beliefs	• Beneficial socio-cultural practices • Social support

There is currently a consensus that to address issues of non-adherence and suboptimal retention in care, a variety of ART adherence support interventions has to be conceived and implemented. These interventions range from individual-level interventions to relational (patient-provider

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relationships such as continuity of care) to health systems interventions (e.g. task-shifting and medication distribution systems). Interventions for improving retention in care and adherence at the individual and relational level and for which there is evidence include psychosocial assessment and treatment, medication adherence counselling, home visits / a buddy system, directly observed therapy, reminder systems through Short Message Service (SMS), improving clinic accessibility, and social support [17]. **Table 2** presents various adherence intervention types to improve adherence among patients on ART.

Table 2: Types of interventions to improve adherence [18]

Intervention level	Intervention	Intervention type
Individual	- Adherence monitoring	- Behavioural
	- Directly observed therapy	- Behavioural
	- Reminder systems (SMS)	- Behavioural
	- Pre-treatment education	- Cognitive
	- Counselling (motivational counselling)	- Cognitive - Biological
	- Food parcels	
Relational	- Peer support	- Affective
	- Home visits	- Affective
	- Treatment partner/buddy system	- Affective
Health system	- Task-shifting	- Structural
	- Simplifying medication	- Structural
	- Alternative distribution	- Structural
	- Antiretroviral chronic clubs	- Multifaceted
	- Community adherence groups	- Multifaceted

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Although theories have been employed by researchers to understand how each of these single ART adherence support interventions (e.g. motivational counselling) work at a certain point in time, the long-term effectiveness of these interventions has not been established. According to Simoni et al. [18], the effects of each of these adherence-enhancing interventions targeting affective, cognitive, behavioural or biological aspects are usually small to modest and tend to fade over time. To achieve effective and sustained effects, community-based ART models employing a combination of patient-related, relational and health system-related interventions have been proposed [19]. According to the World Health Organization [20], multifaceted – use of two or more adherence-enhancing strategies – interventions should consider "*a combination of actively involving patients in their own healthcare decisions, provision of appropriate*

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support, multidimensional educational programmes that teach behavioural skills to the patient to enhance his or her adherence, and tailoring of the regimen to fit the patient." Examples of such interventions include the ART adherence club intervention in Western Cape Province of South Africa [21], the community adherence group in Tete, Mozambique [22] and Lesotho [23] and the medication adherence club in Nairobi, Kenya [24]. These interventions have shown better results with regard to the retention of patients in ART care and adherence to ART compared to the standard care operated within the various health facility settings [25–28].

The evidence of the effectiveness of single interventions targeting the behavioural, cognitive, affective or biological aspects of patients on ART is mixed [28]. A review of qualitative studies conducted by WHO revealed that factors such as stigma and discrimination undermine the success of single ART adherence-enhancing interventions [29]. It has been demonstrated that the effectiveness of these interventions could be enhanced "when delivered in a way that resonates with local cultural norms, religious beliefs and socio-economic development" [30]. We conclude that for better benefits, multifaceted, long-term and flexible approaches that target specific barriers to adherence may offer an opportunity for success as they seek to address barriers to medication adherence at all levels while reinforcing adherence behaviours.

The evaluation of the effectiveness, efficacy and performance of multifaceted adherence-enhancing interventions has been conducted in various settings. There is evidence that these interventions produce better results with regard to improving and sustaining adherence to ART and retaining patients in care compared to various standard treatment and care schemes operative in the various contexts [31]. Recently, there is an impetus to evaluate such programmes, not only to inform their efficacy and the effectiveness, but evaluators are encouraged to also unearth the "programme theory" [32] – a theory, model or set of assumptions of how and why an intervention contributes to a set of specific outcomes [33] – that underpin these interventions.

This study is nested within a larger project, "Realist evaluation of the antiretroviral treatment adherence club programme in selected primary health care facilities in the metropolitan area of Western Cape Province, South Africa" [34]. The first step of this realist evaluation is to elicit an initial programme theory of the adherence club intervention. To start, we explored the perspectives and assumptions of the programme designers and managers [35]. We then reviewed the literature on how similar interventions that have been implemented work, why they work, for whom they work and under what circumstances. In this paper, we report on a

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scoping review of various (social science / psychological / behavioural) theories applied to explain adherence to ART. The aim was to identify and assess the use of theories in the adherence literature and to see whether we could draw additional mechanisms from that literature, which could help us to refine the initial programme theory that will be empirically tested.

Understanding 'mechanism' in realist evaluation

Realist evaluation is a member of the family of theory-based evaluation approaches [36]. It operationalises the causal mechanisms that are likely to operate for a programme to work and the contexts in which these mechanisms are triggered to lead to the outcomes. Realist evaluation begins by eliciting an initial programme theory, which is subsequently tested, often by employing qualitative and quantitative research methods. The initial programme theory is revised based on the empirical findings and can lead to the forming a middle range theory that explains in which contexts the intervention works by triggering specific mechanisms. Realist studies do not only answer the question 'what works?' but 'how or why does this work, for whom, in which circumstances?' [36].

While conducting a realist evaluation, identifying the 'generative mechanism' – the underlying social drivers of behaviour – is key, as it is one of the central elements of its explanation strategy. Pawson and Tilley explain that when programmes are implemented, they provide a resource, an opportunity or a constraint of some kind that influences the target person's decision-making [36]. Therefore, a generative mechanism is "*the process of how subjects interpret and act upon the intervention (or components of the intervention)*" [37]. Lacouture and colleagues offered another description of 'mechanism' from a public health perspective: "*a mechanism is hidden but real. It is an element of reasoning and reaction of agents in regard to the resources available in a given context to bring about changes* [outcome] *through the implementation of an intervention and evolves in an open space, time and open system or relationships*" [38]. Based on these definitions, three main characteristics of mechanisms can be identified: (1) they are usually invisible; (2) sensitive to variations in context, and (3) generate outcomes [39].

The other two components required to complete theory building in realist evaluation are context (of action) and outcome [40]. According to generative causality in realist evaluation, a generative mechanism can only be triggered in specific context conditions to cause the expected outcome. This causal relationship is represented thus: an outcome (O) is generated by a

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mechanism (M) being triggered in context (C). In realist evaluation, this relationship is explored using the context-mechanism-outcome (CMO) configuration heuristic [36, 41]. To facilitate understanding, the intervention (I) and the actors involved in the intervention (A) are also being represented, leading to the Intervention-Context-Actor-Mechanism-Outcome (ICAMO) configuration [42].

From our previous work on framing the concepts of ART adherence and retention in care using realist logic, we developed the framework presented in **Fig 1**. This framework illustrates that the resources (information, skills, material resources, support) provided by the adherence club intervention, works through mechanism(s) acting through the actors (patients, lay counsellors and clinicians), which [the mechanisms] are sensitive to various contexts (distal and proximal), to *cause* the intended outcomes (adherence to medication and retention in care). Our conceptualisation considered both psychological and relational (social) mechanisms. Examples of psychological mechanisms include motivation, self-efficacy and empowerment as these emerge from an individual's cognition. The relational mechanisms were considered with regard to the relationship that the patient shares with the care providers (e.g. trusting relationship and social support) and fellow group members (group dynamics and culture that exist within each group). These are in essence *relational mechanisms* that causally affect people by virtue of the individual's position relative to his/her social relationships. Therefore, with regard to group-based adherence models, mechanisms can play out at the level of individuals, dyadic relations (between provider and patient, for instance) and/or the group.

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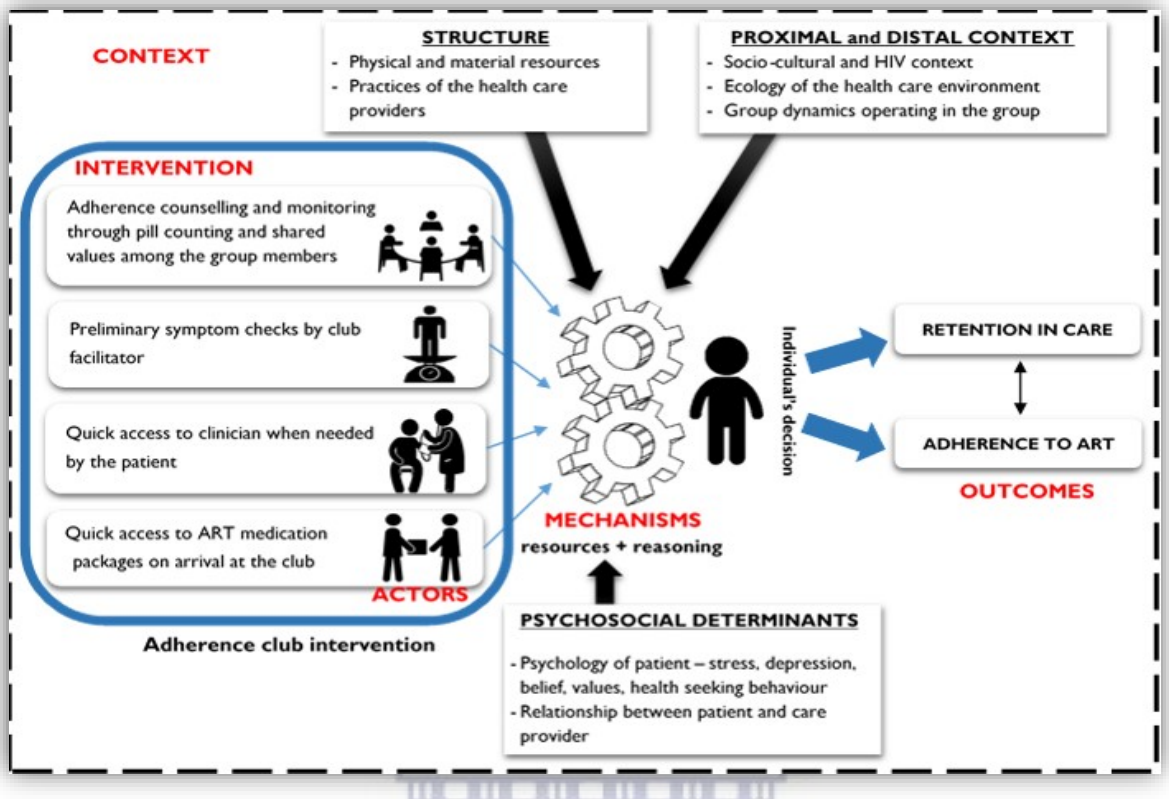

Figure 1: A framework representing how and why the adherence club intervention works

Methods

We carried out a scoping review [43], with a narrative integration of the relevant evidence [44]. The approach allows for the identification and review of theories and concepts and for summarising empirical and theoretical literature to develop a comprehensive picture of a particular phenomenon. We aimed at reviewing, critiquing and synthesising the literature on theories that are used to explain how adherence-enhancing interventions work or are expected to work. The narrative integration of the relevant evidence holds the potential to integrate the literature on these theories into frameworks as well as generate new perspectives to develop a meta-theory – the means of conceptual exploration – across theoretical domains [45].

Conducting a scoping review following the guidance of Arksey and O'Malley [43] suited our purpose because our focus was not primarily on the study designs and the findings that the studies presented, but rather on the theories that guided the conceptualisation of the studies. For this reason, there was no need to conduct a methodological appraisal of the studies that were included in the review. In conducting the review, we followed the five iterative steps: (1)

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Problem identification; (2) Literature search; (3) Data collection: Extraction of data from selected literature; (4) Collate, summarise and report the results; (5) Discussion of results.

Problem identification

Various reviews have been conducted to identify and investigate the roles of health behaviour change theories and health psychology theories in developing strategies to improve HIV/AIDS medication adherence [46]. With this review, we aimed at searching for research-based (peer-reviewed) application of behaviour change theories to provide explanations of how adherence-enhancing interventions work, with the overall goal of developing an initial programme theory of a group-based adherence intervention – the adherence club intervention.

Literature search

The first author and a research assistant searched for articles for possible inclusion in the review. We applied two methods to search for papers: electronic database searching (PubMed, EBSCOhost, CINAHL, PsycARTICLES and Google Scholar) and manual reference list search. We searched each database using the following Medical Subject Headings (MeSH) search phrases "Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models." We also searched the reference list of the papers identified through the database search. We defined the inclusion criteria for the review using the PICOT mnemonics for reviews.

- ***Patient population***: Adult (18+ years) patients on ART
- ***Intervention or Interest area***: Adherence (compliance theories)
- ***Comparison interventions***: Depends on study
- ***Outcome***: ART adherence and retention in care
- ***Time***: 2000 – 2015

We excluded non-English papers. We assessed the search hits and selected only the articles with relevant titles. We stopped searching for articles when we reached saturation, ie. when no new papers were identified. **Table 3** below illustrates the data search process and the final number of studies that were retained for review.

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Table 3: Search terms used and number of articles identified

Database	Keywords used	References identified	Selected
Psych ARTICLES	Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models	25	7
CINAHL	Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models	173	12
ScienceDirect	Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models	4,137	9
PubMed	Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models	735	18
Google Scholar	Adherence [OR] compliance to antiretroviral therapy [AND] theories [OR] models	11,470	23
Manual Search	Titles using related to adherence or compliance to antiretroviral therapy theories and models	15	15
Total			84

The screening of the 84 articles was conducted by the first author and the research assistant and proceeded in three stages: (1) screening by title, (2) screening by abstract, and (3) reading the full article. Twenty-six (26) articles were obtained for the inclusion in the review process. **Figure 2** outlines the data screening and selection process following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram protocol.

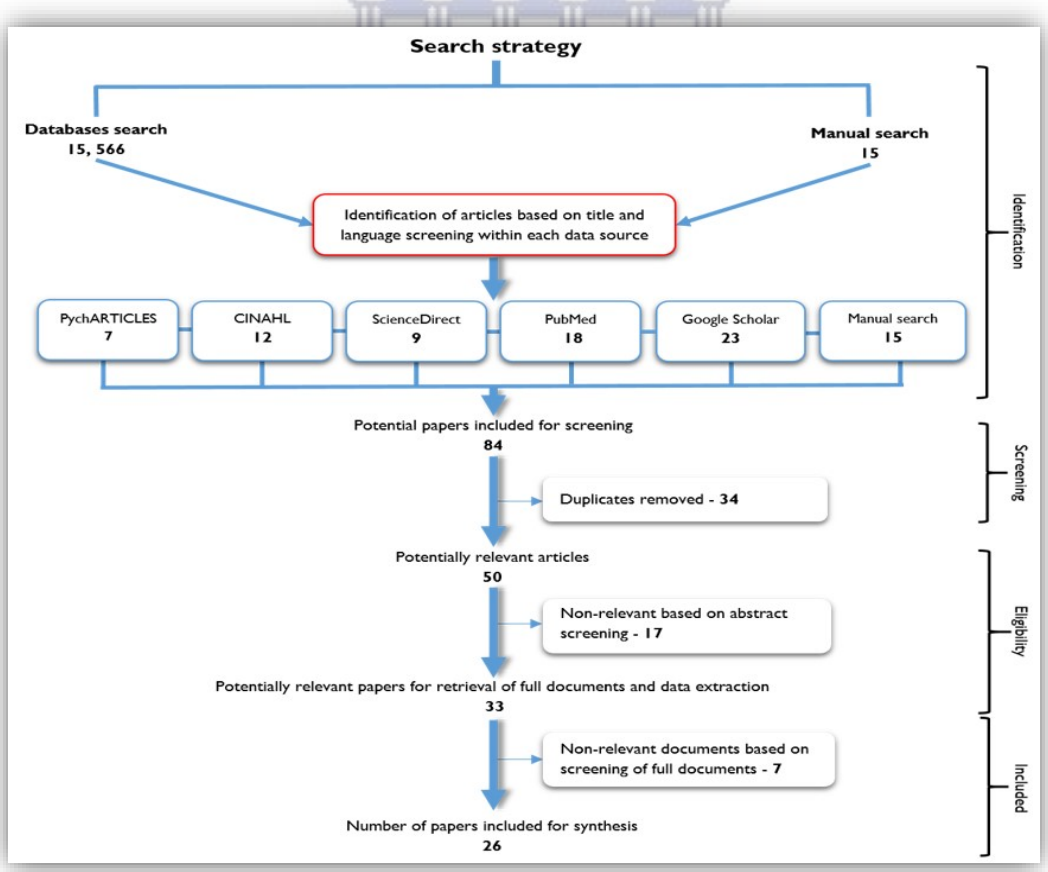

Figure 2: Article screening process based on the PRISMA protocol

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Data collection

Extraction of data from the identified papers was done under the following topics: (1) Study citation and setting, (2) Study purpose and theory of interest, (3) Study design and methods, (4) Study limitations, (5) Quality of evidence, (6) Conclusions/Recommendations. Refer to **Additional file 1** for the data extraction process.

Analysis

We examined each theory to see if it would provide us with insights that would help in identifying context, mechanism and outcome components as defined in realist terms (**See Additional file 2 - 'Data code manual**). We then assessed to what extent the theories could inform a generative causality using the intervention (I) leading to outcome (O) by triggering a mechanism (M) in context (C) for specific actors (A) conceptualisation. Following this assessment, we identified the possible mechanisms – the underlying social drivers of behaviour – from each of the theories that showed potential to explain ART adherence in the realist sense.

Results

Characteristics of sampled studies

We summarised the characteristics of the studies under the following topics: Evidence type, research approach, study design, objective of theory inquiry, and study setting (continent). **Table 5** below shows the general characteristics of the 26 studies included in the review. It should be noted that 17 out of the 22 primary research papers used a quantitative approach.

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Table 5: Characteristics of the studies included in the review.

Characteristics	N
Evidence type	
Primary research	22
Review article	2
Commentary	2
Research approaches	
Quantitative methods	17
Qualitative methods	5
Reviews	2
Commentaries	2
Study design	
Cross-sectional survey	9
Cross-sectional interviews	5
Randomised controlled trial	4
Within-subject comparison design	1
Systematic review	4
Elicitation (theory) design	1
Participatory research	1
Qualitative exploratory	1
Objective of theory inquiry	
Application of model to ART adherence	8
Theory testing	11
Model development	1
Conceptualisation of factors into a model	6
Study setting (continent)	
Africa	2
North America	18
South America	1
Europe	2
Not applicable	3

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Identified theories

The graph below (**Figure 3**) represents the various theories that are discussed, tested or developed in the identified studies.

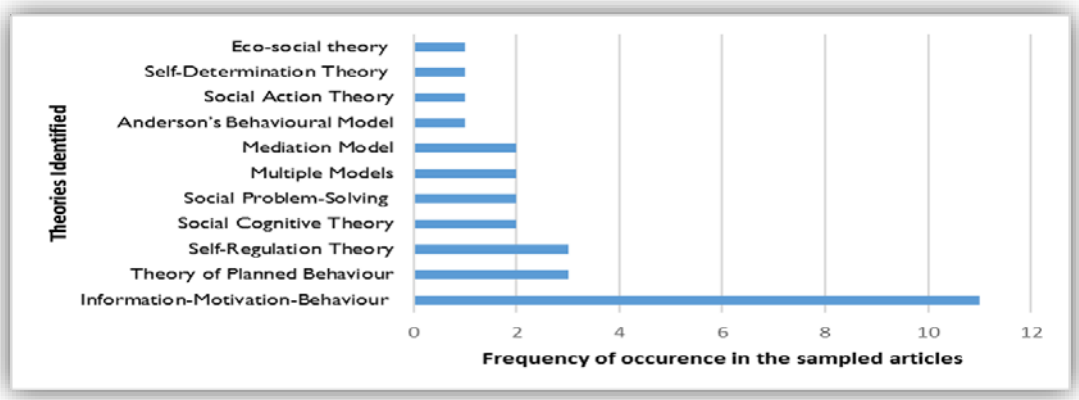

Figure 3: A graphical representation of the theories identified in the studies included in the review and the frequency of their occurrences

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According to our judgement, three of the 11 theories applied to explain adherence to ART identified in the review featured conceptualisations that are consistent with the realist logic of causality: Information-Motivation-Behaviour [47], Ewart's Social Action Theory [48] and the Health Behavioural Model [49]. In the section that follows, we look into the framing of these theories.

Information-Motivation-Behaviour (IMB) model

The Information-Motivation-Behaviour (IMB) model was discussed in 11 of the 26 articles that were included in the review. Some of the articles applied the IMB model to explain adherence to ART, or to conceptualise the factors affecting patients' adherence to ART while others used the IMB model to develop an explanation on how ART adherence occurs [50–60]. Based on the IMB model, "well-informed, well-motivated patients who possess adequate skills for enacting complex patterns of adherence-related behaviour will adhere to their ART regimen optimally over time"[57]. However, what is missing is how Intervention, Context and Mechanism interact to cause that Outcome. **Figure 4** indicates how the IMB model is used to explain adherence to ART.

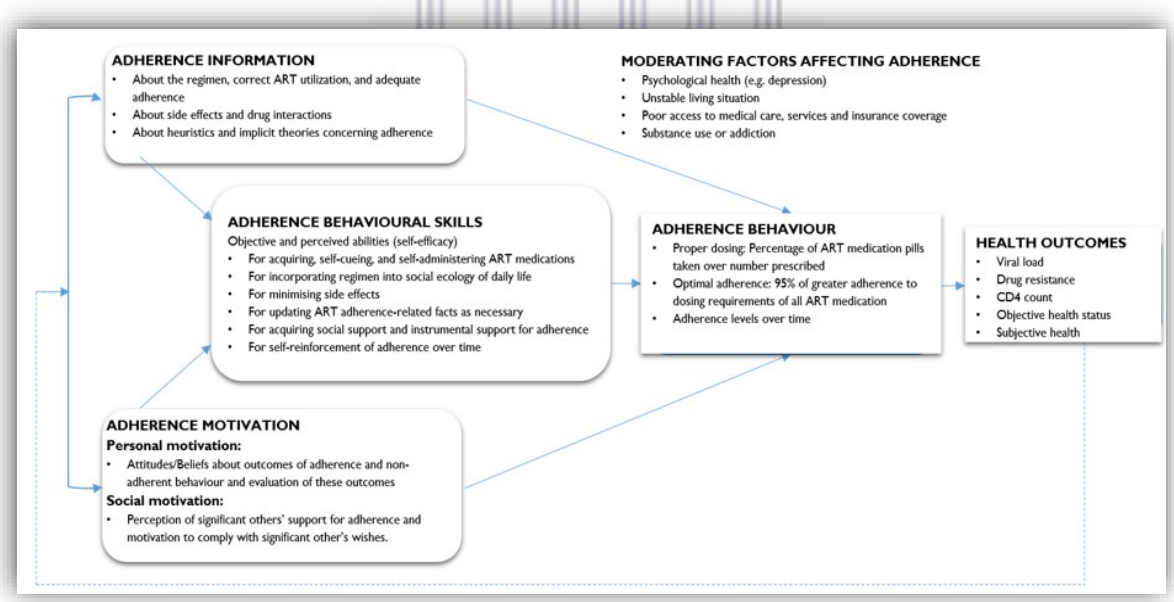

Figure 4. An information-motivation-behavioural skill model of antiretroviral therapy adherence. Adapted from Fisher & Fisher [47].

In **figure 4**, adherence information is (part of) the intervention that the patient receives. This information relates to the regimen, correct use of ART and the importance of adequate

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adherence. Additional information offered to the patients relates the side effects of the medication and possible drug interactions. According to the IMB model, this information can be a source of motivation for the patient (motivation in the psychological sense). Social support (also labelled social motivation by IMB authors) is based on how the patient perceives the support of his or her significant others. The patient's motivation (psychological or social) and self-efficacy are moderated by actor-related elements such as the psychological health of the patient (e.g. depression), unstable living situation, poor access to medical care services and substance use. The patient's motivation can be influenced by the context conditions.

According to the IMB model, adherence behavioural skills (including objective ability and perceived efficacy for performing critical skills such as acquiring self-administering ART medications) play a vital role in determining whether a patient adheres to their medication or not. This notion was applicable when ART medication regimens were very complex to self-administer and required some skills. Today, ART medication is less complicated to self-administer, as it is in most regimes, a single tablet taken once a day. The IMB model also specifies that adherence information and adherence motivation may be directly related to ART adherence in cases where medication-taking behaviours are not complex or demanding [52]. However, the IMB model is not clear about what connects each of the boxes, for instance why it is that a person with adherence behavioural skills changes his/her behaviour and becomes adherent. Neither does it present a configurational approach that builds an explanation of the outcome by linking all of the precedents in a coherent causal configuration. Therefore, the IMB model somehow remains a descriptive model of precursors, and not a causal model.

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Ewart's Social Action Theory (SAT)

Ewart's Social Action Theory (SAT) was explored in two studies [61, 62]. The theory focuses on behaviour change and factors such as social context and support that can assist to foster and maintain that change. According to SAT, health behaviours result from an interplay of three domains: (1) context, in the sense of the social-environmental and the specific personal attributes of the individual, (2) processes of self-change that create new or modified action scripts and (3) self-regulation as an action state (in this case adherence to medication) [62].

SAT holds that health behaviours are a result of self-change or self-regulatory processes by which an individual makes the transition from old actions to adopting new behaviours [62]. Specific mechanisms of behaviour change that are identified in SAT include (1) problem-

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solving, (2) motivation, (3) generative capabilities (empowerment) and (4) social interaction processes. Remien et al., [62] suggested that the ability to problem-solve is related to social and emotional adjustments. According to SAT, patients can become motivated to adhere to their treatment based on their outcome expectancy – an evaluation of their personal capacities to carry out the intended behaviour – as well as when they generate goals that could stimulate the expected behaviours. Empowerment as an essential generative capability refers to a sense of personal control, mastery, and power to effect change. Social interaction processes between the patient and health care providers and with other significant others are important elements in the self-change processes.

According to SAT, the intended health behaviours are shaped by broader social-environmental systems and intrapersonal factors of the individual, representing contextual influences that can either facilitate or hinder behaviour change. Physical settings and social systems both affect and interact with biological structures and processes within the individual to create intrapersonal contexts that influence goals and generative capabilities [48]. Ewart suggests that these larger social-environmental systems "*contextually* determine how personal change mechanisms operate" [48]. This is in accordance with the realist logic that suggests that the mechanisms can only be fired in the right contextual environment, which leads to the intended outcome. These contextual conditions according to SAT include patient's demographics, living circumstances, social network, organisational systems and physical environmental factors [62].

Ewart [48] suggests that SAT could potentially be used to specify mediating mechanisms linking organisational structures to personal health. According to Ewart, behavioural interventions (such as the adherence club intervention) strengthen self-regulatory systems in individuals that foster capacity for self-protective action. **Figure 5** represents the conceptualisation of SAT to explain ART adherence.

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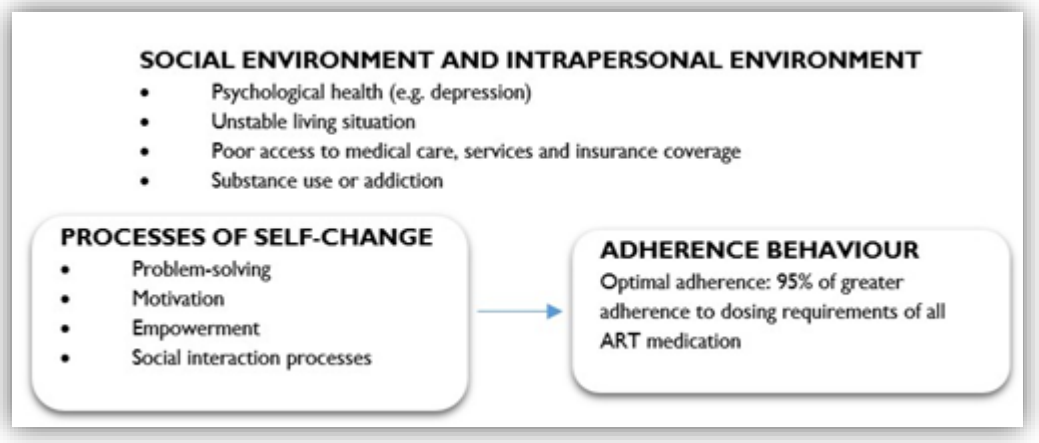

Figure 5: Conceptualisation of the Social Action Theory for ART adherence. Obtained from Ewart [48].

Notably, while SAT presents a precedent of behaviour in the form of processes of self-change and stipulates that context matters, it conflates environment with personal (psychological) factors. Secondly, it does not explain which of the sub-elements of environment and self-change are linked to which other. Therefore, although SAT presents three categories (context, mechanisms and outcomes) that can be useful to describe an adherence intervention, it falls short of explaining exactly why and how these factors combine to explain positive or negative outcomes.

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Health Belief Model (HBM)

The Health Belief Model (HBM) also offers a potential explanation for adherence to ART and was explored in one study [60]. The HBM aims at assessing health behaviour of individuals through examination of perceptions and attitudes a person may have towards disease and negative outcomes of certain actions. The HBM was conceptualised around the individual's beliefs and attitudes captured in four constructs representing the perceived threat and net benefits [63]. These constructs are perceived susceptibility and perceived severity that make up perceived threat and perceived benefits and perceived barriers representing the net benefit [49]. In relation to ART adherence, perceived severity refers to an individual's subjective assessment of the severity of the consequences of non-adherence to ART. Perceived susceptibility refers to the individual's assessment of the personal risk of developing problems with regard to ART medication non-adherence. Perceived benefits, on the other hand, relate to an individual's assessment of the value of adhering to ART. Finally, perceived barriers relate to an individual's

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assessment of the obstacles to taking the medication. These constructs represent possible mechanisms that could be triggered to enforce adherence behaviour.

The 1950 model of HBM was consolidated when Becker et al. [64] published a paper that considered a range of alternative approaches to understanding the social and psychological determinants of health and illness behaviour [63]. The authors added the influence of the patient's demographic variables and psychological characteristics on the identified mechanisms. These demographic variables and psychological characteristics of the individuals are important conditions that could trigger the mechanisms identified. Finally, to complement the HBM, Becker et al. [64] included the concept of 'readiness to be concerned about health matters' which represents an individual's general health motivation. **Figure 6** indicates the operationalisation of the identified concepts relevant to HBM.

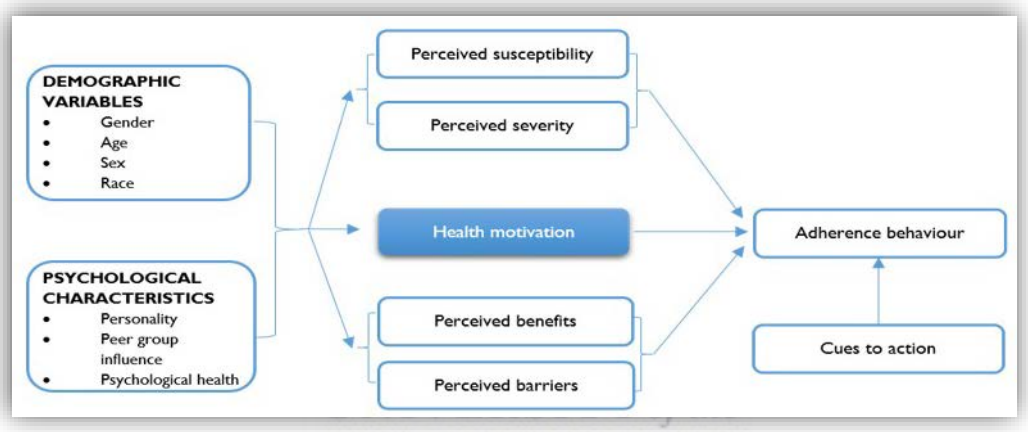

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Figure 6: Health Behavioural Model. Obtained from Munro et al. [60].

When conceptualised in the context to chronic medication adherence such as ART, it translates to the desire to achieve a better quality of life and the belief that adherence to ART will ameliorate the health of the patient and this would influence whether a patient adheres to their medication or not. According to Janz and Becker [49], if an individual has high perceived threat towards a disease or a health issue; low barriers to adopting healthy behaviours; and high perceived benefits to action that would help avoid the health issue; then there is an increased likelihood of the individual engaging in the recommended behaviour.

We would say that the HBM usefully describes demographic and psychological factors that influence health motivation, and more interestingly identifies the factors (candidate mechanisms) that perpetuate actual adherence behaviour. However, it also fails to operationalise

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a realist causal explanation. It failed to identify what mechanisms or sets of mechanisms are triggered under what context of action to cause the expected outcome of interest.

Discussion

Our review identified some theories of health behaviour that have been applied to understand and enhance treatment adherence to ART and other medical treatments by a number of authors. Nevertheless, as observed by Holmes et al. [46] and Krueger et al. [66] no single theory provides a comprehensive picture. Our review also indicates that most studies use quantitative methods to test the theories and models, thereby adopting a variable-oriented approach to analysis to estimate the casual influence of the various variables representing the determinants. The limited qualitative papers also focused on thematically identifying barriers to adherence to medication using a theoretical framework rather than providing an explanatory model of adherence to ART using generative mechanisms.

While most of the theories applied to explain adherence identified various concepts that carry the *sense* of a 'mechanism' to identify and define central explanatory element(s), these concepts do not qualify or fulfil all the characteristics of a generative mechanism (social and/or psychologic drivers), that is invisible, sensitive to variations in context and can generate outcomes. Nevertheless, these concepts could be seen as related to the set of attributes of generative mechanisms. Examples of such central elements include adherence attitude (Theory of Planned Behaviour), behavioural intention (Theory of reasoned behaviour and Theory of Planned Behaviour), problem-solving (Social Problem Solving), health belief (Health Belief Model), knowledge and behavioural skills (Self-regulatory model).

Based on our review, three theories had conceptualisations that are somewhat similar to the realist logic: IMB, HBM and SAT. Although these theories showed potential to provide an explanation of how ART adherence occurs by identifying relevant concepts and indicating possible relationships and effects between these concepts, they fall short in explaining exactly why and how these concepts – identified as variables – combine to explain positive or negative outcomes. In other words, they fail to show how possible mechanisms introduced by an intervention are triggered by various contextual conditions to generate the expected or observed outcome. Therefore, they fail to show generative causality. At best, these theories/models remain descriptive model of precursors, and not causal models.

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While a number of authors use the term 'mechanism' to identify and define central explanatory element, these concepts do not exactly qualify as mechanisms in the 'realist' sense (social and/or psychologic drivers). Possible 'mechanisms' identified from the Health Belief Model that may qualify as a mechanism in the realist sense include: perceived susceptibility, perceived severity, perceived benefits and perceived barriers. From the IMB model, possible 'mechanisms' identified were motivation and self-efficacy. From Ewart's SAT, possible mechanisms following the realist logic include empowerment, perceived social support and motivation. Although these theories identified various concepts that could possibly be conceptualised in the realist sense, in most part, they only provided descriptive models of how adherence to ART could be achieved. In this sense, they failed to provide an explanation of exactly why and how these factors and concepts combine and contribute to explaining positive or negative outcomes.

Having identified some potential mechanisms for ART adherence, the next step is to relate this information to how the adherence club intervention contributes or is expected to contribute towards generating these mechanisms and how does the contextual environment activate these mechanisms to cause the intended outcome (adherence to ART). The generative mechanisms identified in the review represent psychological mechanisms (motivation, self-efficacy, empowerment, perceived threat and benefits) and relational mechanisms (perceived social support). Bandura [67] suggested that understanding cause-effect should be regarded as a causal system in which "socio-structural influences operate through psychological mechanisms to produce behavioural effects." The generative mechanisms identified in this review will be examined and coordinated with other mechanisms and context conditions identified from an exploratory study of the opinions and assumptions on the adherence club managers and designers to elicit the initial programme theory of the adherence club intervention.

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Strengths and limitations of the review

The review was limited to an extent by the fact that most of the studies did not fully describe the theories that they applied, but mostly conceptualised these theories into variables to test for associations. In addition, most of the studies included in this review applied the cross-sectional study design that could not fully accommodate dynamic theoretical propositions that capture the notion of adherence to ART or make inferences on the causality of effect [46]. This limitation was minimised by returning to the original theories to understand their explanatory power in relation to adherence to ART.

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Conclusion

The focus of the review was to explore the link between behaviour change theories (or models) and mechanisms that operate during the propagation of ART adherence behaviours. We acknowledge that most social and cognitive (psychological) theories identified in this review were not formulated with the realist perspective of generative causality in mind. This is because these theories are presented in conceptual of sensitising schemes (causal models), whereby individual behaviours are explained based on various individual and environmental 'determinants'. Nevertheless, these theories offered possible underlying social drivers of behaviour that could be used to explain adherence behaviour to ART and other chronic medications using generative causality (explanatory theory). The candidate mechanisms and possible explanations that we have obtained from this study have implications for eliciting the programme theory of a group-based adherence intervention. Eliciting the initial programme theory entails synthesising the assumptions and perspectives of the adherence club programme designers and managers and the review of how other group-based intervention work, with the candidate mechanisms and possible explanations of ART adherence behaviour obtained from this study.

List of abbreviations

AIDS	- Acquired Immune Deficiency Syndrome
ART	- Antiretroviral therapy
CMO	- Context-Mechanism-Outcome
HBM	- Health Belief Model
HIV	- Human Immuno-virus
IMB	- Information-Motivation-Behaviour
ICAMO	- Intervention-Context-Actor-Mechanism-Outcome
PLWHA	- People Living with HIV and AIDS
PRISMA	- Systematic Reviews and Meta-Analyses
SAT	- Social Action Theory
SMS	- Short Message Services

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CHAPTER SEVEN

Paper 5

A Realist Approach to Eliciting the Initial Programme Theory of the Antiretroviral Treatment Adherence Club Intervention in the Western Cape Province, South Africa. BMC Health Research Methodology (*Under Review*).

Abstract

Background: The successful initiation of people living with HIV/AIDS on antiretroviral therapy (ART) has engendered challenges of poor retention in care and suboptimal adherence to medication. The adherence club intervention was implemented in the Metro area of the Western Cape Province, South Africa, to address these challenges. This programme has shown potential to relieve clinic congestion, improve retention in care and treatment adherence in the context of rapidly growing HIV patient populations being initiated on ART. Nevertheless, how and why the adherence club intervention works is not clearly understood. We aimed to elicit an initial programme theory as the first phase of the realist evaluation of this adherence club intervention.

Methods: The realist evaluation approach guided the elicitation study. First, information was obtained from an exploratory qualitative study of programme designers' and managers' assumptions of the intervention. Second, a document review of the design, rollout, implementation and outcome of the adherence clubs followed. Third, a systematic review of available studies on group-based ART adherence support models in sub-Saharan Africa was done, and finally, a scoping review of social, cognitive and behavioural theories that have been applied to explain adherence to ART followed. We used the realist evaluation heuristic tool (Intervention-context-actors-mechanism-outcome) to synthesise information from the sources into a configurational map. The configurational mapping, alignment of a specific combination of attributes, was based on the generative causality logic – *retroduction*.

Results: We identified two rival theories. The first theory supposes that patients become encouraged, empowered and motivated, through the adherence club intervention to remain in

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care and adhere to the treatment. The second theory suggests that stable patients on ART are being nudged to remain in care and adhere to the treatment with the goal to decongest the primary health-care facilities.

Conclusion: The initial programme theory describes how (dynamics) and why (theories) the adherence club intervention is expected to work. By testing theories in "real intervention cases" using the realist evaluation approach, the theories can be modified, refuted and/or reconstructed to elicit a middle-range theory of how and why the adherence club intervention works.

Introduction

By 2016, an estimated 37 million people were living with HIV and AIDS (PLWHA) globally, and as of June 2016, 18.2 million PLWHA were accessing antiretroviral therapy (ART) [1]. Nevertheless, more than one-third of patients are not adhering to treatment (an estimated 62% of PLWHA are adhering to their ART (taking ≥ 90% of ART)) worldwide [2]. Adherence to ART has been reported to be better in sub-Saharan Africa than in North America (77% vs. 55%) [3].

In South Africa, it was estimated that one in every seven (14%) people were living with HIV/AIDS in 2016 [4]. With an estimated 7 million PLWHA, South Africa had the highest number of PLWHA in the world [5]. In 2011, the country had a 75% increase in access to ART, becoming the largest ART programme in the world with an estimated 3.2 million PLWHA currently initiated on treatment [6]. Managing a large number of patients within a large ART programme poses various challenges. Prominent among these challenges are the problems of suboptimal retention in ART care (high levels of lost-to-follow-up), poor adherence to medication and overcrowded health-care facilities.

The impact of the growing numbers of patients in care was demonstrated by Médecins Sans Frontières (MSF) at the Ubuntu Clinic, a public health clinic in a densely populated, low-income residential area in Cape Town. This site was the largest ART clinic in the Cape Town Metro District, situated in an area with an extremely high HIV prevalence [7]. From 2006 the capacity of the facility to enrol new patients on ART showed a decline. As the clinic became saturated, the loss-to-follow-up rates of patients 12 months after enrolment increased with each successive annual cohort initiated on ART from 2005 to 2008. The decline was largely attributed to the facility-based and staff-intensive model of care that was used for managing PLWHA on ART

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[8]. In a context of scarcity of nurses and doctors, this accentuated the need for a more efficient model for managing large cohorts of patients on ART and specifically with the effective use of community-based strategies.

In the search for effective long-term retention models, a differentiated care model [9] – consisting of streamlined HIV treatment and care adapted to the needs of a targeted group – was developed and piloted at Ubuntu Clinic. The adherence club comprises a group of patients whose appointments have been harmonised. Patients attend sessions that are modular, and that can theoretically be placed outside of the clinic to reduce further congestion. The adherence club model demonstrated promising outcomes regarding improved patient flow, an increase in the monthly enrolment of patients on ART and decreased loss-to-follow-up while increasing the overall number of patients in care [7]. Two years after the first enrolment of patients in the adherence clubs, only 2.4% club patients had a negative outcome – 0.7% had died, and 1.7% were lost to follow-up [10]. Altogether, 97.6% of patients were still in care: 89.5% remained in the club system, 4.8% had returned to mainstream care at Ubuntu clinic, and 3.3% had been transferred to other clinics [10].

Based on these results, the adherence club model was selected as a potential intervention to address the challenges of poor patient retention in care, suboptimal adherence to ART and health-care facility congestion [11]. In 2011, the model was rolled out as a system improvement intervention aiming at streamlining the treatment and care of 'stable' patients in the Western Cape Province, South Africa. The rollout and implementation of the adherence club model was conceived and executed through the collaboration between the Western Cape Provincial Department of Health (WC DoH), the non-governmental organisation Treatment Action Campaign (TAC), the Cape Town Municipality City Health department (CoCT DoH), Médecins Sans Frontières (MSF), and the Institute for Healthcare Improvement (IHI).

During the first phase of the rollout, from January 2011 to March 2015, 77% of ART sites in the Cape Metro area of the Western Cape Province implemented the adherence club intervention [11]. The graph (**Figure 1**) shows the progressive coverage of patients on ART in the Western Cape Province by the adherence club care model from December 2010 to June 2016.

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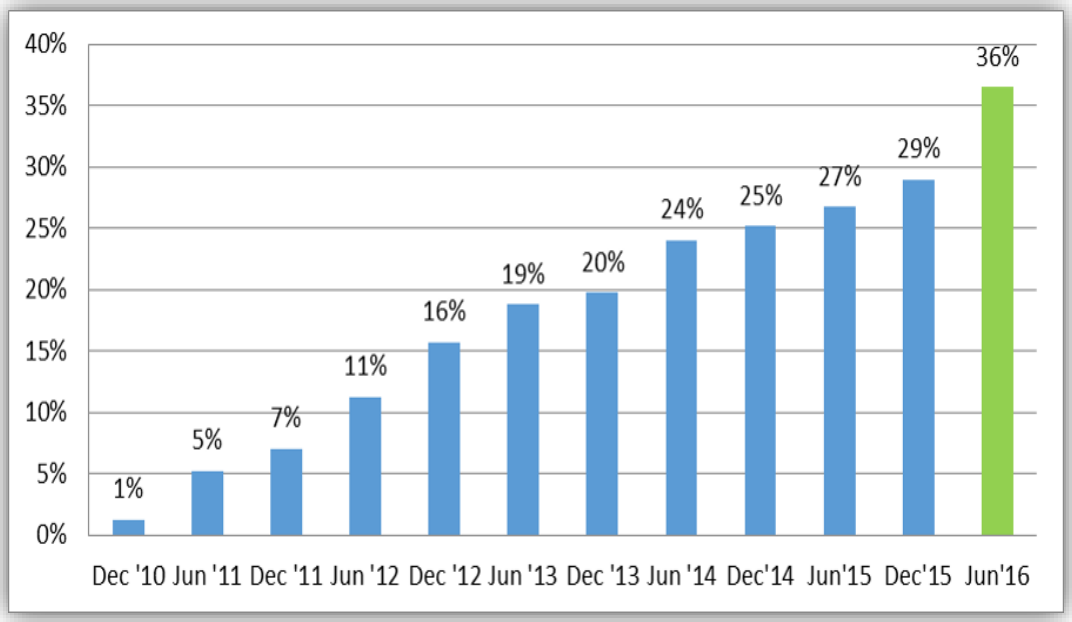

Figure 1: Percentage of patients in adherence clubs in the Cape Metropolitan region

In this article, we report on the results of the first phase of a study called "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health-care facilities in the metropolitan area of Western Cape Province, South Africa" [9]. While other papers describe how the adherence club is organised and run [7–11], we provide a comprehensive description of the programme based on a document review and participant observations of adherence club sessions in six primary health-care facilities. Furthermore, we present the initial programme theory of the adherence club intervention based on the realist logic – i.e. exploring how, why, for whom and in what circumstances the adherence club intervention is *expected* to work.

This article is structured as follows. We first describe the adherence club intervention. This follows from the fact that a proper understanding of the programme theory requires a comprehensive picture of the various modalities, the implementation and coal phase execution of the adherence club intervention. Secondly, we describe the process of eliciting an initial programme theory of the adherence club intervention based on the realist evaluation approach. We present the initial programme theory and the ensuing hypotheses that will be further tested through empirical research.

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Methodological approach: realist evaluation

Realist evaluation seeks to understand how and why, for whom, and under what circumstances a programme works (or not) [12,13]. The philosophical basis of realist evaluation is scientific realism. The realist evaluator aims to identify the context-mechanism-outcome (CMO) causal relationship to explain "how, why, for whom and under what conditions a programme works" [14]. Because realist evaluation is focused on providing explanatory models, it has the potential to open the "black box" of programmes by making explicit the generative mechanisms to explain how the programme modalities lead to the intended outcome(s) [15].

The realist methodology is a "theory driven, interpretative approach to uncovering underlying middle-range theories (or logics) driving interventions and their multiple components, as well as illuminating the contextual factors that influence mechanisms of change to produce outcomes" [16]. The interpretive approach is driven by various forms of reasoning; deductive methods (based on testing specific hypothesis), inductive reasoning (formulating general inferences), but central to the realist method of inquiry is abductive or retroductive reasoning [17]. Retroduction is a mode of inference in which events are explained by postulating (and identifying) mechanisms which are capable of producing outcomes [18]. According to Wynn and Williams [19], retroduction is characterised by the use of causal mechanisms as the basis for explanation, the possibility for multiple potential explanations, and the understanding that these causal mechanisms may or may not be observable empirically.

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Typically, realist evaluations start with an initial programme theory (hypothesis) and end with a more refined theory. Therefore, the evaluator hypothesises in advance the intervention (I) (or its components), the relevant actors (A), mechanisms that are likely to operate (M), the contexts in which they might operate (C), and the outcomes that will be observed if they operate as expected (O). This hypothesis is formulated by conceptualising the components of a programme implementation process (programme modalities, context, actors, mechanisms and outcomes) to form theories about the underlying causes to arrive at explanations of what we observe. Based on this, realist evaluators seek to understand how and why programmes work by for formulating programme theories.

According to Westhorp, "Realist evaluation is most appropriate for evaluating new initiatives or programmes that seem to work but where 'how and for whom' is not yet understood; programmes that have previously demonstrated mixed patterns of outcomes; and those that will

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be scaled up, to understand how to adapt the intervention to new contexts." [20] Since the adherence club intervention fulfils all the above conditions, we adopted the realist evaluation approach for the evaluation of the adherence club intervention.

The Programme Theory

One of the central elements of realist evaluation is the programme theory. Realist evaluation starts and ends with a theory or theories. Thus, eliciting an initial programme theory is the 'pre-requisite of realist evaluation' methodology [20]. Developing a programme theory follows from the notion that programmes are theory-incarnate [12]. A programme theory is described as "a set of explicit or implicit assumptions of how the programme should be organised and why the programme is expected to work" [21]. Programme theories link activities and outcomes to explain how and why the desired change is expected to take place and represent how "the mechanisms introduced by the programme into pre-existing contexts can generate outcomes" [22]. This process is guided by a 'generative' model of causality, in which causal links are demonstrated through a fine-grained explanation of what happens between cause and effect.

Developing programme theories serves two main purposes: as a planning tool and/or as an evaluation tool. If used for planning, Sharpe [23] suggests that it is beneficial to develop a programme theory before starting the programme. In this instance, the programme theory indicates how different elements are intended to work together and to identify the intermediate outcomes of a programme or an intervention [24]. This gives a clear indication of the goals and objectives of the programme and of the pathways through which they could be attained. Programme theories are also used to guide monitoring and evaluation [24]. They are especially important for the evaluation of complicated and complex aspects of programmes. To this end, the goal of the evaluator(s) is to understand not only patterns related to the outcome of the intervention but also to reveal how and why the intervention attains the outcome of interest [25]. Whatever their use, programme theories should be concrete enough to be tested and refined through empirical research, and abstract enough to generalise from the case-specific theories [26].

What differentiates the programme theory in realist evaluation from those conceived in other theory-driven approaches, such as Theory of Change [27] or theory-driven evaluation [28, 29] is that realist evaluation specifies what mechanisms will generate the outcomes in what context. Thus, a realist programme theory provides a conceptual framework for putting the underlying

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CMO components centre stage [30]. The evaluation of the programme's theory is notably an evaluation of the programme rather than the evaluation of the programme theory [23].

Methods

To describe the state-of-the-art of the adherence club intervention, we adopted a descriptive research approach. We carried out a document review of 12 programme documents describing the adherence club model and implementation strategy, the adherence club toolkits, policy documents, implementation reports and news clippings (**Additional file 1**). To obtain these relevant documents, the first author searched various databases (PubMed, Google search, Google Scholar, and EBSCOhost) and relevant websites (Médecins Sans Frontières, the provincial Department of the Western Cape and Health E-news) using the terms 'adherence club', 'ART adherence club', 'ART clubs', 'facility-based adherence club', and 'MSF innovation in ART management in South Africa' [31].

Additionally, we conducted 24 structured non-participant observations of the adherence club programme in six facilities in the Western Cape Province – three with a record of good retention in care rates (≥80%) and three with a record of poor adherence to care rates (≤70%) in 2014 (ART retention in care report 2015). Non-participant observations allowed us to gain insights into the various types of club sessions, different activities and the dynamics of interactions between the patients with one another and with the health-care providers. We used an observation guide that details the interactions, processes, or behaviours to be observed during the club sessions (**Additional file 2**).

Regarding eliciting the initial programme theory of the adherence club intervention, we adopted an elicitation research approach – an approach that employs any number of data collection techniques to gather knowledge. Eliciting the programme theory or theories of a programme in the realist sense entails identifying and making explicit the elements of the intervention, actors, mechanisms, outcomes, and contexts using the concept of generative causality. To obtain information on the relevant intervention, actors, mechanisms, outcomes and contexts, realist evaluators typically review programme documentation (policy documents, implementation reports, programme descriptions, etc.), interview or discuss with various programme stakeholders, and/or draw on a systematic review of previous research and evaluation literature [24, 25]. Then, these elements are connected and aligned using the CMO configurational tool,

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following the generative model to obtain the programme theory (theories). In **Figure 7.2**, the various methods applied to obtain relevant information for the formation of the initial programme theory of the adherence club intervention are shown (this process is described in more detail in the results section).

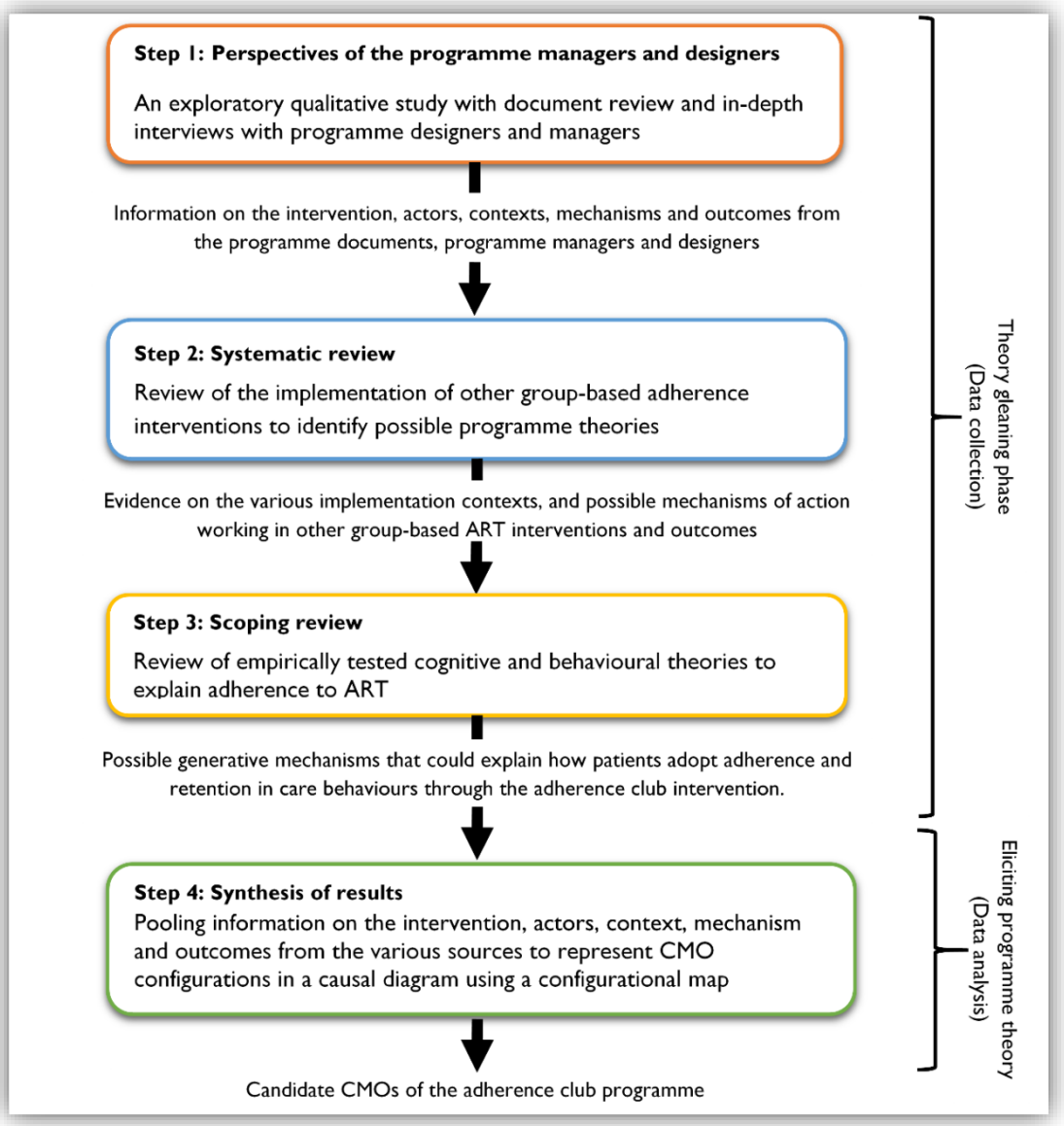

Figure 7.2: Steps employed to elicit the final Intervention-Context-Actor-Mechanism-Outcome configuration hypothesis

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Data collection

To obtain information on the relevant intervention, actors, mechanisms, outcomes and contexts, realist evaluators typically review programme documentation (policy documents, implementation reports, programme descriptions, etc.), interview or discuss with various programme stakeholders, and/or draw on a systematic review of previous research and evaluation literature [24, 25]. Then, these elements are conceptually aligned using the ICAMO configurational tool, following the generative model to obtain the programme theory (theories). The various methods applied to obtain relevant information for the formation of the initial programme theory of the adherence club intervention are shown in **Figure 7.3** (this process is described in more detail in the results section).

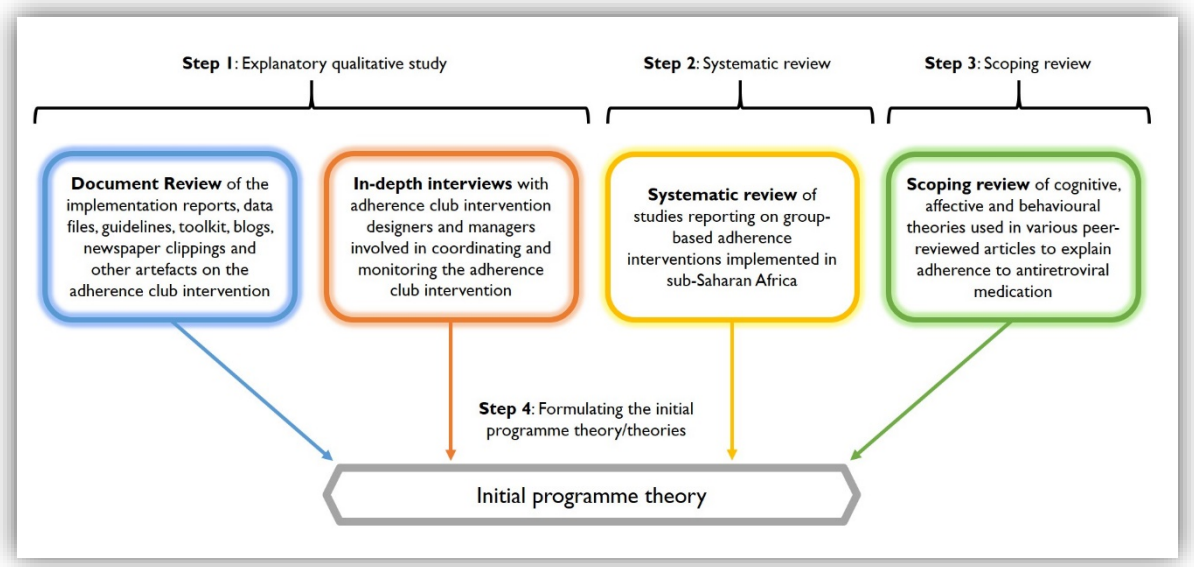

Figure 7.3: Sources of information for eliciting the initial programme theory

For each of these steps, we used specific methods and sources of information. In the first step, we conducted an exploratory qualitative study, employing two methods. A document review of 12 documents on the design and implementation of the adherence club intervention, and key informant interviews with 12 purposively selected programme designers and managers [33]. Thematic content analysis was used to identify themes attributed to the programme actors, context, mechanisms, and outcomes (**Table 7.1**). A description of the entire study which includes the study design, methods employed and the findings is reported elsewhere [33].

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Table 7.1: Intervention-Context-Actor-Mechanism-Outcome configuration components obtained from the explanatory qualitative approach

Outcomes	Context	Mechanisms
Long-term Outcomes - Programme standardisation - Retention in care and adherence to medication - Healthier communities	**Distal (Macro) Context** - Monitoring and evaluation - Higher level support - Stakeholder collaboration	**Provider/Management Level** - Buy-in - Interaction - Motivation
Intermediate Outcomes - Decongestion of clinic - Improved patient self-management	**Organisational (Meso) Context** - Sustained hierarchical pressure - Human resources (staffing dynamics) - Implementation methodology	**Social mechanisms** - Group dynamics - Social/Peer support - Mutual learning - Bonding
Immediate Outcomes - Decreased workload for operational staff - Decreased patient opportunity cost	**Local (Micro) Context** - Availability of conducive space - Programme champions - Oppressive Surveillance	**Patient (individual)-Level** - Encouragement - Trust - Nudging - Fear - Motivation

Source: Mukumbang et al. [33].

In the second step, we conducted a narrative synthesis of primary studies focusing on the mechanism(s) at work during the implementation of group-based interventions for adherence support among PLWHA on ART. Twelve articles reporting primary studies on group-based models of ART care were included in the review. Evidence from these studies was analysed using thematic content analysis to identify CMO patterns. The six studies that employed a quantitative study design to identify outcome patterns failed to identify aspects of the context and mechanisms. In the other four studies, a qualitative and two mixed methods studies were applied, and some of the aspects of the context and mechanisms identified that could trigger the outcomes of group-based ART interventions. Nevertheless, none of the identified studies conceptualised the relationship(s) between the intervention modalities (I) context (C), Mechanism (M), Actors (A) to explain the outcomes (O). The entire systematic review, starting from the selection of the studies to the analysis and the findings obtained is described elsewhere [34]. The themes that were identified are summarised in **Table 7.2**.

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Table 7.2: Propositions obtained from the systematic review process of group-based antiretroviral therapy models

Context	Mechanism	Outcome
- Staffing dynamics	- Active involvement in care - Perceived support from a counsellor and other health professionals. - Feeling empowered by their expanded roles	- Adherence to medication - Reduced operational staff workload
- Acceptability (buy-in) from health workers - Educational level of patients	- Understanding treatment - Trust and communication - Patient empowerment - Motivation	- Improved retention in care - Improved rate of medication adherence
- Availability of physical space for group activities - Buy-in from both operational staff and patients	- Positive peer dynamics - Sharing of experience - Bond formation among group members - Conducive environment	- Improved patient support which leads to retention in care and adherence to medication - Decongestion of clinic
- Acceptability (buy-in) from patients	- Patient satisfaction - Continuity of care	- Improved rate of medication adherence - Reduced workload for the clinicians

In step three, we conducted a scoping review to identify generative mechanisms in studies of ART adherence that employed various social, behavioural and cognitive theories to explain or predict patients' adherence to ART. In this review our aim was to identify existing mechanisms in the theoretical knowledge of ART adherence and to verify if these mechanisms could be adapted to fit those in the explanatory framework of the adherence club programme [19].

Twenty-six articles were included through searching five databases (PubMed, Ebscohost, CINAHL, PsycARTICLES and Google Scholar) using keywords and manual search of citations from the reference list of the studies identified from the electronic databases. Three theories (Information-Motivation-Behaviour (IMB), Social Action Theory (SAT) and Health Behaviour Model (HBM)) were of potential relevance to explaining the ART adherence through generative mechanisms and the influence of context of action. Six salient constructs were identified as candidate mechanisms to explain adherence behaviour of patients toward ART: motivation, self-efficacy, perceived social support, empowerment, perceived threat, and perceived benefits and barriers. The approach, methods and findings of this scoping review have been reported elsewhere [35].

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Data analysis/synthesis

Collating findings into an initial programme theory

After identifying the various aspects of the relevant actor, context, mechanism and outcome components (steps 1-3), we used the intervention-context-actor-mechanism-outcome (ICAMO) configuration (**Figure 7.4**) as a heuristic to formulate the initial programme theory [36,37].

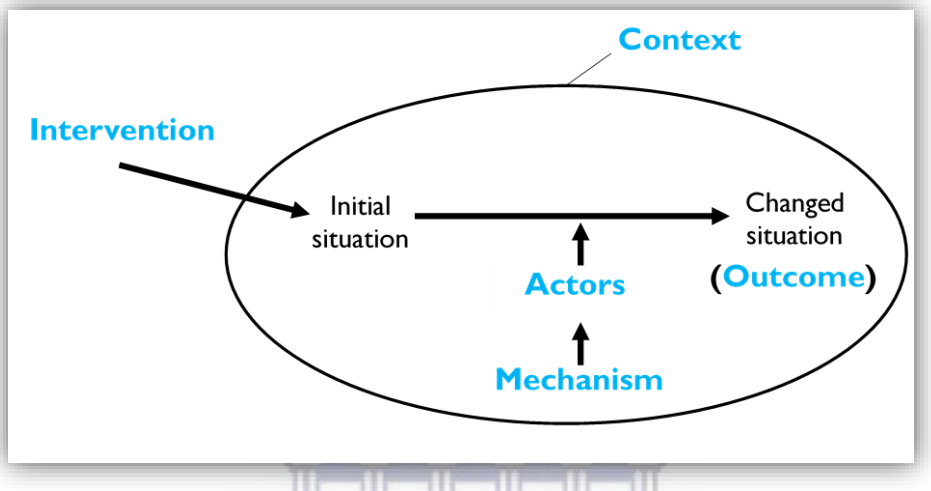

Figure 7.4: The intervention-context-actor-mechanism-outcome configuration (van Belle [36] and Marchal et al. [37]).

Based on the ICAMO heuristic tool, we applied the process of configuration mapping [38] – an approach to causality, whereby, outcomes are considered to follow from the alignment of a specific combination of attributes [13]. The configuration process was achieved through the logic of *retroduction.* By applying retroduction, the realist researcher moves from the description and analysis of concrete phenomena (usually obtained from actors by interview) to reconstructing the basic conditions (theory) for these phenomena [39].

Following the logic of retroduction, first, we identified mechanisms that were related to the different actors (patients, health professionals) and the different outcomes that these mechanisms were likely to perpetuate. Then, we examined the context conditions that were associated with the mechanisms identified as informed by the data. Finally, to elicit the initial programme theory based on our data, we found it useful to distinguish between different sub-elements of the adherence club programme, including the individual, interpersonal, group, family and community level. The configuration map developed through this process is represented in **Figure 7.5**.

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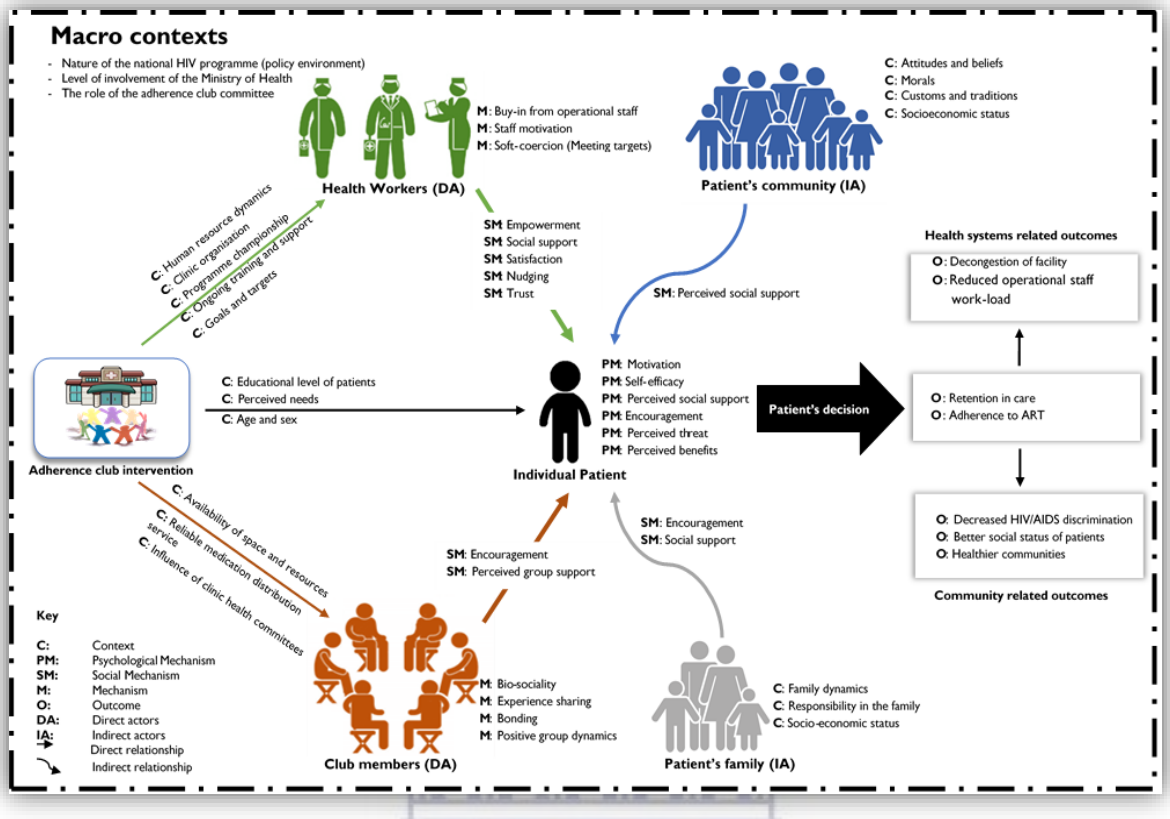

Figure 7.5: An intervention-context-actor-mechanism-outcome representation of the programme theory used in the adherence club intervention

Formulating the testable hypotheses

By bringing together the ICAMO configurations using the "*if*…, *then*…, *because* …" statement [20,38], we identified two rival programme theories.

Results

We first describe the adherence club intervention, casting light on the various modalities that the intervention offers, how the intervention is implemented, and how, why and who executes what aspects of the intervention. This is an important part of eliciting a programme theory in the realist logic because it is the first component of the ICAMO heuristic tool and provides valuation information on context and actors. After describing the adherence club intervention, we present the initial programme theories that were elicited through the elicitation process.

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The intervention: the adherence club programme

Objectives of the adherence club programme

The adherence club programme was designed to shift the majority of consultations and ART collections for stable patients to ‘clubs’ organised and facilitated by facility counsellors or peer educators [40]. Hence, it strives to (a) retain patients in ART care by providing a more efficient way to manage stable patients; (b) achieve and maintain good long-term adherence in PLWHA on ART by maintaining good quality care and creating a convenient environment for clinical visits that accommodate their lifestyle needs; and (c) decongest the health facility through group sessions that are facilitated by trained non-clinical staff [41].

Eligibility to the adherence club

An adherence club comprises 25–30 ‘stable patients on ART. Evidence from the document review shows that although patients are encouraged to request their admission into the clubs, it is clinicians who determine whether a patient qualifies for admission. Eligibility is centred on the patient being 'stable' – clinically well and adhering to treatment [42]. The patients can be recruited if they are 18 years or older, weigh more than 40 kg, and have been on the same ART regimen (1 or 2) for at least 12 months. Clinically, the two most recent consecutive viral loads of the patient should be undetectable (<400 copies/mL) with a CD4 count of more than 200 cells/mm^3 in the last six months [40,43]. Furthermore, the patients should have a reliable clinical attendance as evidenced by their attendance card, and no medical condition requiring regular clinical consultations including tuberculosis (TB).

Club membership can be terminated if the patient has a viral load above 400 copies/mL or a significantly abnormal low CD4 count <200 cells/mm^3. Also when they develop active TB infection, switch ART regimen for clinical reasons, develop any condition requiring frequent clinical follow-up, or when a woman becomes pregnant [7]. In addition, when patients fail to attend mandatory club sessions regularly or fail to send a 'treatment buddy' to collect their medication from the club facilitator or club nurse within five days (grace period), they are returned to the main clinic care [44].

In practice, when it comes to allowing patients into an adherence club more things are taken into consideration. For instance, if a patient in the club develops a chronic co-morbidity, such as hypertension or diabetes that is well-controlled, and if the patient is 'stable' according to the

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clinician's assessment, he/she will still be eligible for a club on condition they fulfil the 'HIV-related' criteria. Similarly, some facilities choose to keep pregnant women in the club as long as their viral load is undetectable, in which case their antenatal visits are managed by the staff responsible for antenatal care separately. However, in some settings, pregnant women are placed out of clubs and are only allowed to re-enter after pregnancy, particularly where mother and baby will be managed as a pair in the post-natal period or if antenatal care is delivered at another facility other than the facility rendering club services.

Management structure and running the club activities

Running the adherence club requires a club team. Ideally, a team of five comprising a club manager, club facilitator, professional nurse, pharmacist, and a data capturer should run the club [40]. The club facilitator is responsible for operating the club. The duties and responsibilities of each of these staff are outlined in **Table 7.3** below.

Table 7.3: Personnel required running the adherence club and their responsibilities

Cadre category	Personnel type	Responsibility
Club Manager	• Medical doctor • Professional nurse	• Ensure that the Standard Operating Procedures are adhered to • Schedule annual return dates for club visits • Perform six-monthly scripting of club patients • Monitor outcomes
Club Nurse	• Professional nurse	• Responsible for seeing patients who present with unexpected weight-loss and/or symptomatic for opportunistic infections and or adverse drug reactions • Collects blood for annual viral load and CD4 count screenings
Club Facilitator	• Clinic counsellor • Community health worker	• Preparing and running the club sessions • Making sure pre-pack medications are available and distributing them • Filling in the club register
Pharmacist	• Pharmacist • Pharmacy assistant	• Ensures scripts are submitted and pre-packs are received and correct • Dispensing the ARVs and packaging the medication for the clubs (Chronic Dispensing Unit)
Data Capturer	• Data capturer	• Captures the information on the club activities including the visit, the weight and enters any results.

Activities of the adherence club

The observations showed that facility-based adherence clubs take place in available spaces or rooms, such as the clinic boardroom, makeshift buildings or buildings constructed for the purpose. During the introductory visit to the club, patients are provided with the rules governing the adherence club and its activities. Patients are considered enrolled in the club after they have

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attended their first club meeting and picked up their pre-packed medication. According to the document review and as confirmed by our observations, if patients are unable to attend a club appointment for any reason, they are entitled to send someone known as a 'treatment buddy'. Usually, this person is a family member, friend or companion who supports the patient on ART – to collect their treatment from the adherence club [45].

The activities of the adherence club are organised bi-monthly. A regular club session lasts approximately one to one and a half hour [40]. On days when blood tests are carried out for routine adherence monitoring through CD4 count and viral load, the sessions take much longer. Once a year, club members attend a regular clinic. In **Table 7.4** a standard attendance schedule of the adherence club programme is shown.

Table 7.4: An example of an adherence club's annual session schedule [40].

Type of club visit	Activities	Script and CDU visits
	Recruitment + clinician scripting for three months	1 month supply by pharmacy
Enrolment visit	Scripting for six months	1 x 2 months pre-packed
Routine visit		1 x 2 months pre-packed
Blood visit	Bloods taken	2 x 2 months pre-packed
Clinical visit	Clinical consultation + re-scripting for 6 months	3 x 2 months pre-packed
Routine visit		1 x 2 months pre-packed
Routine visit		2 x 2 months pre-packed
Re-scripting visit	Re-scripting	4 x 2 months pre-packed

Note: The cycle repeats from month 12

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Based on our observations and as reported in some of the programme documents, during a standard club session (medication pick-up), the patients arrive in the morning and hand their clinic cards to the clinic facilitator. At each visit, club members are clinically assessed (weight and symptom screen) and participate in a group adherence support and/or education activity. They are then issued with two months' pre-dispensed medication. Next, the club facilitator gives health education talks to the assembled group on relevant topics. These topics include challenges that patients face with taking their medication. Sometimes a patient is asked to give a talk. The club facilitators do not have the licence to *dispense* medication; therefore, they collect the pre-packaged medication (labelled for each patient and supplied by the Chronic Dispensing Unit) and *distribute* these to the patient (or treatment 'buddy'). The drug distribution task can also be done by an 'expert' patient.

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According to the adherence club guidelines [41] and adherence club toolkit [40], the club facilitator refers any patient who reports or presents with symptoms suggesting illness, adverse drug effects or weight loss to the club nurse for further consultation. Based on the outcome of the consultation, they are either sent to collect their medication from the club facilitator (minor ailments and medication side effects) or removed from the club (uncontrolled comorbidity such as diabetes or hypertension). The activities of a standard adherence club session are outlined in **Figure 7.6**.

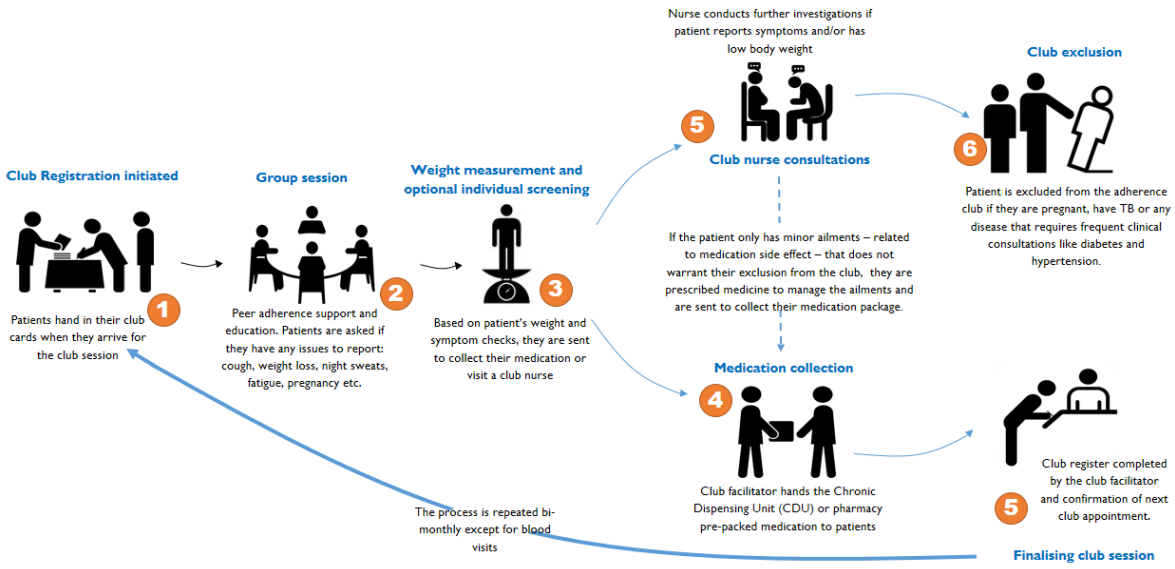

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Figure 7.6: A pictorial representation of a typical facility-based adherence club session

Based on the adherence club toolkit [40] and as confirmed by our observations, on the appointment days for blood checks and annual clinic visits, the patient attends in person. If a patient sends a buddy on a blood-taking or clinical visit day or for the second time in succession, the buddy is told to inform the patient to visit the club manager at the facility within five working days [41].

Based on the adherence club guidelines [41], when a club patient has not sent a 'buddy' to collect his/her medication and does not come to the facility within the 'grace' period of five working days, he/she will be referred to the club manager. The guideline recommends that at the end of the 'grace' period, the club facilitator should record the appropriate outcome of the patients who did not attend the group session after efforts have been made to contact the patient.

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Our observation showed that the grace period is sometimes longer than five days as the operational staff tend to be more lenient. The club manager informs the patient that he/she can no longer attend the club and must return to mainstream care. Where a patient has been returned to mainstream care for clinical reasons, the club clinician can set the conditions for the patient's re-enrolment in the club system. In such case, the patient is considered a new club patient from monitoring and evaluation perspective [44]. The clinic data clerk transfers all relevant information in the club register to the facility ARV register (paper or electronic). Information such as the CD4 count and annual viral load test results are recorded in the club register by the club facilitator and transferred to the electronic register by the data clerk.

Comparisons and effectiveness of the adherence club to standard clinic care

Based on structured observation of the adherence club in six health-care facilities, we identified some critical differences between the adherence club model of ART care and the standard clinic ART care. These differences are outlined in **Table 7.5**.

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Table 7.5: A comparison of the adherence club intervention and the standard clinic ART service

Nature of service	Standard clinic ART care	Adherence club
Reception	Patients queue at the waiting area to be seen by a clinician. The waiting times at larger facilities can be up to 4 hours.	Patients have an area reserved for them with a club facilitator at their disposal. They have scheduled times when the adherence club session starts.
Drug Dispensation	Medications are provided by the clinic pharmacy, after the consultation with the clinician. The patient is expected to queue at the pharmacy waiting area for their medication to be served. Patients receive one month's supply of medication and possibly two months' supplies when the patient shows positive signs of adherence.	Medication is pre-packed by a central packaging and distribution centre, the Chronic Dispensing Unit, and distributed during the club session by the lay counsellor. Patients receive two months' supplies of medication. They can be given up to four months' supplies of medication during festive periods.
Blood sample collection	Patients queue in front of the preparation room to be seen by a professional nurse so that blood can be drawn for routine CD4 and viral load measurements	Patients in the ART club have a professional nurse allocated to them, who prepares their laboratory forms and collects their blood samples at the set time. Members do not have to wait.
Attendance Frequency	For each appointment, the patient is expected to be seen by a clinician for routine consultation and then by a lay counsellor for their drug accountability assessment and counselling. Patients are thus expected to attend in person at all times.	The lay counsellor conducts most of the activities at the ART clubs and the patient is only expected to consult a clinician once a year except when he/she develops any opportunistic infection. Patients can send a 'buddy' to collect their medication and can only show up when it is time for their blood to be collected.
Accountability	There is less accountability for these patients as they are not allocated to particular lay counsellors	Better accountability and follow-up from the lay counsellors as they feel responsible for the smooth running of their clubs and the patients in their clubs.

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The facility-based and community-based adherence club models have shown better results and effectiveness in retaining patients in care and improving adherence to medication in comparison with regular clinic services [10,42]. Recent evidence shows that patients receiving care in the adherence care model show more satisfaction with ART care compared to those who receive care from the standard ART scheme [46]. There is also evidence that the adherence club model of ART care is cost-effective compared to standard care [47].

The initial programme theories

Based on the above process described to elicit the initial programme theory of the adherence club programme, we identified two salient programme theories.

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Programme Theory 1

From our analysis, we identified quick access to medication at the convenience of the patient with reduced frequency (bi-monthly), regular counselling and education sessions, and quick access to a clinician when required as central elements of the adherence club intervention. The context includes the availability of resources, programme buy-in from the operational staff, and the club and clinic organisational culture and activities. Important actor-related elements include the educational level of patients, the willingness to be included in the intervention, and the age and sex of the patient. Self-efficacy, motivation, perceived social support, encouragement, and perceived threat and benefits emerged as individual-level mechanisms. Grouping patients in the adherence club may trigger other mechanisms operating at the group level such as experience sharing, bonding and group dynamics. Programme Theory 1 is succinctly expressed in **Box 7.1**.

Box 7.1: Programme Theory 1 of the adherence club intervention

IF adult (18+ years) clinically stable patients with evidence of good clinic attendance are group-managed and receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,
THEN these patients are likely to adhere to medication and remain in care,
BECAUSE they develop a group identity, which improves their perceived social support, satisfaction and trust, and acquire knowledge, which helps them to understand their perceived benefits and improves their self-efficacy.
As a result, they become empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

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Programme Theory 2

The second programme theory is somewhat contrary to the first and suggests that the patients are being nudged, pressured, or coerced to attend club activities. In other words, an external force prompts the patients to attend the club activities rather than their own volition, control or willingness. The nudging process stems from the desire of the health system managers to decongest the health facilities by keeping the patients in club care. Thus, goals and targets are set at the provincial level and imposed on the facility to enrol more patients into the adherence club programme and maintain them within this system. The promise of being returned to the main treatment stream if they patient miss a club appointment and do not send a treatment buddy is implemented by the operational staff to ensure that patients remain in care. This promise translates into a perceived threat (fear of losing the privileges patients enjoy as adherence club members). Programme Theory 2 of the adherence club intervention is summarised in **Box 7.2**.

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Box 7.2: Programme Theory 2 of the adherence club intervention

IF operational staff receive goals and targets set to continuously enrol patients in the adherence club and strictly monitor their participation through strict standard operating practices (The promise of exclusion in the event of missed appointment and poor adherence outcomes),
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they fear (perceived threat) of losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules.
As a result, they become nudged to remain in care and adhere to the treatment, which might decongest the health facility.

Discussion

We elicited the initial programme theory by obtaining information from various sources. Constructing and refining the initial programme theory required us to explore the assumptions and perspectives of the programme managers and designers on how the adherence club could work. Consolidating the initial programme theory, which we elicited from the document review and programme designers, required that we explored evidence on how similar interventions worked (or not) in other contexts. We also explored cognitive and behavioural theories that have been applied to explain adherence to ART behaviours. We integrated the evidence from these sources using the ICAMO configuration to formulate the initial programme theories. Based on our configurational mapping, two programme theories, each offering an opposing explanation of how, why and in what circumstances the adherence club works, emerged.

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According to Pawson and Manzano-Santaella [48], "programmes never offer up a single theory." This is because of the multiple mechanisms – a proliferation of ideas within a programme, creating different resources that trigger different reactions among the actors [48]. Similarly, there are the individual-level, institutional-level and structural features that modify the action of the assorted mechanisms provided through the adherence club intervention. This indicates that there are multiple context conditions involved in modifying how the intervention plays out, which presupposes multiple potential outcomes. The theories obtained in this study will be tested during the next phase (Phase 2) of our study. The initial programme theories will guide the design and data collection methods for the empirical work [15].

Pawson and Tilley [13] suggested that while eliciting a programme theory based on the realist logic, the findings (theories) obtained should have three main characteristics: 'configurational', 'middle-range' and 'adjudicationist'. By configurational, the authors implied that the theories

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should be able to show how combinations of programme-related attributes need to be in place for a programme to be effective. Regarding theories being at the 'middle range', they said the theories should have the potential for transferability on the basis that they are imbued with concepts that "link to other programme theories and thus rest on further bodies of findings." Finally, regarding being adjudicationist, the findings obtained should provide alternative explanations to the fore to sift and sort them. Our programme theories possess these three characteristics.

We applied the retroduction logic to configure the elements of the realist heuristic tool (configurational mapping) – assuming the outcomes to follow from the alignment of mechanisms fired in particular contexts – to construct the programme theory. Secondly, we considered the explanatory potential of other ART adherence theories and models that have been previously developed as well as explored the how and why other group-based adherence-enhancing models work (or not). Finally, concerning adjudication, our findings present two potential rival theories that will be tested and refined accordingly in the subsequent phases of the project.

Marchal and colleagues [49] found that in attempting to specify the CMO configurations while formulating realist programme theories, some authors fail to demonstrate the explanatory nature of the realist logic. Authors often come up with exhaustive fragmented 'catalogues' of plausible contexts, followed by other lists of mechanisms and another list of outcomes as opposed to properly structured and interconnected relationships among programme context, its mechanism and outcomes. While formalising the testable hypotheses, we used "if…, then…, because…" statements to avoid simple cataloguing of context, mechanisms and outcomes.

We found that the configurational logic of the realist analysis was strengthened by including a description of the 'Intervention' and the 'Actors' in the CMO heuristic [36,37]. Dalkin et al. [50] and Jagosh et al. [16] also proposed modifications to the CMO heuristic. Dalkin et al. [50] suggested the importance of conceptualising mechanisms as operating on a continuum, rather than as an 'on/off' switch. They argued that this conceptualising can have more explanatory value in understanding how interventions work [50]. Jagosh et al. [16] suggested that CMO configurations could be linked to each other in a 'ripple effect' type pattern. We found that the ICAMO stimulates the analyst to figure out the configuration for each group of actors in function of the different modalities of intervention implementation.

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Study limitations

The identified limitation to studies of this nature relates to the fact that the process of making the associations of the various elements in the configurational mapping depends largely on the judgement of the researcher(s). Therefore, this process could be subjective based on the interpretation that the researcher applies to the available data. This limitation was minimised by using more than one researcher in the process of doing the analysis and making connections and presenting the configurational map at a journal club for comments. Comments received at the journal club were also applied to refine the final configuration map obtained.

Conclusion

In this paper, we have described the process of eliciting the initial programme theory of the adherence club intervention. Based on our analysis, we identified two testable hypotheses for the adherence club intervention. The first theory supposes that patients become encouraged, empowered and motivated through the adherence club intervention to remain in care and adhere to the treatment. The second theory suggests that stable patients on ART are being nudged to remain in care and adhere to the treatment with the goal to decongest the primary health-care facilities. These programme theories will be the starting point of an evaluation of the programme. In the next phase of this project, we will test the two hypotheses elicited in contrastive sites, which will allow us to confirm, refute, modify or consolidate the two possible initial programme theories.

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SECTION III

TESTING THE INITIAL PROGRAMME THEORY

Overview

In Phase 2 of evaluating the adherence club intervention following the realist logic, the goal is to test the elicited initial programme theory in real life situations (clinics running the adherence club programme) to refute, validate or refine the initial programme theory. The initial programme theory is used as the hypothesis tested within the various cases. Phase 2 is indicated by the encircled section on the research process diagram in Figure III-I below.

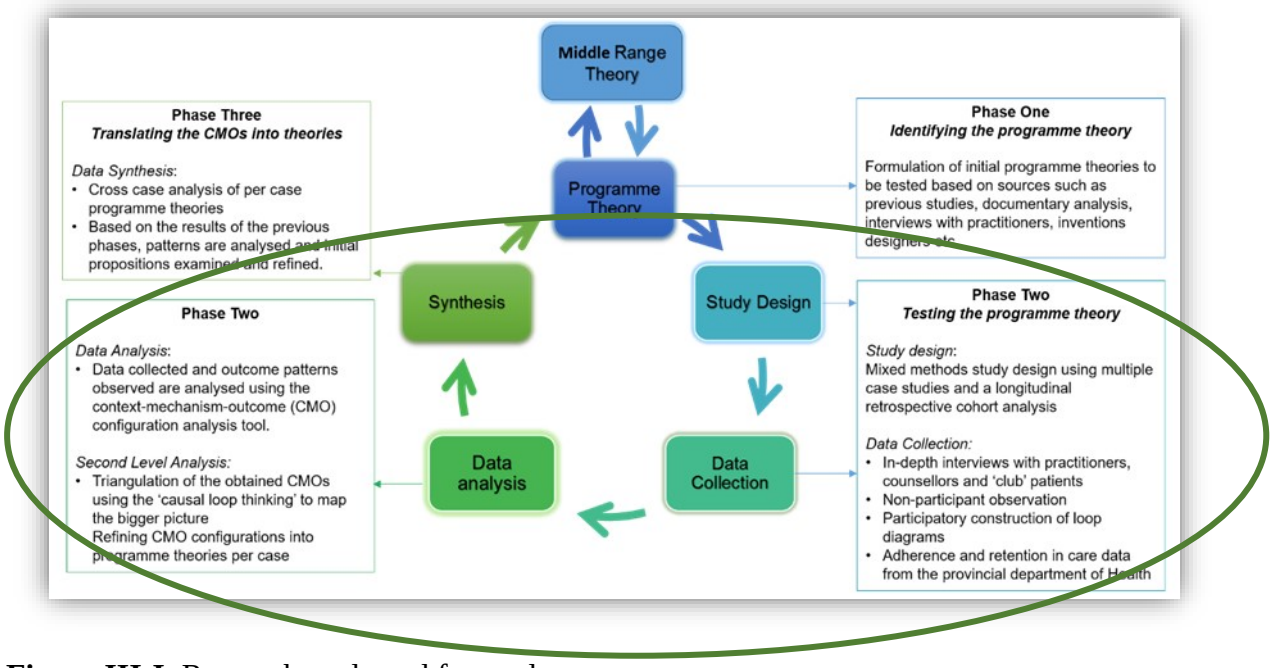

Figure III-I: Research cycle and focused step

Methods

The realist methodology is method neutral and the method adopted during data collection is determined by the type of information needed and how it contributes towards constructing and validating the realist theory. Within each case, we conducted non-participant observations and collected retrospective data from the adherence club register to describe the principal outcomes of the adherence club intervention using the Kaplan-Meier descriptor. Using data from these

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methods, we performed inter-case analysis to elicit case-based theories of how, why the adherence club works based on the ICAMO configuration as supported by the data obtained from each of the cases examined.

In **Chapter 8** the application of the various methods applied in the evaluation of the adherence club intervention is described. The principal method adopted in this study was the realist interviewing technique and is described in detail in this chapter.

Case studies

Three contrastive sites were selected for testing the initial programme theory. The cases were described as typical, deviant or crucial.

In **Chapter 9**, the Mitchell's Plain community health centre (MPCHC) is described – Facility X, identified as a 'typical' case regarding the rollout of the adherence club programme, had 79.9% retention in care. The MPCHC was among the initial facilities scheduled for the first phase rollout of the programme in 2012 and has shown steady growth since the adherence club programme was introduced at the facility despite various challenges.

In **Chapter 10**, the testing of the initial programme theory at the Vanguard community health centre (VCHC) is described – Facility Y was selected as a 'deviant' case (poor performing from the onset) for testing the initial programme theory of the adherence club intervention. This was because the VCHC showed poor retention in care rates of 63.0% based on the routine monitoring and evaluation data on the adherence club intervention in 2015. Although the VCHC was selected for the first phase rollout of the adherence club intervention in 2012 along with other clinics in the health sub-districts, this CHC only rolled out the intervention in September 2014. Reasons were because of challenges related to a lack of physical space and poor buy-in from the facility health-care providers.

In **Chapter 11**, we elaborate on the testing of the initial programme theory at the Heideveld CHC (Facility Z). We selected this centre as the 'critical' case because, after a seemingly successful implementation of the adherence club programme (2011 to 2014), the facility implemented a form of 'service integration' where PLWHA, diabetes, hypertension and/or epilepsy are managed in the same unit. This service integration changed the dynamics around the adherence club programme and negatively affected the retention in care and adherence behaviour of patients on ART at the facility.

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CHAPTER EIGHT

Paper 6

A practical demonstration of the realist interview technique within a realist evaluation study. American Journal of Evaluation (Under review).

Abstract

Realist evaluation submits that theories of how, why, for whom and under what circumstances programs work could be formulated by conceptualizing the relational links between the context within which programs are implemented, the generative mechanisms the programs trigger and the outcomes of interest. Qualitative and quantitative approaches promote the description of relevant context, the generative mechanisms and the emergent outcomes of programs and provide explanatory power to link these elements. The 'realist interviewing technique' whereby interviewees comment on a suggested "program theory" to provide refinement is proposed as a distinctive approach for conducting interviews within realist research. However, the application of this interviewing strategy to reinforce and maintain theoretical awareness within realist evaluation studies is underutilized. In this study, we demonstrate how the realist interview technique contributes to trustworthiness through three theory-building phases: theory gleaning, theory refining and theory consolidation and encourage its application where suitable.

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Introduction

The use of realist evaluation to evaluate the implementation of policies, programs and interventions in health services and other fields of research and evaluation has multiplied in the last two decades (Wong, Westhorp, Manzano, Greenhalgh, Jagosh, Greenhalgh, et al., 2016). Realist evaluation is a theory-driven approach to evaluation (Westhorp, 2014; Wong, et al., 2016) drawn from the seminal work of Pawson and Tilley (1997). The aim is to elicit and test the program theory of a program, policy or intervention to explain how, why, for whom and under what circumstance it works (Pawson & Tilley, 1997). This explanation is achieved by conceptualizing the causative links between the contexts (C) within which programs are implemented, the generative mechanisms (M) the programs trigger and the outcomes (O) of

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interest. The realist evaluation is method neutral to obtain information regarding the context, mechanisms and outcomes. Often, a mixed methods approach is used, involving the integration of quantitative and qualitative research findings for confirmation, completeness and abductive inspiration (retroduction) (McEvoy & Richards, 2006) to enable the researcher to formulate and test the program theory.

In principle, qualitative approaches are used to explore implementation features related to the context, the underlining mechanism and the intervention modalities, while quantitative approaches are used to identify and describe patterns in the outcome. In other words, the qualitative methods allow identification of relevant context elements, the generative mechanisms and the choices and behaviors of the actors. According to Smith and Elger (2012), traditional interviewing techniques (structured, semi-structured, or unstructured) could be used to obtain information on 'the social contexts, constraints and resources within which those informants act' (p. 6) to formulate theories. Pawson and Tilley (1997) suggest that in addition to eliciting theories through various interviewing techniques, placing the formulated theories before various program actors for examination could inspire, validate, falsify, and/or modify hypotheses about how programs and interventions work, which is an essential process for theory refinement.

Nevertheless, it has been observed that in many realist evaluation studies, investigators fail to report on the program theories they are investigating, suggesting that they do not actively involve the program actors in the process of verifying any theory. A review by Manzano (2016) revealed that in most realist research studies, the investigators used traditional qualitative interviewing methods either as part or as the only method to refine the program theory. While a good interviewer could explore the different angles to the research questions that can be explored with the participant, or even reflect with the participant on the subject matter to inspire a theory, traditional qualitative interviews might not be the best way to verify the preliminary theories formulated. This is because traditional qualitative interviews are based on the principle that 'if one puts a straight question, then most of the time one gets a straight answer', an understanding inadvertently shared between the researcher and the respondent (Pawson & Tilley, 1997, p. 165).

Manzano (2016) also found that most qualitative interview approaches used in the reviewed studies aimed to evaluate the program effectiveness and/or describe barriers to using the program. Her findings suggest that the research methods employed in most realist studies

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(theory-driven inquiry) gravitate towards data-driven approaches. By adopting a data-driven approach, the investigators may fail to offer the respondents the opportunity to examine and comment on the preliminary theories that the investigators formulated (hypothesis). The inclination to employ data-driven approaches to a realist inquiry could arguably be related to the influence of other paradigms and research approaches such a grounded theory or the investigator's inclination to understand the process, which presupposes unstructured interviews (Pawson & Tilley, 1997).

For instance, Linsley, Howard and Owen (2015) conducted a realist evaluation study to understand how and why aggression management training programs provided to healthcare staff for preventing and managing violence and aggression from mentally ill patients work. Although this study was conducted with the realist evaluation framework, it was situated in an 'interpretivist paradigm' (Linsley et al., 2015, p. 30), which informed the nature of the approach applied. This example typifies how other paradigms could influence how data are collected in realist inquiry with some realist investigators failing to adopt theory-driven approaches to conduct realist inquiries.

McLachlan and Garcia (2015), arguing for philosophical and methodological commitment while conducting qualitative interviews but, nevertheless, recognized that applying critical realism to inform their qualitative interview practice was 'difficult and inadequate'. They mentioned, *trying 'to be' critical realist in an interview setting led to an approach that sought to isolate ontology and epistemology and as a consequence, disregarded the simultaneity and immediacy of the interview experience* (McLachlan & Garcia, 2015, p. 207). Although they had set out to develop a critical realist approach to qualitative interviewing, based on these challenges, they found themselves adopting constructivist principles to conduct qualitative interviews framed within a critical realist study (McLachlan & Garcia, 2015). Thus challenges relating to maintaining philosophical and methodological commitments in the realist philosophy are not uncommon as applied to the field of realist evaluation or in critical realism.

The 'realist(ic) interviewing' approach was proposed by Pawson and Tilley (1997, p. 164-169) to describe the management of the flow of information between the researcher and the study participants as an important methodological strategy to examine theories in realist evaluation studies. The realist interview technique focuses on creating *a situation in which the theoretical postulates/conceptual structures under investigation are open for inspection in a way that allows the respondent to make an informed and critical account of them* (Pawson, 1996, p. 313).

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In this article, we report on our experiences of applying the realist interviewing technique within a realist evaluation study. We elaborate on the application of the realist interviewing technique through the phases of developing a theory: theory gleaning interviews, theory-refining interviews and theory consolidation interviews. We particularly demonstrate how this technique can be used to tease out the various components (intervention, context, actor, mechanism, and outcome) of a program theory. We argue that this practical demonstration could provide a direction on how the realist interview could be applied. Consequently, we encourage its adoption where applicable.

The realist approach to interviewing

In **Figure 8.1**, three ontological domains identified in the realist philosophy are indicated, the real, actual and empirical domains (McEvoy & Richards, 2006). The real relates to the existence of (usually) invisible mechanisms with generative power causing what is actual. The actual defines the things that happen, independent of whether they are observed or not (events) and the empirical domain relates to our experiences of what actually happens (Eastwood, Jalaludin & Kemp, 2014). The domain of the actual includes events generated by mechanisms, while the domain of the real represents mechanisms that has the capacity to generate actual events.

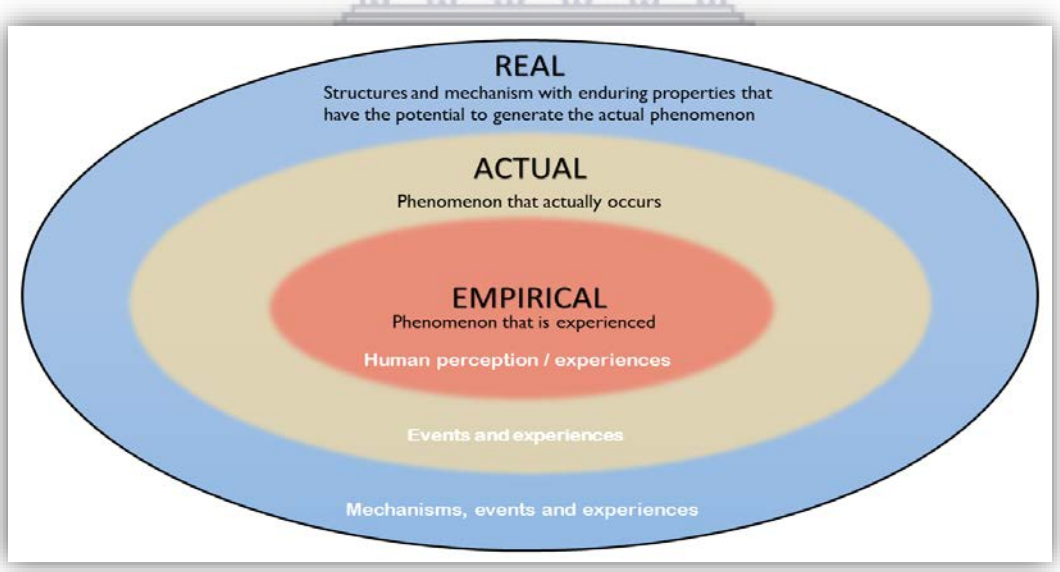

Figure 8.1: Ontological positions of realist philosophy informing realist interviews

The epistemological implication of these three domains is that in collecting data, realists give importance to construction and communication of meaning among actors, as a topic of investigation and as an essential medium of research and theorizing (Smith & Elger, 2012). This

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follows from the fact that realists advocate the use of explanation, abstraction and interpretive logic to make causal inferences – drawing conclusions regarding causation by applying forms of reasoning (Eastwood et al., 2014).

Retroduction, a form of inference that seeks to identify and verify mechanisms that are theorized to have generated the phenomena under study, is used in realist studies. According to Wynn and Williams (2012), retroduction is an explanatory model characterized by the use of causal mechanisms as the basis for this explanation, the possibility for multiple potential explanations, and the understanding that these causal mechanisms may or may not be observable empirically. By applying retroduction, the realist researcher moves from the description and analysis of concrete phenomena (usually obtained from actors by interview) to reconstructing the basic conditions (theory) for these phenomena (Eastwood et al., 2014).

While conducting a realist evaluation, the evaluator starts by eliciting an initial program theory – assumptions of how the program should be organized and why the program is expected to work (Westhorp, 2014). The next step entails testing the hypothesis in selected cases: the realist investigator is interested in investigating whether a program theory holds (Manzano, 2016). To this end, Pawson (1996, p. 304) proposes the realist interview technique comprising the *teaching-learning* function and the *conceptual focusing* function. The realist interview incorporates components of presenting the respondent with a formal description of the parameters of the initial program theory for verification (teacher-learning function) and offers the respondent the opportunity to explain and clarify the thinking of the researcher based on their (respondents) ideas (conceptual focusing function).

In realist research, the assumptions and expectations of the program designers (folk theories) must be explored. In addition, the sense and the experiences that the program actors use to construct, maintain and negotiate the expected behavior are vital. To obtain information from these program actors, the investigators use appropriate multi-method data collection and analysis approaches. These methods are usually applied to glean the information on the program modalities, important context conditions, mechanisms provided and/or triggered by the program and the potential outcomes of the program that could be used to formulate the initial program theory. Exploratory or explanatory interview approaches are usually applied during the theory-gleaning phase, thus referred to as *theory-gleaning interviews*. An initial program theory is formulated based on the information gathered from the theory-gleaning interviews, but also document and systematic reviews, observations and other relevant methods. Manzano (2016)

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suggests that the use of theory-refining and theory-consolidation interviews along with other methods is central to obtain a more refined program theory.

The phrase, *I'll show you my theory if you show me yours*, coined by (Pawson, 1996, p. 307) and Pawson and Tilley (1997. p. 169) captures the essence of the teaching-learning function of realist interviewing. In applying the teacher-learner approach, the interviewer is advised against adopting the *deliberate naiveté* position (Kvale, 1996, p. 33), but rather the position of an expert. Pawson directs that the interviewer should adopt an active and explicit role in teaching the preliminary theory that has been developed in a previous exploratory study to the interviewee. In this case, the respondent gains an understanding of the conceptual structure of the investigation or the program, and in turn, the interviewee can make sense of the individual questions that will emanate during the interview process. Through this process, the interviewer will learn, in turn, how the respondent constructs meaning through the conceptual framework received from the interviewer. Pawson (1996, p. 307) suggests that in 'teaching' the interviewee, the intuition that the interviewee should get is 'Yes, I understand the general theoretical ground you are exploring, this makes your concepts clear to me, and applying them to me gives the following answers …'. Therefore, the respondent becomes more of a participant in the meaning-making process than simply a source of information.

Regarding the conceptual focusing function of the realist interview, Pawson and Tilley (1997, p. 160) suggest that this function is applied to obtain responses related to the program mechanisms relating to how the respondents take decisions and make choices in relation to a program. The authors state that conceptual focusing occurs when the respondents are given the opportunity to express their points of view based on their own thinking and decision-making process in the context of the interviewer's theory. Pawson (1996, p. 303) writes that the expertise related to the 'generative mechanism' of a program often lies with the informant as s/he describes the detailed way in which reasoning contributes to the observed outcomes. Thus, their contribution plays a vital role towards confirming, falsifying and/or refining the researcher's theory.

Another important aspect relevant to conducting realist interviews is the notion of 'knowledgeability' of the interviewees. This notion relates to 'who knows what' regarding the program. In this regard, Pawson and Tilley (1997, p. 160-161) identify two important categories of potential informants relevant to realist evaluation of a program, 'practitioners' and 'subjects'. The identification of potential key informants for realist interviews is important for the selection

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of participants and for how the interviews will be focused and conducted in relation to teasing the intervention modalities, context, actors, mechanisms and outcomes elements.

The context-mechanism-outcome configuration and the realist interview

The context-mechanism-outcome (CMO) configuration is a heuristic analytic tool used to construct theories in realist evaluation studies. Therefore, in eliciting the program theory of a program or an intervention in realist evaluation, the investigator strives to configure the causal relationship between the context within which the program is implemented (individual, organizational and environmental), the mechanisms that are provided by the program and the expected outcome(s) of the program. CMO configurations postulate how programs activate mechanisms (M) among whom and in what conditions (C), to bring about alterations in behavior or event or state regularities (O) (Pawson & Tilley, 2004, p. 9). These propositions bring together mechanism-variation and context-variation to explain outcome pattern variation (Pawson & Tilley, 2004, p. 9).

Van Belle (2013) and Marchal et al. (2017) elaborated on the CMO configurational logic proposed by Pawson & Tilley (1997) to include components of the 'Intervention' and the 'Actors'. This follows the understanding that people are not passive recipients of innovations (Greenhalgh et al., 2004) and programs can only work when the relevant actors adopt either all or parts of the intervention modalities. In this regard, generative *mechanisms* are used to explain how the *intervention* (or aspects of the intervention) unfolds in a particular *context* and in relation to the various *actors* to produce the observed *outcomes*. Thus, representing the intervention modalities (I) and the relevant actors (A) provides a comprehensive representation of how and why a program works (or not). Following this, these authors suggested that an intervention-context-actor-mechanism-outcome (ICAMO) configuration would provide a better analytical tool because aspects of the intervention are accounted for which provide the mechanisms and the actors through whom the intervention works. In this article, we adopted the ICAMO heuristic.

Pawson and Tilley (1997) suggest that the selection of the potential interviewee should be based on their contributions toward clarifying the program theory. Different respondents might contribute to different components (Manzano, 2016, p. 350). Practitioners will have specific ideas on the intervention modalities what is within the intervention that works, knowledge on

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the outcomes of the intervention (because they are likely to have experienced successes and failures), and some awareness of actors and places for whom and in which the intervention works (Pawson & Tilley, 1997, p. 161). On the other side, the program users are more likely to be sensitized about mechanisms and intervention modalities than to its contextual constraints and outcome patterns (Pawson & Tilley, 1997, p. 160).

Program theory and the realist interview phases

The adherence club intervention – a group-based adherence-enhancing intervention – was implemented in the Western Cape Province, South Africa to address challenges of clinic congestion, poor retention in care and suboptimal adherence to antiretroviral treatment (ART). This intervention realized in the context of the rapidly growing HIV patient population on ART in South Africa (Wilkinson, 2013). The aims are to (a) retain patients in ART care by providing a more efficient way to manage stable patients; (b) maintain good long-term adherence in PLWHA on ART through quick access to medication and (c) decongest the health facility through group sessions (facilitated by trained non-clinical health-care workers) (Department of Health, 2015).

The adherence club intervention is designed to streamline ART care for an adult (18+ years), treatment-experienced patients with good clinic attendance record and evidence of medication adherence (two most recent consecutive viral loads undetectable (<400 copies/mL) (UNAIDS & MSF, 2012). Through group consultations, convenient medication pick-up processes, and providing access to a clinician when needed, the adherence club drastically reduces the waiting times for the patients. The club facilitator refers any patient who reports with symptoms suggesting illness, adverse drug effects or weight loss to the club nurse for further consultations. Based on the outcome of the consultation, they are either sent to collect their medication from the club facilitator or removed from the club (having uncontrolled comorbidities such as diabetes or hypertension). The use of a lower level healthcare cadre, usually a peer, to facilitate the club activities also facilitates the counseling and educational aspects of the intervention. In this way, better efficiency of health professionals is ensured. The intervention also provides a social environment that encourages patient interaction. The adherence club intervention has been described in greater details elsewhere (Wilkinson, 2013; Bateman, 2013; Mukumbang et al., 2016a).

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Realist evaluation is about theory testing and refinement. In this regard, during the realist interview, the researcher's theory is the subject matter. The realist interview process, therefore, creates the teacher-learner relationship in which the medium of exchange is the program theory and the role of the interviewee is to confirm, falsify and refine the theory. The interviewer should not present program theories to the participant but is advised to verify the questions asked.

Realist researchers enter the field with prior theory/theories with the goal of verifying, disproving or rectifying these. The process of obtaining the initial program theory is described as theory gleaning. Because the purpose of conducting a theory-based evaluation is to test the initial program theory to explain the program, the obtained initial program theory is tested using the case study approach. In this phase, the theory is refined and consolidated. In accordance with the process of eliciting and testing the initial program theory, Manzano (2016, p. 343) proposed three types of realist interviews, theory gleaning, theory refinement and theory consolidation interviews. We describe how we applied the three types of interviews during the realist evaluation of the adherence club intervention.

Phase 1: Theory gleaning interviews

The first step in conducting a realist evaluation is to elicit the initial program theory that explains how the intervention is expected to work according to the program designers and implementers (Pawson & Tilley, 1997, p. 88). Thus, the theory gleaning phase or 'theory elicitation' is represented, where different sources are used to obtain relevant information that could be useful to articulate the preliminary understanding of how, why and under what conditions a program works. The researcher, therefore, strives to make sense of the program's original intention by conceptualizing, categorizing and ordering (Andersen & Kragh, 2010) the experiences and assumptions of the program designers and implementers to formulate a preliminary theory.

Recent suggestions were that information could be obtained through reviewing the program documentation, existing ideas about the family of programs and social/psychological theory, and interviews with key stakeholders (Nebot Giralt et al., 2017). Regarding the latter, the assumptions and perspectives of the program designers and managers on how and why the program works or should work are important.

According to Pawson and Tilley (1997, p. 161), program designers and people working to implement the program are useful sources of information at this phase of the study. This follows the assertion that managers, stakeholders and workers involved in a program have 'cognitions'

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(or ‘mental maps’) about the organization and the environment of the program (Leeuw, 2003, p. 14). In accordance with this suggestion, we interviewed the program designers and senior and middle-level managers (Mukumbang et al., 2016b). We included the facility level managers in the second phase of theory refinement.

The questions asked during the interviews in the theory-gleaning phase were predominantly exploratory. At the initial phase of the study, we conducted a review of documents such as program descriptions, implementation guidelines, and a toolkit on the adherence club. The information obtained from the document review served as pointers to the aspects that required more probing during the interview process with the key informants. The goal was to identify the assumptions – folk theories of the respondents. Indeed, according to Leeuw (2003, p. 14), the use of well-designed questions during the interview process could unearth the ‘theory in use’ of the program. Byng, Norman and Redfern (2005) suggested that at this stage, the inquiry should involve generating ideas about which contextual factors are likely to be important, considering potential mechanisms and looking at the main outcomes of interest. In this way, the discussions could also focus on developing prototype ICAMO configurations regarding each identified outcome - which means focusing the questions on eliciting details of the intervention modalities, contexts, actors and mechanisms (Byng et al., 2005).

Our approach at this point was to understand the nature of the adherence club program, how and why the program designers/managers envisaged it should work. For this reason, we adopted a standard semi-structured in-depth interview method (Mukumbang et al., 2016b). We also used trigger questions to obtain specific information. The excerpt in **Table 8.1** illustrates the exploratory nature of the questions asked, focusing on obtaining details of relevant contexts, potential mechanisms and main outcomes of interest.

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Table 8.1: Example of an exploratory interview with a program manager

Participant	Contribution	ICAMO themes
Interviewer:	I am interested in formulating a program theory based on what was going on in the minds of the people who designed the adherence club and the people who are implementing it, what was driving it, what made them get into this program? So the first thing that I want to know is what you see as the purpose of the adherence club.	
Participant:	Well initially, when it started, I was not part of the initial process. My understanding then, when it was started without me being involved, was that it was a way to get our stable patients into a club system where they could pick up medication quickly and they could get out of the clinic quickly because as it was before patients were sitting in clinics for hours just waiting for the meds pick-up, and basically their consultation was 2 to 5 minutes because they were stable, they were 'well' patients.	Mechanism: Perceived benefits Context: Facility organization
	So we needed a program where these patients could be seen quicker and get out quicker. That was my understanding because remember our patients caused a lot of congestion in the facilities and medical officers and very experienced nurses were seeing these stable patients where you had a lot of sick patients still that needed to be attended to and they were waiting long in clinics.	Intervention modality: Quick service provision Actors: Patients and Health care worker
	So it helped two things, one, for systems to be improved in clinics in terms of Triage and secondly getting these patients out faster and reducing waiting times (number 1) and (number 2) reducing, the burden on Pharmacy.	Outcome: Reduced waiting times and workload

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As illustrated in the excerpt (**Table 8.1**) as well as the overall interview guide, the interviews were designed to obtain information on the accounts and viewpoints of the respondents on salient issues and events. We started each interview with the managers and program designers with general questions on adherence to medication, retention in care and the interviewee's role. Later, we asked about the context and then probed for information on the outcome of the adherence club intervention. The open-ended nature of some of the questions was designed to explore those management decisions and ideas that were proposed. We also touched on some of the changes and the evolution the adherence club intervention has undergone over the years.

The results from the document analysis and the analysis of the semi-structured in-depth interviews were used to formulate ICAMO configurations that informed the further development of the adherence club's initial program theory. To further consolidate it, we carried out a systematic review of available studies on group-based ART adherence support models in sub-Saharan Africa (Mukumbang et al., 2017a) and a scoping review of social, cognitive and behavioral theories that have been applied to explain adherence to ART (Mukumbang et al., 2017b). Using information collected from these sources and following the logic of retroduction, we applied counterfactual thinking (creating possible alternatives) to develop the initial program theories of the adherence club program as an ICAMO configurational map – a logic in which outcomes are considered to follow from the alignment, within a case, of a specific combination of attributes – of the elements of the realist heuristic tool (Pawson & Tilley, 2004). This was done by linking each active mechanism identified from the various intervention modalities as being associated with an outcome (M-O links), then we looked for the context on which the mechanism is contingent. After obtaining conjectured ICAMO configurations, we applied counterfactual thinking (testing possible alternative explanations) to argue towards *transfactual* (mechanism-centred) conditions (Eastwood et al., 2014). By converting the ICAMO explanatory configuration to "if …, then …, because…" phrases, we obtained testable hypotheses of the initial program theory (**Box 8.1**)

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Box 8.1: Initial program theory of the adherence club intervention represented by two tentative theories (hypotheses)

Initial programme theory 1

IF adult (18+ years) clinically 'stable' patients with evidence of good clinic attendance are group-managed, receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they develop a group identity, which improves their perceived social, support, satisfaction and trust; and acquire knowledge, which helps them to understand their perceived threat and perceived benefits and improves their self-efficacy. As a result, they become encouraged, empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

Initial programme theory 2

IF operational staff receive goals and targets set to continuously enrol patients in the adherence club and strictly monitor their participation through strict standard operating practices (the promise of exclusion in the event of missed appointment and active patient tracing),
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they fear (perceived fear) of losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules. As a result, they become nudged to remain in care and adhere to the treatment, which might decongest the health facility.

Phase 2: Theory refinement interviews

Once the initial program theory is elicited, the goal of the program evaluator is to verify it through an empirical study. The theory refinement interviews were conducted within the ambit of a multi-case study research approach. According to Andersen and Kragh (2010), the use of the theory-building approach in case studies treats the theory being tested, the data being collected and analysis as equal, interacting elements of the research process. The role of the realist interviewing technique in this phase is to use the initial program theory as the basis for obtaining further information that could be used to clarify or discredit the initial program theory. In addition to this, other methods were applied to triangulate or support the information obtained through the realist interview techniques.

Evidence of how mechanisms are triggered and working can only be discovered *a posteriori*, not generated by the researcher. Therefore, during the theory refining phase of the study, both quantitative and qualitative data were collected in function of the initial program theory that was being 'tested'. The use of a multi-method evidence base was meant to ensure good documentation of the implementation of the program (Sharpe, 2011). We employed quantitative data collection and analysis methods to identify and classify the outcome patterns and qualitative data to explore implementation features related to the context (observation) and the mechanism

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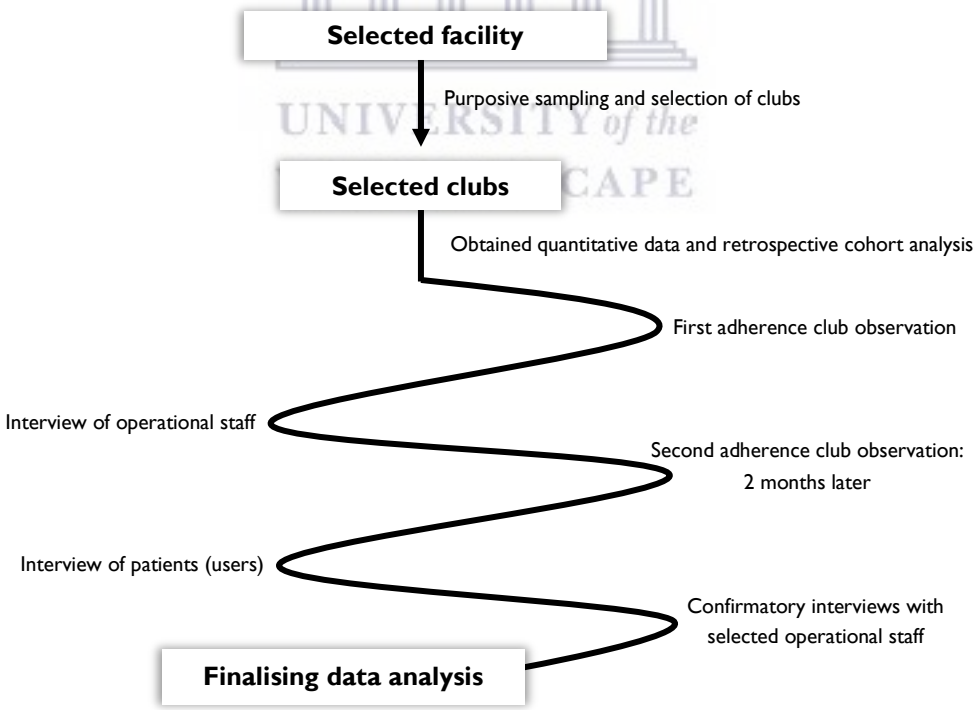
(realist interviews). We thus combined a retrospective cohort analysis and an explanatory qualitative approach. The retrospective cohort analysis was conducted to describe the primary outcomes of the adherence club intervention (retention in care and adherence to medication) and the qualitative explanatory design provided evidence regarding the ICAMO configuration links in the implementation chain (intervention modalities, actors involved, generative mechanisms, relevant context and outcome patterns).

Two qualitative data collection methods were used: non-participant observations (Mills, Eurepos, & Wiebe, 2010; Patton, 2015) and semi-structured realist interviews (Manzano, 2016; Pawson, 1996). We conducted four non-participant observations of the adherence club meetings, where we observed club sessions without interfering in any of the processes. These included two sessions of exclusive medication collection and a blood sample collection plus medication collection. The goal of the non-participant observation was to obtain insights into events and activities and the meanings that the club members attach to the sessions. We captured the dynamics of interactions of the group members with each other and with care providers in our field notes. During each observation session, we took detailed field notes. **Figure 2** illustrates the data collection strategy adopted in the study.



Our focus, once again, will be on the role of the interview technique applied. In essence, this is the point at which the teacher-learner and the conceptual refining function become apparent.

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During this phase, *the researcher's theory is the subject matter of the interview, and the subject is there to confirm or falsify and, above all, to refine that theory* (Pawson, 1996, p. 299). First, in accordance to Pawson and Tilley (1997), the interviewer explained the theories that were obtained during the exploratory or theory-gleaning phase to the respondent. Then, the respondent, having understood the proposition of the interviewer, commented on the theory based on their experiences and offered their opinions on how and why they think the program works (or does not).

During the theory refinement phase of our study, we interviewed three categories of actors, clinical staff (doctors and nurses), club facilitators (lay counselors) and the users (patients). These distinctive groups of actors were purposively selected based on their knowledge of the adherence club intervention. Therefore, the purpose of interviewing these different stakeholders was to obtain their interpretations of their social contexts and their reasoning regarding the resources and constraints.

We explained our initial program theory to the program managers and the adherence club facilitators and used their responses to refine the initial program theory. In **Table 8.2**, we show an excerpt from an interview with a club nurse to illustrate the teacher-learner conceptualization of the realist interview method. Notably, we described the two theories explicating how and why we think the adherence club hypothetically would work. First, we wanted to know if based on their understanding and experience of working on the program they could identify which of the two theories (or if both of the theories are applicable). Then, we allowed them to provide more information to back up their choice of theory. This process was enabled using probing questions.

Table 8.2: Excerpts from an interview with a club nurse to illustrate the teacher-learner conceptualization of the realist interview method

Participant	Contribution	ICAMO themes
Interviewer:	So, this is how we think the Adherence club works. We think the Adherence club motivates patients to take their medication. It empowers them because the whole goal is self-management. People are trying to make them be able to manage their disease themselves. That is the ultimate goal. So, we think that it motivates, we think it empowers	

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	them. In addition, on the other hand, because of the club rules and regulations…we think that you people also nudge them…guide them in a little bit strict way to do that. So, this supposed understanding that we have is: on the one side you are trying to encourage them 'Do your own thing, we give you the resources… Use these resources to help yourself' and on the other hand, there are rules 'You need to do this, do that' so that everything should work. Therefore, that is the summary of how we think the Adherence club works. So, in your opinion, how does it work?	
Participant:	So, there are a lot of patients, our criteria for patients to be put into the club: you need to be at least 6 months on ARVs [Antiretroviral medication] with a low viral load (LDL). And if it's females, then we want them to have a Pap smear done, right? So, then we place all these patients into clubs. And then it is a good motivation for them, they like it because number one, the waiting time in this waiting area, in the ARV unit is reduced.	Context: Patient criteria Mechanism: Motivation Outcome: Reduced waiting times
	We [Health care workers] also tell them [patients] they do not need to go and fetch their folder because in this facility you need to wait in a pre-waiting area, wait for a Clerk to come to get your card according to your waiting time. Then you go into the main waiting area and you wait for your folder to be taken out by the clerk, then, they wait until they get a few folders and then they send you through to our ARV department. And then from here, you have to wait until another clerk puts your ARV stationary into your folder and then wait for a nurse to weigh you and then wait for a Sister to call you. So, it is a whole long procedure. So we tell patients, we encourage them that 'if you take your ARVs and you are	Actor: Patients Context: Facility organization Context: Preparation Actors:

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compliant with your ARVs, we can put you in a Club if you are 6 months and longer but on condition your, your viral load has to be lower than detected and if you are a female, a pap smear must be done, then we will put you into a club. Then, you just come straight into the facility, straight to the Counselor. You avoid all those waiting periods and medication collection. You do not have to go to the Pharmacy where you have to sit with the mainstream and your medication is here because our Counselors collect the medication the day before.' And so, our Counselors come in their own time at 7 and they are ready for our patients, they explain to them the rules and they get their medication.

So, by 8, half past 8 for the latest they [patients] are out of the facility, as a result, they can still go to work, they do not have to sign a day's leave and all those things. While they are in the club they form a bond because our Counselors open up a group chat so in that it is also a support group. So, they would remind each other 'do not forget your club date is tomorrow.'

One of the rules [of the adherence club] is that you need to attend your club sessions. You need to be complaint with your dates. If you are unable to come you send someone or you can phone but you've got five days grace period to collect the medication. If you do not communicate with us or you do not collect your tablets within five days, you are going to be placed out of the club and back into the mainstream where you have to go through that whole waiting procedure.

That is why I say it is a combination of your theories.

Patients and Health care worker

Context:
Patient criteria

Mechanism:
Perceived benefits

Intervention modality:
Use of 'treatment buddy'
Actors: Counselors

Context:
Service organization

Mechanism:
Perceived benefits

Mechanism:
Bonding (group identity formation)

Intervention modality:
Club rules

Mechanism:
Nudging through rules

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What we have also done now is, all the patients, because we provide a holistic, integrated service in this [ARV] department, we have made a chronic club - we have 3 chronic clubs. So, if you have hypertension or diabetes then we will put you together in one group - in one club. So we know when those patients come we will take your blood pressure, we will do your blood sugar test, we will send you on your yearly eye testing and we have a feet exam. So that you are also not disadvantaged.	Actors: Patients and Health care worker Context: Service organization Intervention modality: Quick medication pickup
The other thing is that our patients' blood gets taken twice a year, every 6 months, therefore, they also know that if their viral load is not lower than detected they get placed back into the mainstream. So that is also a way of them also being encouraged to be a complaint, taking their medication.	Mechanism: Perceived support Intervention modality: Adherence monitoring Mechanism: Perceived fear of losing club benefits

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The excerpt (**Table 8.2**) illustrates how respondents, having understood the program theory with which the researcher/interviewer is working, frame their responses with the goal of providing clarity to the researcher. The respondent identified the two theories that we elicited as being applicable to a certain extent. The respondent also provided further information to back up the choice of theory or theories. Because we had two theories on which the respondents had to comment reflecting their experiences, we used some exploratory questions to 'guide' their reflections. This captures the potential conceptual function of the realist interview process whereby the respondents have the opportunity to recount their own decision-making process. We have coded the interview to indicate how the responses of the respondent, having understood the framed theories of the interviewer, provide the various elements (ICAMO) that could be used to validate, eliminate or modify the initial program theory.

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Notably, we described the two theories explicating how and why we think the adherence club hypothetically would work. First, we wanted to know if based on their understanding and experience of working on the program they could identify which of the two theories (or if both of the theories is applicable). Then, we allowed them to provide more information to back up their choice of theory. Therefore, in addition to 'teaching' the respondent the initial program theories in the view of obtaining information to validate or discard aspects of them, we asked structured qualitative questions. These structured questions fell within the ambit of the conceptual focusing component of the realist interviewing technique whereby, the respondent clarifies the thinking of the researcher based on their own ideas, knowledge and experiences. An example of structured qualitative questions is illustrated in **Table 8.3**.

Table 8.3: Example of structured qualitative questions with the club nurse

Participant	Contribution	ICAMO themes
Interviewer:	How is the adherence club program organized at the facility?	
Participant:	We have a separate space at the back [of the clinic] where we allow the club people to gather. So they have their own privacy, their own space… So they have that freedom.	Context: Availability of space Intervention modality: Grouping patients
Interviewer:	How important is having their own space and privacy?	
Respondent:	I think it plays a big role because like you can say it is 35 patients that we have per club yet it is also intimate and they are able to form bonds …and they know it is *that* group and they try as far as possible to *remain* within that group because they have that support.	Actors: Patients Mechanism: Bonding Outcome: Retention in club

As mentioned previously, the focus of the questions to the program users did not require them to comment on the initial program theories but on how they made decisions in response to the

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resources, constraints and opportunities provided by the adherence club intervention. Therefore, while interviewing the program users, our focus was on collecting information about (or related to) the reasoning of the patients leading to their decision to adhere (or not) to their medication or to remain (or not) in care. This represents the conceptual focusing component of the realist interviewing technique. An example of the conceptual focusing questions with a program user is illustrated in **table 8.4.**

Table 8.4: Example of structured qualitative questions with a program user (patient)

Participant	Contribution	ICAMO themes
Interviewer:	So now, what was important about you people sitting and discussing?	
Participant:	Especially for me, what is very important is when you have a problem, you may think that the problem is affecting only you, but once you come to the club, you can hear other people also speaking about the same problem. You will be sharing that problem, that is why I like the club, because you can share problems and you do not have to stress yourself because when you are at home, … you can see may be your problem is better than some others problems	Intervention modality: Grouping patients Actors: Patients and Health care worker Mechanism: Perceived benefits Outcome: Reduced stress

Phase 3: Theory consolidation interviews

According to Manzano (2016), consolidation interviews lead to the establishment of third-level theories. The initial program theories are first-level theories. Second-level theories result from the data analysis and third-level theories from the confirmation of the conjectured theories through consolidation interviews. When a researcher conducts a theory test, then propositions, i.e., logical conclusions or predictions, are derived from the theory and are compared to observations, or data, in the case (Cavaye, 1996). The more often and the more conclusively the theory is confirmed, the more faith there is in that the theory reflects reality. To this end, our aim at this point was twofold, to strengthen or reduce support for the test theories, and to determine which of the two theories best explains how, why and in what circumstances the intervention works.

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Two approaches were applied. First, we conducted a working meeting with the adherence club program designers and managers at the three contrastive sites. We presented them with the initial program theory that we elicited, and ICAMO configurations that we obtained after testing of the initial program theory. After we completed an hour's presentation of the elicitation and testing of the program theories and their ICAMO representations, we divided the attendees into two groups. Then we asked them to discuss on which of the program theories' motivation, empowerment and self-efficacy or being nudged by club rules represented how and why the adherence club works in their opinions. Both groups agreed that both theories provided potential explications of how the adherence club intervention works. This begged the question, which theory provided the stronger explanation?

After some discussions were held, a consensus was reached that both theories should be combined to explain the functioning of the adherence club intervention. This decision was backed by the argument that different patients have different attitudes and responses to healthcare resources. That is, some patients would perceive the resources and opportunities offered by the adherence club modalities as a source of motivation (Ryan & Deci, 2000). Others might respond more to the restrictive nature of the club rules and prefer to be nudged rather than given the opportunity to make the decisions (Thaler & Sunstein, 2008). This process was, therefore, very instrumental in addressing the rival explanations that we had and gave us more confidence in our findings.

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The second approach to theory consolidation that we considered, was having conversations with the relevant stakeholders, who *should be guided with the help of the specificities of the individual cases, and from there, they can be directed into the general program* (Manzano, 2016, p. 356). The theory obtained after the theory consolidation interviews should represent *a detailed description of events that reflect the primary actors' and researchers' interpretations of meanings and intentionality* [mechanisms], *and the reciprocal influences of social action and context* (Wynn & Williams, 2012, p. 789).

The process of fine-tuning theories could involve repeating interviews with some key participants to probe, confirm or receive clarifications on aspects of the program theory. This is typically done during the data analysis process when the investigators identify gaps or issues that require further clarification.

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The following excerpt (**Table 8.5**) represents part of an interview that was conducted to obtain clarification on the program theory. The goal was to obtain missing information relating to the role of the health talks that are provided as part of the adherence club intervention. To this end, we scheduled an appointment with the supervisor of the club facilitators at the sub-district level.

Table 8.5: An interview demonstrating the use of the conceptual focusing approach to theory verification

Participant	Contribution	ICAMO themes
Interviewer:	So, this question is how important are the talks that patients receive? Do you think the talk really has an impact in terms of encouraging and motivating them to be adherent to their medication?	
Participant:	Yes, it is a very big impact you know, because it keeps on reminding them the do's and the don'ts. Because if you do not, do the talks, they will forget the rules, they will forget that in order for me to belong what I need to do you know. So, because in our talks we talk about condom use, we talk about STIs [sexually transmitted infections], we talk about things that can interact with your medication …meaning that the amount of the virus will go up and then you will be failing from the line that you are. Then, we will have to take you to the other line meaning that we have to take you out of the club and then blood and other things will need to start afresh you know.	Mechanism: Knowledge acquisition/learning Intervention modality: Health talks Outcome: Reduced waiting times
	Sometimes we [Health care workers] give them [patients] opportunity to come up with topics and they discuss whatever amongst themselves, or sometimes we say, 'guys tell us, on the news there was this story, what do you think about what happened', because you do not want each and every time when they come here we talk about HIV …	Actors: Patients and Health care worker Context: Program organization

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Applying the discussions with the adherence club program designers and implementers with confirmatory interviews led to the formulation of a single theory to explain how, why and under what conditions the adherence club intervention works (**Box 8.2**).

Table 8.2: Refined progam theory

Grouping clinically stable patients on antiretroviral therapy **[Actors]** with available resources and buy-in from healthcare workers in a convenient space **[Context]** to receive quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required while guided by rules and regulations **[Intervention]**, works because their self-efficacy improves and they become motivated and nudged **[Mechanisms]** to remain in care and adhere to medication **[Outcome]**.

Discussion

Pawson and Tilley (1997) proposed that although realist evaluation is method neutral, the use of traditional interviewing techniques is not sufficient for mining the theories that would explain what works, for whom and under what circumstances regarding an intervention. In response to this challenge, Pawson (1996) and Pawson and Tilley (1997, Chap 6) proposed a theory-driven approach to interviewing – the realist interview, which describes the management of the flow of information between the interviewer and the interviewee. Manzano (2016) argued that although the number of realist inquiries has grown at an astonishing rate since realist evaluation was initially introduced by Pawson and Tilley (1997), the application of the realist interviewing technique within these studies is conspicuously absent.

In this paper, we sought to demonstrate the practical application of the realist interview technique through our project of evaluating the adherence club intervention using the realist evaluation approach. We conceptualized the overall interviewing process in three phases: Theory-gleaning, theory-refinement and theory-consolidation. In the theory-gleaning phase, we applied explanatory/exploratory interview questions to elicit the initial program theory of the adherence club intervention (**Box 8.1**).

Following the theory-gleaning phase, we applied the two components of the realist interviewing process: teacher-learner function and conceptual focusing within the theory-refinement and theory-consolidation phases. In the theory-refinement phase, the teacher-leaner function was the

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dominant component of the realist interviewing technique. This is because our goal was to obtain a reflection from the participant on the initial program theory that was formulated.

In the third phase, the conceptual focusing function was the dominant component as it was based on seeking precise information to confirm or validate other information. **Figure 8.2** represents our conceptualization of the interview management process incorporating the realist interviewing technique.

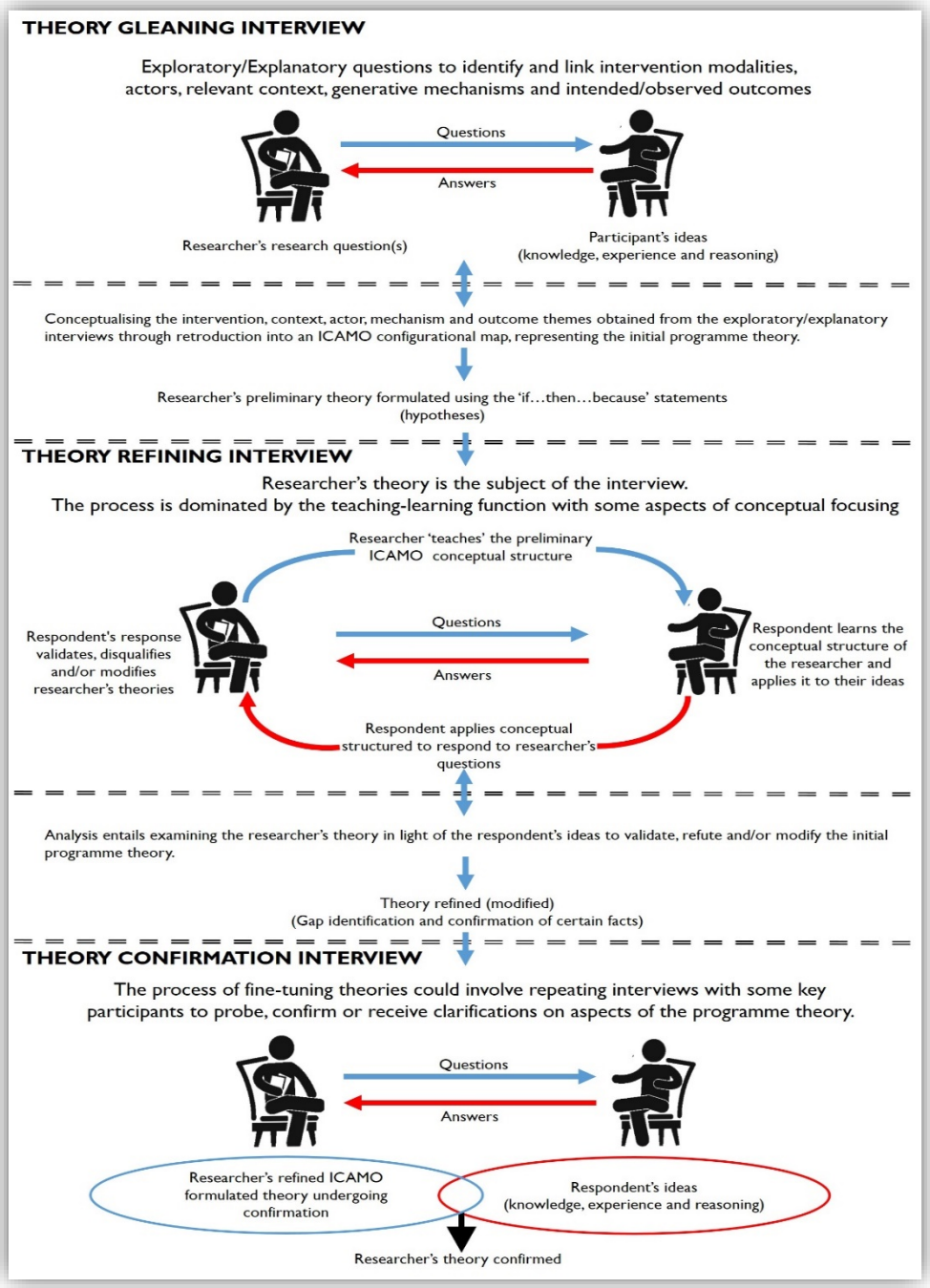

Figure 8.2: Conceptualized information management process in a realist evaluation study

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Following the notion that the realist evaluation approach is in essence theory-driven, the realist interviewing approach provided a scaffold that maintained the theoretical awareness throughout the evaluation process. This scaffolding role was particularly useful as we had to navigate from the emic (the perspective of the actors) to the etic (the perspective of the researcher). To this end, the realist technique was instrumental in maintaining our focus on identifying and conceptualizing the components of the ICAMO heuristic tool. Maintaining a theoretical awareness during the entire process was particularly important because the evaluation of the program's theory is an evaluation of the program rather than the evaluation of the program theory (Sharpe, 2011).

Adopting the realist interviewing approach allowed us to navigate from the emic (the perspective of the actors) to the etic (the perspective of the researcher). During this process, we ensured that achieving a consensus about which theories provide an appropriate explanation of how the adherence club intervention works were encouraged, but not forced. In doing so, it helped us to avoid naïve falsification – i.e. the lack of relationship between the theory and empirical basis and that of the objective examination of competing theories (Lokke & Sorensen, 2014). According to Lakatos (1970), addressing issues of naive falsifications of theory, which is identified as experimentally falsifiable, is 'acceptable' or 'scientific'. By encouraging discussions between the adherence club program managers and implementers on the initial program theories and through the process of 'testing' these theories in contrastive field sites, the issue of naïve falsification was addressed.

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We found that the realist interview approach bolsters theory development and refinement through its iterative nature (repeated movement between data analysis and collection). According to Manzano (2016, p. 157), the realist analysis process *is an ongoing iterative process of placing nuggets of information within a wider configurational explanation*. Applying the realist interview technique made it easy for us to go back and forth between the data and the program theory that was being developed.

Because the realist interviewing technique allowed us to navigate between the perspectives of the actors and those of the researchers, and simultaneously adopt the iterative process of data collection and analysis, we could fine-tune the program theory based on relevant data. We thus argue, along with other authors (Manzano, 2016; Pawson, 1996; Pawson & Tilley, 1997) that the realist interviewing approach enhances the process of theory development and refinement

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and that it is most appropriate when two or more theories are being tested. To this end, we encourage its application in other realist evaluation studies where suitable.

During the application of the realist interview technique, we encountered some challenges. We noticed when we piloted the interview guide that the respondent would tend simply to agree to what we presented. Because the realist interview technique requires the interviewer to 'teach' the respondent their theory, there was the tendency that the respondent would simply agree to what the interviewer presented, a phenomenon described as acquiescence, whereby the respondent tends to agree with the investigator when in doubt.

Another challenge emerged in the interviews with the program users. The initial program theories should be explained in a comprehensible way so that the respondent understands clearly the logic of thinking of the interviewer. *Yes, I understand the general theoretical ground you are exploring, this makes your concepts clear to me, and applying them to me gives the following answers* …, as Pawson and Tilley put it (1997: 167). In addition, regarding the various components (ICAMO) of the program theory, Pawson (1996) suggests that the program users are not conversant with aspects of context and to an extent the outcome. However, they would be a good source of information concerning the mechanisms as they can explain their thinking and decision-making processes vis-à-vis the intervention.

In practice, it was not easy to present the overall initial program theory that we had developed to the patients. We, therefore, largely applied the semi-structured exploratory interviewing technique. This approach is in line with the conceptual focusing technique whereby we explored how the respondents take decisions and make choices regarding the adherence club.

While we were unable to apply the teacher-learner approach regarding the patients receiving care in the adherence club intervention, it was possible to use conceptual focusing. For this reason, the phases that have been identified here are not prescriptive – we used them to demonstrate clearly the realist interviewing process.

The trustworthiness of the realist interview technique

Different methodologies take different approaches to validity, trustworthiness and rigor (Porter, 2007). The trustworthiness of using the realist interview technique pertains to the accounts and conclusions reached by using the realist interviewing technique in the process of theory elicitation, testing and consolidation within a realist evaluation study. According to Maxwell

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(2008), a realist approach to trustworthiness suggests the evaluation of the conclusions or theories developed based on what data the realist interview technique allowed the researcher to collect towards the development of a refined program theory and not entirely on the appropriate use of the realist interviewing technique. In this way, Maxwell suggests that methods used in realist studies should be "assessed for the purpose for which they are used, the context of this use, the data, conclusions, and understandings that are drawn from them, and, in particular, the ways that these understandings and conclusions could be wrong" (Maxwell, 2008 p 132). We discuss the trustworthiness of the realist interviewing technique in terms of descriptive trustworthiness and theoretical trustworthiness.

With regard to descriptive trustworthiness – obtaining factual accuracy of accounts, we applied the four triangulation types identified by Denzin (1978): (a) method triangulation, (b) investigator triangulation, (c) theory triangulation, and (d) data source triangulation. With regard to method triangulation, we used non-participant observations, systematic literature review approaches, in-depth interviews and retrospective quantitative descriptive approaches to obtain information that informed the theory elicitation. Concerning investigator triangulation, two of the authors (FCM and BVW) were involved in the data collection process.

Our theory triangulation approach, using multiple theoretical perspectives to examine and interpret the data, related to the exploration of various theories that have been applied to explain patient adherence to ART (Mukumbang et al., 2017b). Finally, with regard to data source triangulation, the study was informed by data from a document review and in-depth interviews (Mukumbang et al, 2016b), literature reviews (Mukumbang et al., 2017a; Mukumbang et al., 2017b) and descriptive quantitative analysis of retention in care and adherence behaviors of patients using the adherence club intervention. Furthermore, the in-depth interviews considered comparing people with different viewpoints – intervention users, providers, coordinators and designers.

According to Maxwell (2012), "meanings and constructions of the actors are part of the reality that an account must be tested against in order to be interpretively as well as descriptively valid (p. 139)." After eliciting the initial program theory based on the above-mentioned triangulation approaches proposed by Denzin, we applied the realist interviewing technique to verify the preliminary theories. The realist interviewing of the various actors of the adherence club intervention provided both descriptive and interpretive validity of the program theory of the adherence club intervention.

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The theoretical trustworthiness of the realist interviewing technique relates to the extent to which the realist interviewing technique helps the interviewer to identify aspects or concepts that the theory employs and the relationships that are hypothesized to exist among these concepts. The realist interviewing approach supports the other data collection approaches to identify the various aspects of the ICAMO heuristic explanatory model and also to strengthen the links in the ICAMO configurations. In this case, the interviewees provided responses that strengthened the link by identifying Mechanism-Outcome (M-O) links and the various contextual elements on which the mechanisms are contingent.

Additionally, by holding discussions with the adherence club program designers and evaluators in the theory confirmation phase, we invoked the notion of judgemental rationality, which implies that arguments can be found and these arguments could provide for the validity of a judgement about truth (Bhaskar, 1998). By Judgemental rationality Archer, Collier and Porpora (2013 p 2) suggested that *we can publicly discuss our claims about reality, as we think it is, and marshal better or worse arguments on behalf of those claims. By comparatively evaluating the existing arguments, we can arrive at reasoned, though provisional, judgements about what reality is objectively like*" This approach was very useful regarding validating the theories that we had formulated and how the program designers and implementers could identify with the theories. This was an important step in consolidating our program theory.

This paper shows how the realist interviewing technique is an appropriate way to test the program theory of how, why and under what circumstance the adherence club intervention works. This was achieved by presenting the initial program theory to the interviewees as a conceptual framework and then questioning them in a piece-meal manner to understand how different aspects or modalities of the adherence club intervention provides the mechanisms that promote retention in care and adherence to medication. Through the piece-meal questioning approach and by interviewing the different stakeholders, we could verify aspects relevant to mechanisms, context, and outcome, and how these could be linked by paying attention to phrases identifying M-O links and C-M-O links.

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Conclusion

While Pawson and Tilley (1997) developed the realist evaluation approach as a theory-based approach to evaluating complex programs showing varying outcomes when implemented, they proposed this approach as a distinctive one to verify theories developed through the evaluation process. Nevertheless, the realist interviewing technique is generally underutilized within realist evaluation studies. A key focus and the primary motivation of this article are to bring greater attention to the realist interviewing technique by offering a practical demonstration of making it more applicable.

We showed how the realist interviewing approach reinforced and maintained theoretical awareness throughout the theory-driven evaluation process and we brought to light the trustworthiness that the realist interviewing technique in association with other data collection approaches provide to a realist evaluation study.

Based on our application of the realist interview technique for verifying and confirming theories obtained during the realist evaluation process, we suggest that the realist interview technique provides a unique theory-driven approach to generate the appropriate data for verifying tentative theories obtained during a realist study. We, therefore, recommend the use of the realist interview approach to suitable realist studies.

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CHAPTER NINE

Case Study 1: Testing the initial programme theory at Facility X

Unravelling how and why the Antiretroviral Adherence Club Intervention works (or not) in a public health facility: A realist explanatory theory-building case study. PLoS ONE (Under review)

Abstract

Background: Although empirical evidence suggests that the adherence club model is more effective in retaining people living with HIV in antiretroviral treatment care and sustaining medication adherence compared to standard clinic care, it is poorly understood exactly how and why this works. In this paper, we seek to examine and make explicit how, why and for whom the adherence club model works at a Community Health Centre, a step towards developing a middle-range theory.

Methods: We applied an explanatory theory-building case study approach to testing the initial programme theory with the goal of refuting, validating or refining it. We collected data using a retrospective cohort quantitative design to describe adherence and retention in care behaviours of patients on ART using Kaplan-Meier methods. In conjunction, we employed an explanatory qualitative study design using non-participant observations and realist interviews to gain insights into the important mechanisms activated by the adherence club intervention and the relevant contextual conditions that trigger the different mechanisms to cause the outcomes. We applied the retroduction logic to configure the intervention-context-actor-mechanism-outcome map to formulate generative theories.

Results: A modified programme theory involving targeted care for clinically stable adult patients (18 years+) receiving antiretroviral therapy was obtained. When grouped for targeted care, they feel nudged, their self-efficacy is improved and they become motivated to adhere to their medication and remain in continuous care. Targeted care involved receiving quick, uninterrupted supply of antiretroviral medication (with reduced clinic visit frequencies), health talks and counselling, immediate access to a clinician when required and guided by club rules

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and regulations within the context of adequate resources, and convenient (size and position) space and proper preparation by the club team.

Conclusion: While the initial programme theory suggested that two rival theories could explain how and why the adherence club intervention works, this case study revealed that they actually complement each other. This finding has implications for developing a middle-range theory of *how, why* and under what health system conditions the adherence club intervention works.

Introduction

The number of people living with HIV/AIDS (PLWHA) in South Africa has reached an estimated seven million [1]. Keeping in line with the '90-90-90' goal (90% of all PLWHA knowing their HIV status, 90% of all people diagnosed with HIV infection receiving sustained antiretroviral therapy (ART), and 90% of all people receiving ART achieving viral suppression)by 2020 [2], South Africa has established various policies, programmes and strategies.

To improve the number of people knowing their status, various voluntary counselling and testing campaigns are organised nationwide. To improve the number of PLWHA on sustained ART, the South African government has adopted the WHO's 'test and treat' treatment guidelines of 2015 as at September 2016 [3]. Improving the number of PLWHA suppressed virally entails retaining them under the care umbrella and encouraging them to adhere to their treatment. To this end, in addition to using the primary health-care facilities to drive the HIV-treatment and care programme, various differentiated care models (tailored care packages to suit the needs of different patient groups) of the ART have been designed and implemented.

The adherence club is one such differentiated care model, i.e. health-care worker-managed groups [4]. The model was designed to shift most consultations and ART collections for stable patients into organised group ART care and was implemented in the Western Cape Province, South Africa. The adherence club intervention has been described previously [5–7]. The adherence club programme aims to (a) retain patients in ART care by providing a more efficient way to manage stable patients; (b) maintain good long-term adherence in PLWHA on ART through quick access to medication and (c) decongest the health facility through group sessions that are facilitated by trained non-clinical health-care workers [3]. The adherence club

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intervention has shown better effectiveness of improving and sustaining retention in care and adherence to medication compared to the standard care services reported in four studies [8–11].

Based on the evidence supporting the effectiveness of the adherence club intervention [8–11] and its cost-effectiveness [12], there are calls to adopt this differentiated treatment and care model for the management of HIV [13]. Indeed, the WHO's 2015 consolidated treatment guidelines for HIV recommend the use of group-based ART models to improve retention in care and enhance treatment adherence [14]. Despite these calls, the literature provides little or no theory-based understanding of how and why these interventions work [15].

Van Belle and colleagues [16] argue for more use of theories in implementation studies. The authors proposed that theory-driven approaches, such as realist evaluation, have the potential to demonstrate the complex interplay among a programme (and an intervention), context, targeted actors, causal mechanisms and expected outcomes. In this paper, we seek to examine and make explicit what aspects of the adherence club intervention work, for what patient population and under which contexts. We describe the process of testing the initial programme theory of the adherence club intervention in a public health clinic in the Western Sub-District of the Western Cape Province. This is important for clarifying the programme theory that underlines the adherence club intervention.

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Methodological approach

Realist evaluation is a member of the family of theory-driven evaluation approaches, drawn from the seminal work of Pawson and Tilley [17]. Realist evaluation starts by clarifying the 'programme theory' – the set of assumptions of programme designers (or other actors involved) that explain how they expect the intervention to achieve its objective(s). The realist evaluator hypothesises the intervention, the relevant actors through whom the intervention is expected to work, the mechanisms that are likely to operate, the contexts in which the mechanisms might operate and the outcomes [18]. This process is known as constructing the intervention-context-actor-mechanism-outcome (ICAMO) hypotheses [19,20] (**Figure 9.1**).

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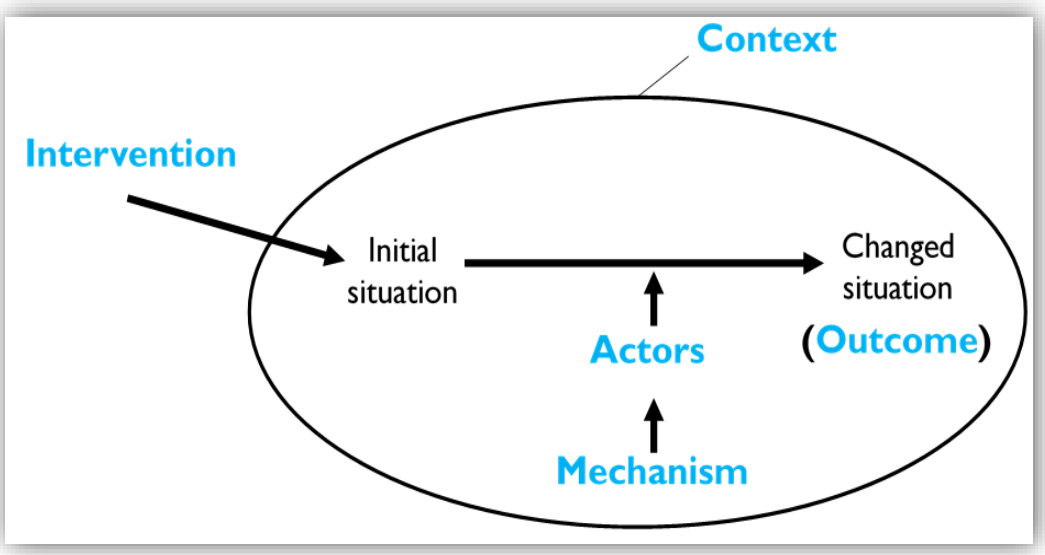

Figure 9.1: The ICAMO configuration.

Realist evaluation is about theory testing and refinement [21], whereby the evaluator assesses whether a programme is designed in such a way that it can achieve its intended outcomes and how it does so [22]. The initial programme theory guides the assessment of the effectiveness of the intervention and the consistency of the implementation [23]. The outcome of this process is a 'generative theory' of causation whereby there is an interaction between the actors and the components of the intervention leading to a transformation (outcome) through causal powers (reasoning of the actors) [24].

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Realist analysis starts with the understanding that the programme under evaluation will have varying implementation outcomes [18]. While implementation scientists suggest that this variation in outcome could be attributed to the variation in the context in which the intervention is implemented [25], for realists, the outcome variations are attributed to variations in the ICAMO as a configuration and not only the context.

Realist evaluators go into the evaluation process with some expectations, guided by the initial programme theory. During the evaluation, some expectations are confirmed, some might prove misguided, and the end product of the analysis is expected to improve the picture of the programme efficacy and inefficacy [26]. In our previous work, we formulated the initial programme theory of the adherence club intervention [27].

We conducted an exploratory qualitative study of programme designers' and managers'

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assumptions and perspectives of the intervention and carried out a document review of the design, rollout, implementation and outcome of the adherence clubs [28]. We also conducted a systematic review of available studies on group-based ART adherence support models in sub-Saharan Africa to tease out their underlining theories [29]. In addition, we carried out a scoping review of social, cognitive and behavioural theories that have been applied to explain adherence to ART [30]. Using the process of configuration mapping, we constructed an ICAMO map representing the initial programme theory of the adherence club, through the process of retroduction – mechanism centred logic and analysis. Finally, we used the "if…then…because" statements to translate the ICAMO configuration map into testable hypothesis (**Box 9.1**).

Box 9.1: Initial programme theories of the adherence club intervention represented by two tentative theories (hypotheses)

Initial program theory 1

IF adult (18+ years) clinically 'stable' patients with evidence of good clinic attendance are group-managed, receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they develop a group identity, which improves their perceived social, support, satisfaction and trust; and acquire knowledge, which helps them to understand their perceived threat and perceived benefits and improves their self-efficacy. As a result, they become encouraged, empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

Initial program theory 2

IF operational staff receive goals and targets set to continuously enroll patients in the adherence club and strictly monitor their participation through strict standard operating practices (the promise of exclusion in the event of missed appointment and active patient tracing),
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they fear (perceived fear) losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules. As a result, they become nudged to remain in care and adhere to the treatment, which might decongest the health facility.

The goal of testing the initial programme theory of the adherence club intervention (an evaluation of the adherence club intervention) is to verify, refute and/or modify it. In this paper, we seek to unravel the mechanisms explicating how, why, for whom and in what circumstance the adherence club programme works at a community health centre in Cape Town.

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Research design

Within a realist evaluation, we applied an explanatory theory-building case study approach to testing the initial programme theory with the goal of refuting, validating or refining it. We adopted the multiple embedded case study design [31] with the Facility X being one of the cases. Facility X is a unit of analysis, each of its ART clubs being sub-units, which are embedded in Facility X.

Theory testing using case studies evaluates the explanatory power of theories and their boundaries [32] so as to develop context-specific causal explanations of how and why programmes work [31]. In realist logic, mechanisms – the process of how subjects interpret and act upon the intervention (or components of the intervention – are at the heart of causal explanations [33] and the case study approach provides a platform to illuminate mechanisms in relation to outcomes.

The case study approach is appropriate in teasing out the mechanisms related to a programme or an intervention because it allows movement from the emic (the perspective of the subject) to etic (perspective of the researcher) accounts of a phenomenon [32]. It also allows for the use of multiple methods of data collection [18] which, favours iterative investigation (repeated movement between data analysis and collection) and recognises the importance of context [6]. These characteristics make the case study approach methodologically complementary to realist evaluation, thus providing a "close-in" on real-life situations to test the theory under investigation [6].

Cases in case study research are described as typical, deviant or crucial [35]. Facility X, where the initial programme theory was first tested, represents a 'typical' example of an ART club in terms of the rollout of the adherence club programme because Facility X was among the facilities where the rollout was initiated in 2012. Since its inception, the adherence club programme in Facility X has shown steady growth at a reasonable pace (**Figure 9.2**).

Study setting

Mitchell's Plain is one of Cape Town's largest townships established on the Cape Flats about 20 miles from the city centre in the mid-seventies as a 'dormitory suburb' for 'Coloured' people.

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The Mitchell's plain township has about 290,000 inhabitants and comprises several sub-sections reflecting the diverse class backgrounds of the population.

Facility X is a primary health-care facility that provides free first-level primary and some second-level health services to the Mitchells Plain community and surrounding areas. Facility X operates a 24-hour trauma unit for emergencies, MOU, mental health services, specialised paediatric services for children up to 5 years old, an outpatient department, pharmacy and dispensary, an antiretroviral clinic, and a chronic diseases of lifestyle (CDL) clinic (including CDL clubs) [36].

Facility X is an accredited ART initiation and on-going management site, which provides HIV counselling and testing (HCT) and associated support services. The Facility X was selected as one of the ART sites for the first phase rollout of the adherence club programme and officially formed its first adherence club in March 2012. Based on the routine monitoring data of the adherence club programme, an estimated 3,600 patients were receiving ART care at Facility X by the end of 2016 and of these, 1,368 adult patients were retained in care through the adherence club. The routine data also show that 53 adherence clubs had been created by the end of 2016 at Facility X. In **Figure 9.2**, the number of clubs that were established each year since the inception of the adherence club programme in 2012 is shown.

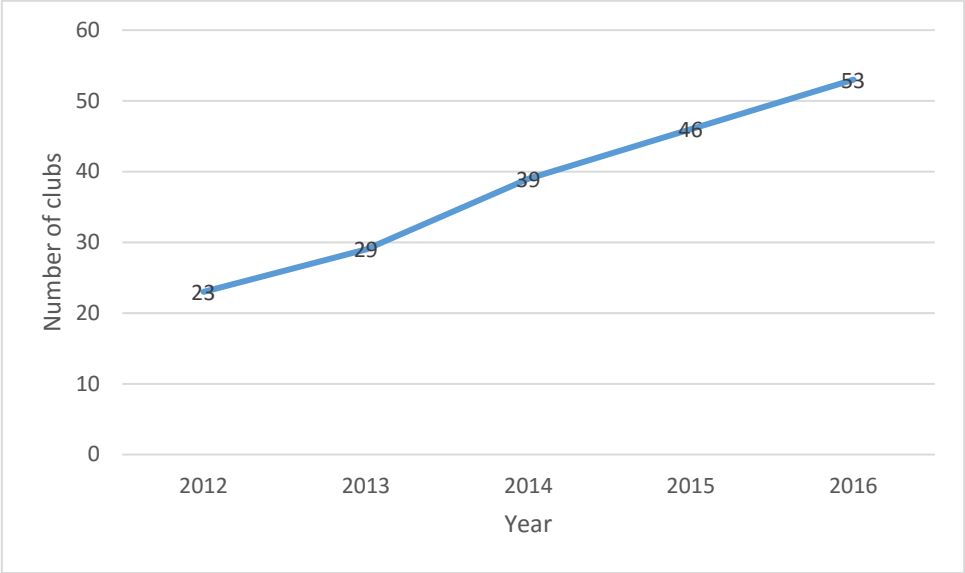

Figure 9.2: Number of adherence clubs which opened from 2012 to 2016 at Facility X

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Methods

The realist evaluation approach is method neutral, i.e. quantitative and qualitative data are collected as part of the programme theory that is being 'tested'. The use of a multi-method evidence base to ensure good documentation of the implementation of the programme is encouraged [37]. To this end, we collected and analysed quantitative and qualitative data.

In our study, we used quantitative data to identify and classify the outcome patterns and qualitative data to explore implementation features related to the context (observation) and the mechanism (in-depth interviews). We thus combined a retrospective cohort analysis and an explanatory qualitative approach. The retrospective cohort analysis was conducted to describe the primary outcomes of the adherence club intervention (retention in care and adherence to medication) and the qualitative explanatory design provided evidence regarding the ICAMO configuration links in the implementation chain (intervention modalities, actors involved, generative mechanisms, relevant context and outcome patterns). **Figure 9.3** is an outline of the data collection strategy that was adopted.

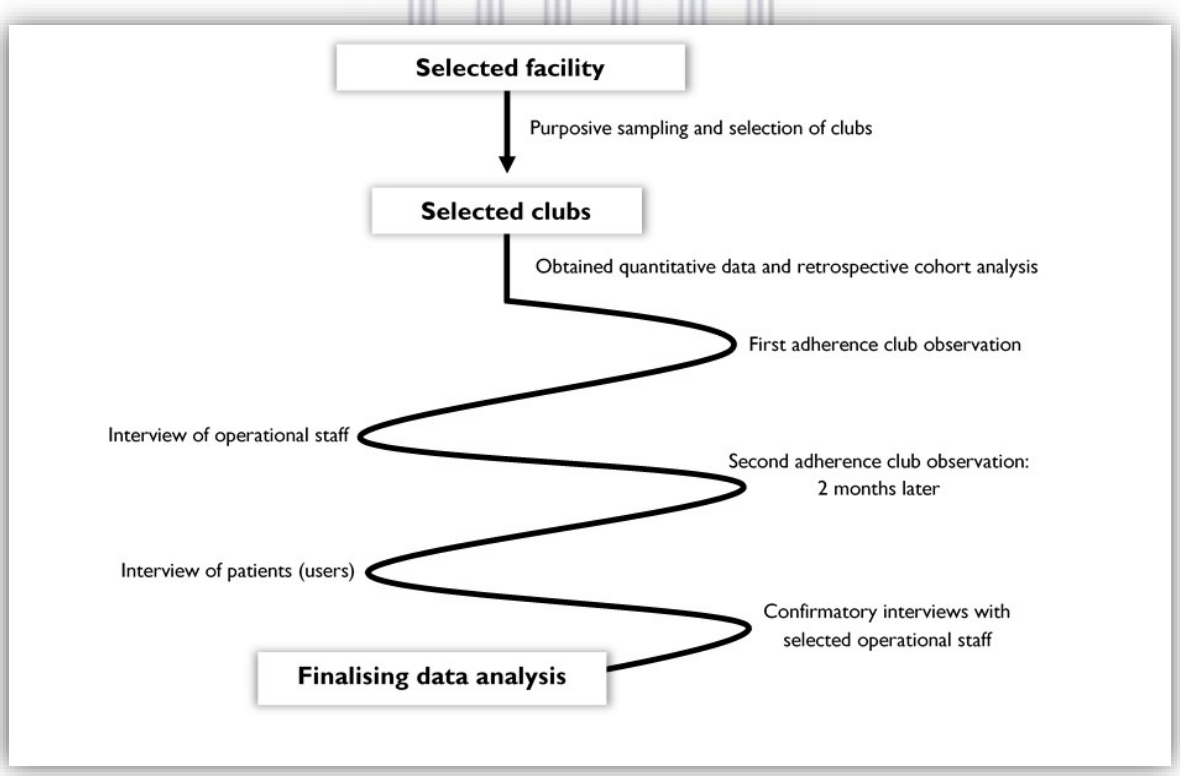

Figure 9.3: Data collection approach/strategy

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Regarding the retrospective cohort study, data were obtained from the adherence club registers from the facility. The adherence club register records details of the retention in care behaviour through club attendance and of adherence through the recoded viral load results. In **Table 9.1** the different modalities related to retention in care as recorded in the adherence club register are shown.

Table 9.1: Codes for recording of retention in care outcomes in the club register

Recorded Outcome	Outcome Event
DNA	**Did not attend** club session and did not come to the clinic or send a buddy within five days after the club sessions
BTC	**Back to Clinic**- Exiting the club for medical reasons and reinstated in routine standard of care
TFOC	**Transferred out to different club** – Patient is transferred out to another club in the same facility
TFO	**Transfer out** – Patient is leaving the facility completely and will attend a clinic elsewhere
RIP	**Rest in Peace** – Patient has died

The outcome of adherence is identified through the recoded values of the viral load measurements taken six-monthly.

Two qualitative data collection methods were used: non-participant observations [38,39] and semi-structured realist interviews [40,41]. Non-participant observations allowed us to gain insights into the various types of club sessions, different activities and the dynamics of interactions between the patients with each other and with the health-care providers. We used an observation guide that details the interactions, processes, or behaviours to be observed during the club sessions (**Additional file 1**).

The second qualitative method we applied was the semi-structured realist interview [42], whereby the initial programme theory is placed before the interviewee to comment with the view of providing refinement. In this way, '*the researcher's theory is the subject matter of the interview, and the subject is there to confirm or falsify and, above all, to refine that theory*' [40]. In addition to commenting on our theories during the interview process, we focused on capturing the participants' perspectives and experiences of the programme [41]. **Additional files 2 and 3** present the questions tailored for the different groups of study participants.

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Sampling approaches

Regarding the quantitative study, selected two clubs among the 23 that were opened and had reached the maximum capacity (35 - 45 patients) in 2012. Of the 23 clubs that opened in 2012, eight had reached the maximum capacity. Then, from the eight identified clubs, we used the lottery or fishbowl method of sampling to obtain two adherence clubs to be included in the analysis. Club A had 47 patients and Club B had 39 patients.

The selection of the interviewees was based on their potential contributions toward clarifying the initial programme theory [43]. To this end, we adopted the purposive sampling technique. Pawson and Tilley suggested that practitioners have specific ideas on what it is within the programme that works (M), knowledge on the outcomes (O) of the programme (because they are likely to have experienced successes and failures) and some awareness of people and places (C) for whom the programme works [40,43]. In their view, the beneficiaries are more likely to provide relevant information related to the mechanisms (M) than to its contextual constraints (C) and outcome patterns (O).

In **Table** 9.**2** the different groups of participants who were interviewed are outlined. Following Pawson and Tilley's insights, we interviewed 12 participants – three categories of actors: clinical staff (doctors and nurses), club facilitators (lay counselors) and the users (patients). These different groups of actors were purposively selected based on their knowledge of the adherence club intervention.

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Table 9.2: Distribution of study participants

Stakeholder	Number of participants	Time on Adherence club
Doctors	1	Since 2012
Nurses	2	Nurse 1 - 2012 Nurse 2 - 2010
Counsellors (Club facilitators)	2	Counsellor 1 – 2012 Counsellor 2 - 2012
Patients	7	Patient 1 – 2017 Patient 2 – 2012 Patient 3 – 2010 Patient 4 – 2014 Patient 5 – 2015 Former club member – 2014 Former club member – 2015

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Ethical considerations

This study is part of a larger project "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health-care facilities in the metropolitan area of Western Cape Province, South Africa" which has received ethics clearance from the University of the Western Cape Research Ethics Committee (UWC REC) (Registration No: 15/6/28). In addition, we obtained ethical clearance from the Provincial Department of Health of the Western Cape Province. Furthermore, we obtained the permission of the facility head and management before data collection processes commenced.

At the level of the study participants, we first provided the interviewed participants with an information sheet of the project. This was followed by a verbal explanation of the role of the participant and the significance of their participation. They were required to sign an informed consent form. We promised and ensured confidentiality and anonymity by identifying the participants using pseudo names and by password-protecting all files related to the study.

Data analysis

The realist analysis process "*is an ongoing iterative process of placing nuggets of information within a wider configurational explanation*" [41]. The data analysis proceeded in two steps: (1) separate analysis of the quantitative and qualitative components of the data, and (2) synthesis of the findings from the quantitative and qualitative arms through configurational mapping using the ICAMO heuristic tool.

The quantitative data were analysed using the Kaplan-Meier descriptor survival analysis approach [44]. The Kaplan-Meier method is a nonparametric method used to estimate the probability of survival past given time points and thus calculates a survival distribution. The goal of this analysis was to describe the rate at which patients enrolled in the adherence club at the facility, became lost to follow-up, and sent back to clinic care or died – proxies to retention in care. We aimed at describing the conditional probability of a patient remaining in club care at the end of six, 12, 24 and 36-month intervals.

Because ART adherence is a behaviour that can be linked to a biological marker (HIV-1 viral load), we used the Kapan-Meier descriptor to describe the rate at which a viral load rebound

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occurred in the patients. This follows the premise that all patients admitted into the adherence club should have viral loads reading at "lower than detectable (LDL)".

Data from the field notes and interviews were analysed using the thematic content analysis method [45] and classified according to aspects of the intervention, actors, context, mechanisms and outcomes – components of the ICAMO heuristic tool. To this end, codes related to components of the initial programme theory were allocated to chunks of the text [46], a process described as deductive content analysis [47]. During the analysis, emergent codes were added to the coding tree, which was periodically revised. Through this process, we obtained conjectured ICAMO configurations, which were confirmed through the application of counterfactual thinking (testing possible alternative explanations).

Results

We first discuss the findings of the quantitative retrospective analysis, then the thematic analysis of the interviews and observation notes.

Quantitative findings

The retrospective descriptive analysis was used to describe the retention in care and adherence behaviours (principal outcomes) of the patients in the ART club. We used the Kaplan-Meier method [44] to describe the rate at which patients dropped out of club care (retention in care) and failed to maintained viral loads lower than detectable (≤400 copies/mL).

Retention in care

The total number of patients retained in care (81.4%) after 36 months in care in the two sampled adherence Clubs A and B is shown in **Table 9.3**. Club A has an overall retention rate of 78.7% and Club B has a retention rate of 84.6%.

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Table 9.3: Percentage of patients receiving care in the two adherence clubs retained in care after three years

Adherence Club	Total Number	Number patients LTFU	Remaining in care	
			Number	Percent
Club A	47	10	37	78.7%
Club B	39	6	33	84.6%
Overall	86	16	70	81.4%

In **Figure 9.4**, the survival distributions of the patients receiving care in the two adherence clubs are shown to help us understand how the survival distributions compare between these two clubs. The frequent 'interactions' among the survival distributions indicate little differences between them.

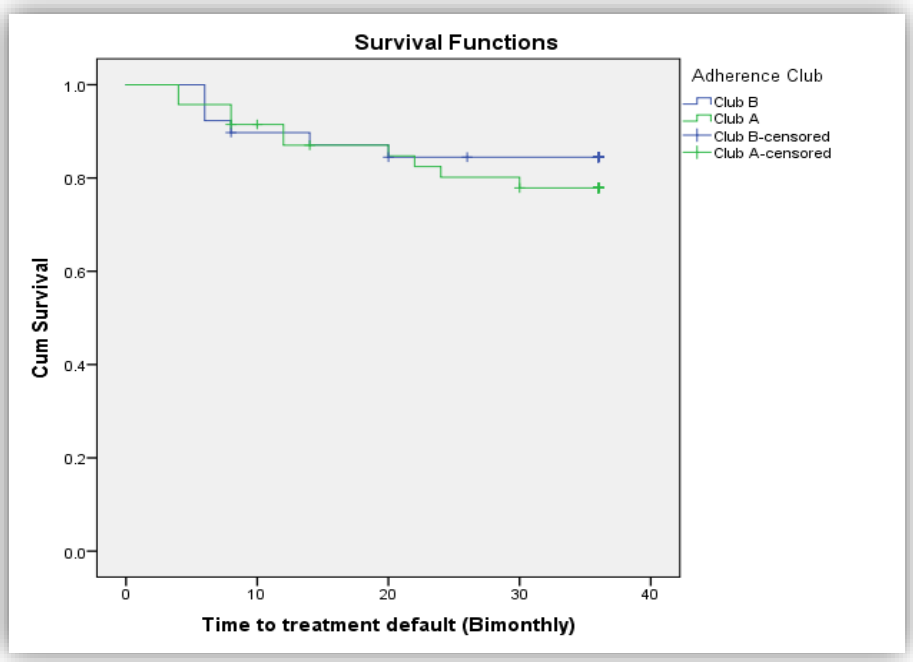

Figure 9.4: Survival distributions of the retention in care behaviours of patients receiving care in adherence Clubs A and B

Apart from describing the overall retention in care rates of the patients receiving care in the adherence clubs, we also investigated the retention in care rates at various intervals. In **Table 9.4** the probability that a patient receiving ART in adherence Clubs A and B will be retained in care at six, 12, 24, and 36 months is displayed.

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Table 9.4: Kaplan-Meier estimates of the retention in care behaviours of patients attending two adherence clubs at Facility X

Duration of follow-up	Remaining in care Club A % (95% CI)	Remaining in care Club B % (95% CI)
6 months	95.7% (84.2 – 99.2)	92.3% (78.0 – 97.9)
12 months	87.0% (73.3 – 94.5)	87.1% (71.6 – 95.1)
24 months	80.1% (65.5 – 89.9)	84.6% (68.6 – 93.4)
36 months	78.7% (62.9 – 88.2)	84.6% (68.6 – 93.4)

We further conducted a log log-rank test (Mantel-Cox) to determine whether the survival distributions of the two adherence clubs are statistically significantly different. The significance value (*p-value*) of this test was 0.5. If significance is defined as $p<0.05$, then we can conclude that the survival distributions of the two adherence clubs are very similar among patients receiving care in the adherence club model. This suggests that there is a level of consistency regarding the capacity of the adherence club intervention to retain patients in care at Facility X.

Adherence to medication

Viral load is used as a proxy for adherence to antiretroviral medication. In the adherence club, viral loads are measured once a year. Our analysis considered three viral load measurements within the three-year period of the study. Using the virological failure indicator (>400 cells/cm^3) to define the outcome of interest, an overall population adherence level of 95% was achieved within the three years of the study at the adherence Clubs A and B. The adherence breakdown of the two adherence clubs are shown in **Table 9.5**.

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Table 9.5: Population level adherence rates of two adherence clubs in Facility X

Adherence Club	Total Number	Number of Non-adhering patients	Adhering patients	
			Number	Percent
Club A	47	3	44	93.6%
Club B	39	2	37	94.9%
Overall	86	5	82	94.2%

Figure 9.2 and **Table 9.6** indicate that the adherence to medication of patients in the adherence club is good. After receiving treatment for six months, the adherence behaviour assessed by viral load of the patients was 100% at both sampled clubs. At 36 months, the adherence rates of

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Club A were 93.6% and of Club B 94.9%. These represent very good population-level adherence levels.

Table 9.6: Adherence rates at various intervals of the two sampled adherence clubs

Duration of follow-up	Adherence Club A % (95% CI)	Adherence Club B % (95% CI)
6 months	100.0% (90.5 – 100)	100.0% (88.8 – 100)
12 months	95.7% (87.1 – 99.8)	100.0% (88.8 – 100)
24 months	92.9% (84.1 – 98.2)	94.9% (79.8 – 98.6)
36 months	92.9% (84.1 – 98.2)	94.9% (79.8 – 98.6)

The survival distributions of patients receiving ART care in the two adherence clubs is displayed in **Figure 9.5**.

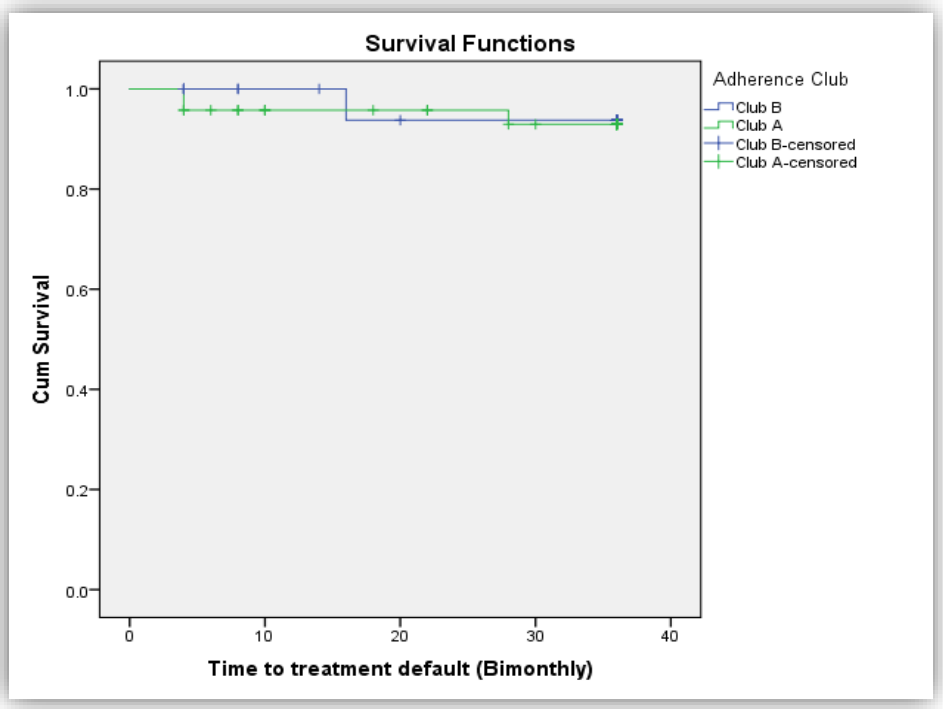

Figure 9.5: Survival distribution of adherence behaviour of two adherence clubs at Facility X

The log-rank test of the survival distributions of the two adherence clubs is 0.786. The lack of statistically significant differences between the survival distributions indicates a consistency in the effectiveness of the adherence clubs to enhancing adherence to medication.

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Qualitative findings

The results of the qualitative studies are presented, based on the framework provided by the two initial programme theories.

Mechanisms related to initial Programme Theory 1

This initial theory relates to how clinically stable patients receiving care in the adherence club programme perceive, interpret and act on the resources and opportunities offered by the club intervention. The mechanisms include perceived social support, perceived benefit, trust, motivation, satisfaction (with care), and self-efficacy.

Perceived social support

Perceived social support relates to the feeling of having received or the possibility of receiving moral, emotional and medication-related support from fellow group members of the adherence club [48]. This social support could come in the form of general discussion, informal counselling, or as a response to a question posed by one of the group members. Sometimes, it involves helping a group member to access their medication when they cannot. These participants' accounts confirmed this.

> It [the adherence club] helps them because if they have problems… then they can talk to each other while they are sitting here [clubroom] waiting for the medication… I heard this one saying that 'I have this problem, that problem' and then the *other one* would be able to advise the other one. Then about their medication, they talk to each other and then they know 'okay, you are using these ones, what did you experience? What happened the first time you took your ARVs?' Then the other one will answer and say, 'I was feeling dizzy, I was feeling like this and like that'. They check each other's medication also and then to support each other. **[Doctor 1]**

> Sometimes, it is just maybe a side effect of a tablet or something. The minute they start discussing it in a group, it is so much better if you hear it from someone that is sitting with the same problem than hearing it from a nurse or a doctor. It does not seem real, because how can they know, but if we talk amongst each other, it is so much more real. **[Nurse 1]**

> There was a time I had a lot of pimples on my back and I was a bit shy to talk to people but there was another lady here with us in the club, she talked to me openly how she is on this

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> medication, *then* that is when I started to talk to people. They also give ideas; maybe you can use that for the pimples, use that before you go see the doctor if it does not stop, go [and] see the doctor and so on. We talk about it [medication], side effects and so on. 'How do you feel, do you feel sleepy when you take your medication', we talk all these things. **[Patient 1]**

We also observed an incident that confirmed the supportive nature of the club members. On one occasion, one of the club members came late, as he had to go to work at a destination (Blouberg) far from the clinic. The patient explained her challenges to the counsellor, who asked her to negotiate with the other club members to get her medication first and leave.

Perceived benefit

Perceived benefit relates to the possible advantages that are associated with being in the adherence club (as opposed to being in the clinic care). The benefit relates, in most part, to the tailored and streamlined services offered at the adherence club, which leads to quick service delivery. Aspects that were commonly cited by the participants as beneficial include the quick access to medication and preferential care when needed.

> It [the adherence club] helps them a lot, because…if a patient comes for a club visit and then we pick up that the patient is sick, we will not send her in front to wait there, no, she quickly sees the Doctor or the Sister. **[Club facilitator 1]**

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> Before it was as if you are sitting here [the main clinic] the whole day in the clinic, here [the ART Unit], they do a very quick job, fantastic job here. However, the problem was always there at the Pharmacy where you go and sit in the queues the whole day, which means you cannot plan for anything else. Once you come to the clinic, you know you are going to be there the whole day. Now since I am in the club, for me like when I am done here I am going to see the doctor in the next 10 to 15 minutes, after that, I am going back to work. **[Patient 1]**

Trust

Trust relates to what extent patients can rely on the health-care providers to provide the support that they need regarding the self-management of their disease. Trust also relates to the integrity of all group members in maintaining a conducive treatment environment. Excerpts from interviews with the various groups of interviewees indicate that the trust that is negotiated

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between the patient and the health-care providers and fellow group members is an important mechanism of the adherence club intervention.

> Patients become so familiar with the Counsellors…they offload with the Counsellor, and they [counsellors] just willingly, happily listen to all the complaints. Whatever they can find problematic in that 'offloading' they will defer, they will advise... Even refer to the Social worker or to the Clinicians in the clinic and we will take it further or refer if need be. **[Nurse 2]**

> Patients feel they can talk to each other because they build trust in the group. Because they see each other all the time, they have that trust that they can share information. **[Club facilitator 2]**

Motivation

The adherence club intervention constitutes an important source of *extrinsic motivation*. Motivation highlights the use of evolved inner resources for behavioural self-regulation – the process by which people control or alter their thoughts, emotions and behaviours. The evolution of the inner resources could result from the support of others (social motivation) or the prospects of using the resources on offer (outcome expectancies) and the outcome of the previous use of the intervention (result-based motivation) [49]. The adherence club enhances patients' motivation by 'removing' barriers to access to medication and health-care professionals as revealed in the following excerpts.

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> The simple fact that they [patients] come here and they pick up their medication, they sit for an hour and a half, 2 hours, sometimes even less, depending on which type of visit it is, it *motivates* them because sitting in the clinic for 1 to 2 hours besides sitting in Pharmacy for 2 hours waiting period is exhausting. [Longer periods in the clinic] requires patients to take off sick leave, which affects their work. Therefore, with the club, they feel that at least their good adherence and the fact that they [are] looking after themselves, they are rewarded for that as being a club patient. **[Nurse 1]**

The interviews of the study participants revealed that patients who are not yet part of the adherence club intervention are 'motivated' to adhere to their medication and remain in care although they are not part of the intervention. This is because these 'non-club' patients are told that if they show evidence of good adherence (undetected viral load) and regular clinic

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attendance, then they qualify to be part of the adherence club. The prospect of becoming part of the adherence club programme motivates the patients to work towards achieving the qualifying goal, which at the same time gets them to adhere to their medication and remain in care. This goal setting and reward system constitute external motivation. This is captured in the following excerpts.

> We explain to the patients [the importance of the club]. So, they say to us, 'I will make sure I am on time. I will make sure I take my tablets. I will make sure my viral load is suppressed. I will show Sister. Next time I will show you.' And that is how the patients become motivated because they know 'okay there is something I need to work towards to benefit at least from something instead of spending a day at this facility, I can spend half an hour at this facility and off I go.' **[Nurse 2]**

> They tell you what you must do and what you must not do, so you must obey the rules, all the rules. Then if you obey the rules and you stick to that then it is easy to come in the club. **[Former club patient 1]**

Satisfaction (with care)

Satisfaction relates to the fulfilment of one's desires, expectations or needs. Satisfaction with ART care received at the club triggers a positive feedback whereby the satisfaction derived from the care received causes increases in their commitment. The patients expressed their satisfaction in the following words.

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> Everybody in the club is very happy because of the way they [the club team] are working. You do not need to take off when you are working, you come to the club then you go to work when you are done… Their service is very good. **[Patient 2]**

> I can say I like it because you can go to work and there are no long queues, especially you come and your medication is already there… its very nice man! I am happy with the club; the club makes things easier for us. **[Patient 4]**

Knowledge acquisition (learning)

Knowledge acquisition or learning is an important cognitive mechanism identified to perpetuate adherence to medication and retention in care. This could be achieved directly or by enhancing the self-efficacy – the perception that one is capable [has the capacity] of doing or accomplishing

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a task – of the patient. The excerpts below show how the patients perceived the health talks and counselling received from the adherence club.

> Yes, I learn new things. If I am not feeling well, I know what helps me so that the next time when I have the same problem I know what could help me. **[Patient 3]**

> It is good to attend those talks because they [patients] pick up false information elsewhere… That one told me I should use that and that…" At the end of the day, it is not suitable for you, for your health. So, we explain to them and they listen to us… **[Club facilitator 1]**

Group (identity) dynamics

Group dynamics relates to the cohesion of the group, and this follows from the concept of group identity. If patients identified themselves as part of a group, they would tend to protect the overall interest of the group. To typify the group identity and the relationship group members share, during an interview, one of the participants described how close she is with the other group members and the support she provides based on this relationship.

> I know all the people in the club, I know okay 'this person-that person.' *For me*, if I do not know some of them personally, at least, I know them by name. We have that relationship 'okay who are you, where are you from, where you stay and since when are you attending the clinic visits' and stuff like that. We talk say for instance somebody asks me and says 'that is my next date I am not going to be in Cape Town, can you get my medication for me and keep it by your house?' That I will do because I am then a club member and I will go to the nurse and explain to them *with* her and say 'okay well can I get her medication? I know where she stays, I can take it for her.' Even if sometimes, say for instance I come here and I see one of the ladies that I always talk to is not here, I am going to phone her or ask her 'what's up, what's wrong, where are you then, I am here, it is our date together.' I know all the club members; our dates are together… We are always together here on the same date. That is, that's how the relationship is. **[Patient 1]**

While most of the interviewees agreed that there is sharing and support taking place within the groups, our observations revealed a relative lack of explicit interactions between the group members of some clubs, and not always a positive vibe or positive group dynamics within all the clubs. We observed how most of the patients sat quietly, waited for their turn to be called to

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collect their medication, and to receive preliminary screening. At some point, we noticed two club members engaging in a discussion. We interviewed one of them and asked about their discussion. The discussion was about the possibility of having family members who are not HIV positive to come and learn about the disease to dispel the stigma and discrimination that they display toward HIV-infected family members.

Mechanism according to initial Programme Theory 2

The following mechanisms that were identified related to initial Programme Theory 2. This theory relates to the role of the club rules and regulations in propagating retention in care and adherence to medication among patients receiving care in the adherence club programme. This could be seen as the constraints of the adherence club intervention. The main mechanisms identified include perceived threat and being nudged.

Perceived threats

In relation to the adherence club intervention, perceived threat refers to an individual's subjective assessment of the severity of the consequences of non-adherence to ART or to failing to follow the rules of the adherence club. When a patient fails to follow the rules, which is principally about attending all club sessions (or send someone) to collect medication and maintain a lower than detectable viral load, they are returned to the main clinic care. This is what some study participants said about in relation to the club rules.

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> If your viral load increases, you are out... Therefore, you will rather stay adherent so that the virus is suppressed. If not, you are going to lose out and return to where you started. They do not want to be back into the clinic. Once you mention that, they will rather sacrifice and stay in the club with all the rules – because we are not strict but keep them on track… They need to take responsibility when it is their club date, if they cannot make it, they must communicate. If their viral load is not suppressed, if it increases while they [are] in the club, when we do the blood tests, they will be sent back to the clinic. **[Doctor 1]**

> We are very *strict* and serious because we tell them each time 'if you do not come for your blood, you do not come to the clinics, no phone call or nothing, no arrangements then we send you back [to clinic care].' Then once we tell them 'we are going to send you back' they think of long queues, long sitting, then immediately they make sure they try to get to the clinic. **[Club facilitator 1]**

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> If you do not phone them or nothing, which means then you have to go back to the main clinic…That is your fault. **[Patient 1]**

Nudging

Being nudged as a mechanism refers to the perception of being stimulated in various ways to make certain choices by setting default options in a specific way. The rules and regulations of the adherence club are meant to guide the patients to attend their club session and adhere to their treatment. This is what the participants think about the club rules and regulations.

> They [clinicians] tell you what you have to do and what you must not do, so you must obey the rules, all the rules. If you obey the rules … then it is easy to join the club. **[Patient 2]**

> If we do not have club rules, you will find that patients will walk in whenever they want. They will not come on their dates and they will not communicate with us. At the end of the day, patients know we do not put them out of the club. They take themselves out of the club by not honouring their appointments and by not looking after themselves because we want them to remain virally suppressed. **[Nurse 2]**

> We need to stick to those rules and we need to make sure that they are also taking responsibility; otherwise, they are not going [to] take it as a serious thing. They will think 'I can do what I want, I can come when I want, nobody checks on me.' **[Club facilitator 2]**

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CONTEXT

Important contextual conditions that were identified are staffing dynamics, collaboration/teamwork, continuity of care, availability of medication, preparation and number of clubs run by the facility.

Staffing dynamics

Staffing dynamics relates to the notion of having the desired interdisciplinary members of the adherence club team available to run the club activities. Furthermore, it relates to workload management and having enough time to be involved in the running of the club. The number of staff members available, work in the adherence club programme within the facility and the distribution of these members to the various tasks of the adherence club intervention relate to

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the context of staffing dynamics. This is what some of the staff members said on staffing dynamics.

> There is no way that one person on their own can do the clubs. You need your admin staff; you need your doctor's input and the rest of the Clinicians' input. You need your Counsellor's input. When it comes to blood visits and scripting visits and when it comes to clinical visits - last year I had to do clinical visits for 52 clubs. I felt *drained*, completely *drained*. **[Nurse 1]**

> You need two people [club facilitators] because one must be focused on the register like when they [patients] come in, you write their next appointment date, you must put the weight in the register, you check everything. The other one [club facilitator] is checking the boxes, the medication in the box so that if the medication arrived or if there is no medication so that we can prepare. The doctor can write up medication for that person if their medication did not arrive. Therefore, we need two people, not just one. **[Club facilitator 1]**

Collaboration/teamwork

Teamwork is defined as "a dynamic process involving two or more healthcare professionals with complementary backgrounds and skills, sharing common health goals and exercising concerted physical and mental effort in assessing, planning, or evaluating patient care" [50]. Regarding the adherence care intervention, teamwork relates to the concerted effort of the club team in planning, organisation and execution of the activities of the club sessions. Teamwork influences the actual implementation and running of the adherence club sessions and thus constitutes an important context element for the adherence club intervention. This is what some of the participants said.

> You need to have a team spirit, where you can go to the Pharmacist and say 'Look, the club medication did not come, *can* you accommodate us?' … Bring the folders in, five at a time, I will prepare the folders and issue the medication.' So, you need to work in a team…for this to work. **[Nurse 1]**

> Teamwork, dedicated team and as you know in the past it used to be Sister A that was running the team with the Counsellors and only now and again when she needs some advice then she will come either to the Doctor or to us as the CNP's [Clinician Nurse Practitioner]. In addition, she had a very good relationship with the Counsellors; they understand one

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> another. The teamwork was great, they knew exactly which club is coming because there was a system in place that she sort of drafted [specified responsibilities] 'club this is due for blood tests, this club is due for medication, this club is due for a clinical visit.' **[Nurse 2]**

Our observation confirmed that the counsellors worked together as a team in both clubs. Although each counsellor has their own clubs s/he facilitates, they come together each day to help each other so that the clubs can be run smoothly and that the patients are served efficiently and as quick as possible. The teamwork extended to the patients themselves. When the patients arrive at their club sessions in the mornings, they find the weighing room open with a scale. They are expected to take their weights and write these down on pieces of paper to be used during the quick-screening process. Encouraging patients to take their weights before the club team arrives fosters the notion of self-management and makes them feel part of the adherence club team rather than just a user.

Availability of medication

Quick access to medication is one of the central modalities of the adherence club intervention. Therefore, the availability (or lack) of medication is a critical context condition for the smooth running of the adherence club intervention. The following excerpt shows how important the availability of medication is.

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> Well, we do not have many challenges but only when the medication does not arrive [from the Chronic Dispensing Unit], then that is the biggest challenge because we have to check the folders, prepare the folders and then run up and down to the Pharmacy. It is very difficult when you are telling the patient 'your medication is not here' then the patient knows 'I am going to sit at [the] Pharmacy'. That is what they do not want. **[Club facilitator 1]**

To demonstrate the importance of receiving one's medication from the adherence club, one patient recalls the frustrations of a fellow group member who threatened to leave the club because her medication was erroneously processed through the pharmacy rather than the club.

> A woman came to the club, but her medication was not here and she had to go to the Pharmacy. Then she said, 'I think I am going to get out of the club'. I said 'No, I think maybe you can still carry on. Do not remove yourself from the club, because maybe next

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> time when you come, your medication will be already here.' So, she was giving up hope because she said it was the second time she was asked to go to the Pharmacy. Then I said 'No, you can still be a part of the club. Maybe when you come for the third time, it is going [to] be here [at the club]. **[Patient 2]**

Preparation

Preparation or the lack of preparation was also identified as an important context element, which sets the stage for how the activities of the club are conducted. The club team agreed that preparation is pertinent to the successful execution of the adherence club sessions.

> If the medication is not there then that also needs to be prepared before the time. If there are blood samples to be collected, the blood forms are being done, and the blood forms are being finished off before the day...? So, if you plan it and prepare it beforehand then it is not that bad. But if you do not, then it makes it hard for you the next day when the patient is in front of you then you need to run around. **[Club facilitator 2]**

> Like now they are preparing for tomorrow's club, I think there is a club tomorrow so we went to Pharmacy to check if medication is there so that we know who is going to have medication and who is not going to get so that we can prepare today. Tomorrow morning, when they come we already know who would be going to go to Pharmacy. We start with those people that are going straight to Pharmacy. The doctor does the scripting for the medication so that when patients return for their next visit, their medication is ready. So, we check everything. **[Club facilitator 1]**

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Our observations confirmed that the adherence club team makes sure that they are prepared before each club session. The preparation for the club activities starts the day before where the counsellors make sure that the folders of the patients have been drawn and that their medication has arrived from the Chronic Dispensing Unit (CDU). Early on the day of the club, the medication packages are organised, waiting for the patients to collect. See **Figure 9.6**.

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Figure 9.6: Organised medication packages

Number of clubs run by the facility

The number of clubs that a facility runs is considered an important context factor that influences the running of the intervention, hence, the mechanisms activated by the intervention. This is because the number of clubs that the facility runs affects the scheduling of the number of clubs to be run per day, thus affecting the staffing dynamics and the workload of the club team. These are the opinions of some of the club team members regarding the number of clubs being run at the facility.

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> Well, it is going to be too much work actually, because we are having lesser clubs compared to other clinics. Other clinics already have about 100, or 150 clubs. So, we are still building up. **[Club facilitator 1]**

> Then we have how many clubs now? Fifty-seven I think...Yeah, then each club has about 30 to 40, and others now have in the club 50 patients that we have in them. **[Nurse 1]**

Organisation of the facility

The organisation of the facility speaks to the way the HIV-management and Care programme is organised at the facility. Some facilities have ART services as a separate entity from the rest of the clinic whereas others 'integrate' ART care services with other chronic non-communicable diseases. Information regarding the organisation of the facility was collected from the structured observations that were conducted. Based on our observation, the MPCHC has organised the

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adherence club as a unit of its own. This is labelled "Chronic club B" to avoid any stigmatisation of patients seen going to this section of the clinic. The understanding is that patients feel free here and avoid the judging looks of other patients. To this end, they feel no one judges them.

OUTCOME

In addition to the two primary outcomes of the adherence club intervention (retention in care and adherence to medication) described using the quantitative methods, other outcomes emerged from the qualitative data. Additional outcomes of the adherence club include reduced workload and decongestion of the facility.

Reduced workload

Reduced workload is defined here regarding the number of patients that the health-care providers see per day. The participants suggest that if patients are successfully retained in care, then the workload of the clinicians will be reduced.

> The clinic is getting less with patients. So, we do not have to see more than 100 patients a day…At least we can see 50 to 60 a day. Therefore, it helps *us* also as the staff, so that we do not have too much workload. **[Club facilitator 1]**

> Definitely, because it looks like now, about plus-minus 1 500 patients are remaining in care *in* the clinic, [who now] are in the club. Which means 1 500 [patients] less that the Clinicians have to see, 1 500 less that [the] Pharmacy has to service except obviously the few who have to go to the Pharmacy [because of scripting errors or whose medication did not arrive]. **[Nurse 1]**

Decongestion of the facility

Decongesting the health-care facility is an important health systems outcome, which is also tied to the successful retention of patients in the adherence club system. This is what one of the participants said in this regard.

> Decongest, I am thinking in terms of decongesting the Pharmacy area, because of sending, say, 30 to 35 patients to Pharmacy to collect their medication from Pharmacy. They do not need to go to Pharmacy because they get their CDU [Chronic Dispensing Unit] parcels from the clinic…. get their medication and off they go, right? So that is minus 35 patients in the waiting area. **[Doctor 1]**

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Synthesis

The above sections indicate how the interviews and observations yielded evidence in favour of many elements of the initial programme theory. However, realist researchers need to identify patterns or demi-regularities that explain the observed outcomes. This synthesis aims at obtaining conjectured ICAMO configurations. The Kaplan-Meier descriptions (quantitative analysis) allowed us to describe the outcome of retention in care and adherence behaviour. While through the qualitative arm of the study, we identified relevant context elements, important mechanisms and emergent outcomes as they relate to the intervention and actors were identified.

Realist evaluators develop an explanatory understanding of how programmes work on the basis of retroductive inference [51]. In retroduction, the evaluator starts from observed outcomes and identifies and verifies mechanisms that are theorised to have generated the outcomes (**Table 9.7**).

Table 9.7: Adherence club ICAMO matrix

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Standard operating protocol - HIV policy	- Patient	- Perceived barriers - Perceived threat - Nudged	- Adhering to club appointments
Grouping patients	- Availability of space for meeting - Longevity of patient the club - Relationship with other club members	- Patient - Group	- Perceived social support - Positive group dynamics	- Better adherence resulting from developed self-efficacy
Quick medication access	- Availability of medication - Proper preparation for club session	- Patient	- Perceived benefit - Motivation - Satisfaction	- Adherence to medication related to medication access
Prompt continuity of care	- Availability of clinicians - Staffing dynamics - Organisation of club activities	- Clinicians - Patient	- trust	- Retained in care through problem resolution
Club facilitator-patient relationship	- Staffing dynamics - Teamwork/collaboration	- Facilitator - Patient	- Trust - Perceived support	- Adherence to medication - Retention in care
Overall intervention	- Buy-in from care providers - Preparation and organisation	- Patients - Club teams	- Motivation - Self-efficacy - Satisfaction (with care)	- Improved retention in care and adherence to medication

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In our retroductive inferencing, we applied the 'configurational' approach to causality, a logic in which outcomes are considered to follow from the alignment, within a case, of a specific combination of attributes (**Figure 9.7**) [17]. After obtaining conjectured ICAMO configurations, we applied counterfactual thinking (testing possible alternative explanations) to argue towards *transfactual* (mechanism-centred) conditions [52]. In applying this counterfactual [and transfactual] thinking, we constructed an ICAMO matrix table (**Table 9.3**).

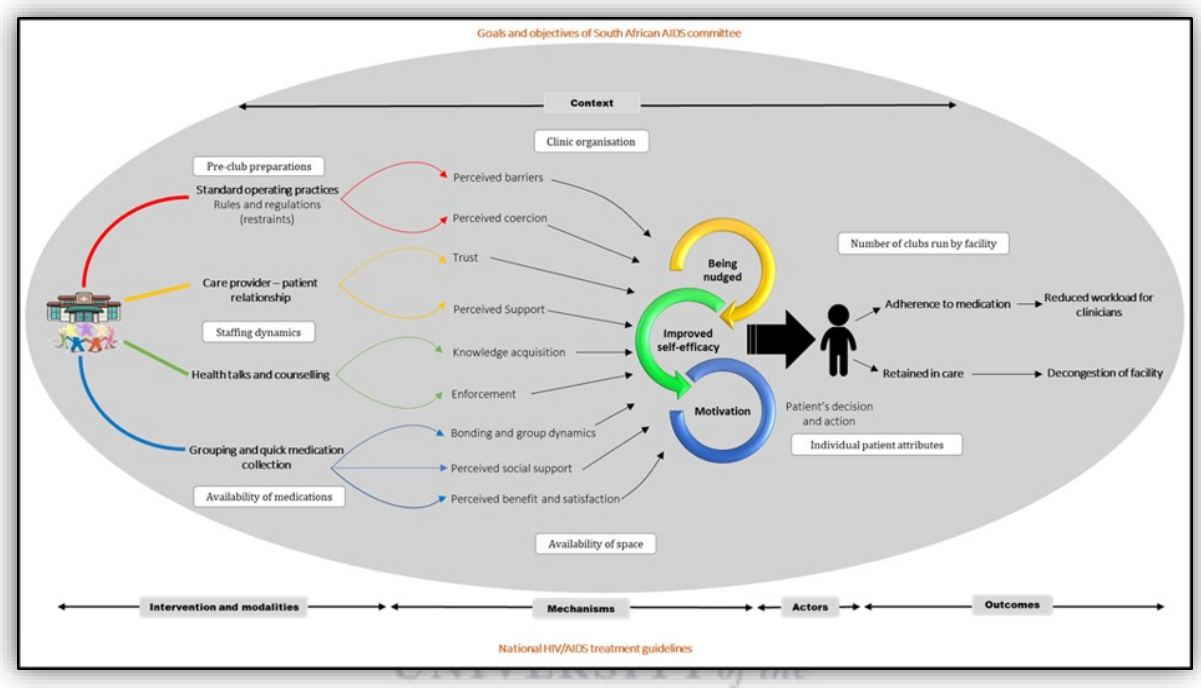

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Figure 9.7: A modified configurational causation model of the adherence club intervention

This ICAMO configuration represents the modified programme theory of the adherence club intervention based on the evidence of the mixed-method approach to data collection and the application of the *retroduction* logic of causal inference. Finally, we used the "if…then…because" statements to translate the ICAMO configuration map into theories (**Box 9.2**).

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Box 9.2: Refined programme theory of the adherence intervention

> If adults (18+) clinically stable patients [**Actors**] receiving antiretroviral therapy are grouped for targeted care in which they receive quick uninterrupted supply of antiretroviral medication (with reduced clinic visit frequencies), health talks and counselling, immediate access to a clinician when required and guided by club rules and regulations [**Intervention**] within the context of adequate resources, and convenient (size and position) space and proper preparation by the club team [**Context**], then they feel nudged, their self-efficacy is improved and they become motivated [**Mechanisms**] to continuously adhere to their medication and remain in care [**Outcome**].

The data also indicated that the prospect of joining the adherence club to benefit from its perceived advantages motivates non-members (usually treatment-naïve patients) to remain in regular care and adhere to their medication to meet the criteria for admittance into the adherence club programme.

Discussion

The aim of the study was to test an initial programme theory of the adherence club in a *real* implementation condition – the MPCHC. We sought to confirm, refute and/or modify the initial programme theory of the adherence club intervention by applying a case-study approach and collecting data through multi-methods. Following the process of eliciting the initial programme theory, we identified two possible programme theories (**Box 9.1**), each offering a different possible explanation of how, why and in what circumstance the adherence club works.

The quantitative findings of this study confirmed those of other quantitative studies [8–11] and, as identified in the initial programme theory that the adherence club intervention enhances adherence to medication and promotes retention in care. A pilot study conducted by Luque-Fenandez and colleagues confirms the good adherence rates of patients using the facility-based adherence club intervention under experimental conditions as obtained in this study [8]. Their findings showed that retention in ART was 94% at 12 months. Another evaluation of the adherence club model under actual implementation conditions also reveals that after 12 months, 95.2% of patients were retained in care [11]. This evidence supports the potential effectiveness of the adherence club in retaining patients in long-term ART care.

Other studies that investigated the effectiveness of the adherence club intervention regarding enhancing adherence to ART showed similar findings as ours [8–11]. Facility-based adherence

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clubs at 12 months had 2% of patients experience viral rebound (≤400 copies/mL) [8] and the community-based adherence club showed only 1.7% of the patients had viral rebound [9]. In this study, at 36 months an estimated 4.5% of the patients receiving ART from two adherence clubs had viral rebound. This finding is significant because the global average rate of reporting ≥90% adherence to ART is 62% [53]. These findings confirm the potential effectiveness of the adherence club intervention to enhance population-level adherence to HIV medication.

The non-participant observations and realist interviews employed in this study allowed us to identify intervention modalities, mechanisms and context factors that interact with the mechanism to cause the expected behaviours. Based on the findings of this study, most of the relevant (important) mechanisms that are thought to trigger adherence and retention in care as elicited in the initial programme theory were identified, confirming the theoretical principles of the initial programme theory.

Through data obtained from this study, and by applying the transfactual and counterfactual thinking, we uncovered that the two programme theories, rather than being rival theories, complement each other. Thus, explaining how and why the adherence club enhances adherence to medication and promotes retention in care among stable patients on ART. Most of the respondents indicated that both theories play a role in explicating how and why the adherence club works. Analytically, Hedström and Swedberg [54] suggest that bundles of identified mechanisms can either work to enhance one another or cancel out each other.

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We modified the initial programme theory (**Box 9.2**) in which case the mechanisms are now considered to complement each other to explain how and why the adherence club works, based on the findings of our study. However, the extent to which they combine is not exactly clear. In other words, this study did not allow assessing the level of contribution made by each of the theories. We deduce that although these two theories may combine to explain how and why the adherence club intervention works, the degree to which they would combine would depend on the implementation context.

Evidence from other cases will be used to further refine and enhance the programme theory of the adherence club intervention. This is based on the premise that (1) the adherence club intervention could work differently in different settings (as identified in the initial programme theory); (2) the adherence club intervention is also implemented in (slightly) different ways at

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various facilities; (3) the adherence club intervention may be more effective with some groups rather than others; (4) the adherence club intervention could be more useful in one location than another; and (5) it may have intended and unintended consequences [17]. After obtaining data from other cases, through the process of cross-case analysis, we will seek to elicit a more refined programme theory of the adherence club intervention.

Rigour and trustworthiness

Several steps were taken to ensure the rigour and trustworthiness of the study. Our sampling process used many criteria to ensure that the information gathered is from a credible source. First, the purposive sampling approach allowed us to select only people who would be information-rich informants. This comprised the health-care providers working directly on the adherence club programme and the patients who were receiving care in the programme.

While seeking for information-rich informants, we also applied the notion of maximum variation sampling. Through this technique, we recruited at least one of each of the cadre working on the adherence club programme. These include the doctors, nurses, club facilitators (counsellors) and the patients themselves. Further to this, we recruited patients of varying duration in the adherence club including those who once were club members and had returned to clinic care or defaulted treatment. Of the five participants included, one of them had been in the adherence club since its inception, while another one had just been in the club for a month. The other three had been in the club within a year's gap.

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To improve the rigour of the study, we applied two levels of triangulation, methods triangulation and triangulation based on the study participants. Adopting the mixed-method approach allowed some aspects of the study to be verified using the other method. Also, using a variety of participants promotes the triangulation of the information obtained from them and assists the research to verify facts.

Frequent debriefing sessions were held between the authors. These sessions took place in all the phases of this study including the data collection, analysis and synthesis phases. In conducting and reporting the findings of this study, we followed the RAMESES II reporting standards for realist evaluation developed by Wong and colleagues [55].

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Limitations

Although we adopted the purposive sampling approach for the qualitative arm of the study, sampling based on who will provide the best information based on pre-existing assumptions is tricky. For this reason, we purposively sampled the participants based on how long they have been part of the adherence club programme. These characteristics are displayed in **Table 9.2**.

Ideally, would have been to investigate the factors influencing survival (retention in club and adherence to medication) based on the personal characteristics of the patients such as age categories, employment status and marital status. However, because each adherence club only has a maximum of 40-45 patients, the results would be misleading. The hazard ratios that would have been obtained would have had wide confidence intervals to make any meaning inferences from the results.

Studies that require the application of logic in the process of making the associations of various elements in a configurational map depend largely on the judgement of the researcher(s). This process, therefore, could be influenced by the line of thinking applied by the researcher(s) to the available data. This is particularly important because it is easy to make causal misattributions given the complexities of the systems we studied and the possibility that different mechanisms can cause the same events.

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To obtain an objective application of the logical reasoning to the data, frequent debriefing meetings were held by the researchers to judge how best the data fit within the conceptual framework. In addition, the obtained configurational map (programme theory) was presented to middle-level managers who are conversant with how the adherence club works, but are not involved in the evaluation process for their objective scrutiny of the obtained programme theory. The aim was for the managers to judge how well the obtained programme theory represented the actual implementation and running of the intervention.

Conclusion

In this study, we applied the realist evaluation approach to testing the programme theory of the adherence club intervention. Based on the findings of this study, we have made modifications to the initial programme theory, a first step towards developing a middle range theory of the intervention. Nevertheless, contributions from other case studies are required to provide further

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confirmations, refutations and modifications of the initial programme theory to obtain a valuable middle range theory. An empirical middle range theory has the potential to inform the adaptive programming and implementation of the adherence club intervention in other areas to improve population-level adherence to ART.

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CHAPTER TEN

Case Study 2: Testing the initial programme theory at Facility Y

"At this [adherence] club, we are a family now": A realist case study of the antiretroviral treatment adherence club, South Africa. Evaluation (Under Review)

Abstract

Background: Poor retention in care and suboptimal adherence to antiretroviral therapy (ART) undermines the successful efforts of initiating people living with HIV in South Africa. To address these challenges the adherence club – a differentiated care model – was designed to streamline aspects of HIV treatment and care to provide efficient and effective services to 'stable' ART patients. Although empirical evidence suggests that the adherence club intervention is effective in sustaining long-term medication adherence and retaining the patients in ART care, it is poorly understood exactly how and why the adherence club intervention works. We previously formulated an initial programme theory that presents how and why the adherence club designers and managers envisaged the intervention to work. In this paper, we report on the process of testing the initial programme theory in a public primary health centre.

Methods: Within the realist evaluation framework, we applied a confirmatory theory-testing case study approach. We collected data using quantitative and qualitative techniques. A retrospective cohort analysis was done to describe adherence and retention in care behaviours of patients on ART over 24 months. In conjunction, an explanatory qualitative study was conducted to identify and link critical mechanisms activated by the adherence club intervention to the relevant context conditions that triggered the different mechanisms to cause observed outcomes. Following the retroduction logic (mechanism centred) of making inferences, we configured information obtained from these quantitative and qualitative approaches using the intervention-context-actor-mechanism-outcome heuristic tool to formulate generative theories.

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Results: Our analysis yielded a modified programme theory. If adult (18+ years) clinically stable patients receiving ART are grouped for targeted care in which they receive quick uninterrupted supply of antiretroviral medication pick-up, health talks and counselling, immediate access to a clinician when required and guided by club rules and regulations within the context of available resources, and convenient space and proper preparation by the club team, then they will continue to adhere to their medication and remain in care because their self-efficacy is improved, they are motivated and are being nudged.

Conclusion: A theory-based understanding of the adherence club intervention in real-life situations provides valuable lessons towards the adaptive implementation of the adherence club intervention.

Background

South Africa has a high HIV epidemic with an estimated seven million people living with HIV/AIDS (PLWHA) as at 2016 [1]. Through a series of National Strategic Plans, policies, programmes and interventions, the South African health system currently runs the largest antiretroviral treatment (ART) programme in the world [2]. Although major successes have been achieved by the South African health system in responding to the HIV epidemic, challenges remain. These challenges are reflected in the sustained high HIV-incidence rates [3], poor retention in ART care and suboptimal adherence to medication [4]. Poor retention in care and suboptimal adherence to medication threaten the success of the South African national ART programme. With an estimated 3.5 million people initiated on ART to date [5] and the recent adoption of the 'test and treat' (treat all) approach [6], the need for sustainable programmes to improve the retention in care and adherence to ART is critical.

A consolidated version of the 2015 WHO's HIV-treatment guideline recommends the use of differentiated care models to improve the access and quality of treatment and care services for PLWHA [6]. Differentiated models adapt HIV-treatment services to specific patient populations and contexts, rather than adopt a one-size-fits-all approach [7]. By tailoring services according to the needs of different patient groups, reducing clinic contact and relying on community-based services for quick medication access for treatment mature patients, these models increase the capacity and efficiency of ART services.

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The adherence club intervention is an example of a differentiated care model designed to streamline ART care for an adult (18+ years), treatment-experienced patients with good clinic attendance record and evidence of medication adherence [8, 9]. Through quick group consultations, convenient medication pick-up processes and direct access to a clinician when needed, the adherence club drastically reduces the waiting times of the patients. The adherence club intervention also provides a conducive social environment to encourage patient interactions with peers. The adherence club intervention has been described in greater details elsewhere [9–11].

The evidence supporting the effectiveness of the adherence club intervention [12–15] and its cost-effectiveness [16] has prompted plans to roll out the intervention nationwide [4]. Nevertheless, there is a limited theory-based understanding of *how* and *why* the adherence club intervention works and in what health system context(s). To this end, a realist evaluation of the adherence club intervention was commissioned [11]. In this paper, we report on the process of testing the hypothesis (initial programme theory) of how and why the adherence club intervention is expected to work under real-life implementation conditions.

Methodological approach

The realist evaluation, a theory-driven approach, guided the inquiry [17]. The goal of realist evaluation is about learning 'for whom, in what circumstances, and in what respects a programme works [17, 18], through identifying, testing and refining programme theories. Therefore, realist evaluation starts with an initial programme theory and the goal is to obtain a more refined programme theory.

Programmes work with the acquiescence of participants (actors) [19, 20], and provide resources, opportunities or constraints of some kind that influence the target person's decision-making [21]. Therefore, understanding why a programme works (or not) rests on the ability of the evaluator to explain the decision making the process of the relevant actors regarding the resources, opportunities and constraints that the programme provides to the relevant actor.

Identifying the important generative mechanisms (social and psychological drivers) of a programme is not enough to explain how and why a programme works (or not). For an intervention to work, it must influence the reasoning (mechanism) of the targeted actors to cause them to adopt an intended behaviour that in a specific context will lead to a specific outcome. Therefore, realists assume that an outcome (O) is generated by a mechanism (M) being triggered

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in context (C) through an actor (A) when an intervention (I) is implemented. This captures how, why, for whom and in what circumstance programmes work. Formulating realist theories is, therefore, achieved through the formation of intervention-context-actor-mechanism-outcome (ICAMO) configurations [22, 23]. The ICAMO configuration is a modification of context-mechanism-outcome (CMO) originally proposed by Pawson and Tilley as the heuristic tool for the development of realist theories.

In the first phase of this project, we elicited an initial programme theory of the adherence club intervention with information obtained from four sources [24–26] (see **Figure 10.1).**

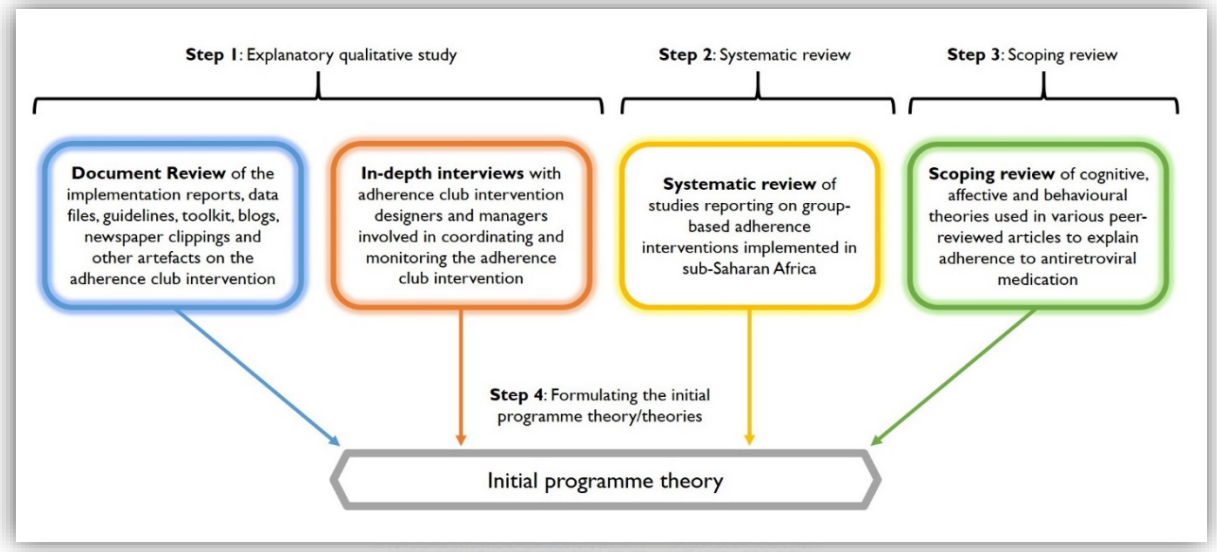

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Figure 10.1: Sources of information towards formulating the initial programme theory

We applied the ICAMO heuristic tool to configure the programme theory by applying the logic of retroduction (mechanism centred analysis and conceptualisation- to make inferences. Testable hypotheses were distilled from the configurational map, an approach to causality, whereby, outcomes are considered to follow from the alignment of a specific combination of attributes [18], using the 'if…then…because' phrase (**Box 10.1**).

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Box 10.1: Initial programme theory of the adherence club intervention represented by two tentative theories (hypotheses)

Initial Programme Theory 1

IF adult (18+ years) clinically 'stable' patients with evidence of good clinic attendance are group-managed, receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,

THEN they are likely to adhere to medication and remain in care,

BECAUSE they develop a group identity, which improves their perceived social support and increases satisfaction and trust; and acquire knowledge, which helps them to understand their perceived threat and perceived benefits and improves their self-efficacy. As a result, they become encouraged, empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

Initial Programme Theory 2

IF operational staff receive goals and targets set to continuously enrol patients in the adherence club and monitor their participation through strict standard operating practices (the promise of exclusion in the event of missed appointment and active patient tracing),

THEN patients are likely to adhere to medication and remain in care,

BECAUSE they fear of losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules. As a result, they are nudged to remain in care and adhere to the treatment, which might decongest the health facility.

The aim of this study was to test these initial programme theories in a primary health-care facility running the adherence club programme, with the goal of obtaining a more refined programme theory of the adherence club intervention.

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Research design

The study is framed within the realist evaluation approach. We sought to test the initial programme theory of the adherence club intervention in a real-life implementation situation to verify, refute and/or modify the initial programme theory of the adherence club intervention. To this end, we adopted an explanatory theory-building case approach. We adopted the multiple embedded case study design [27]. Each facility was considered a case and unit of analysis, with each of its ART clubs being sub-units embedded in the case.

According to Creswell [28], cases selected for case study research could be identified as typical, deviant or crucial. Facility Y was selected as a deviant case (poor performing) for testing the initial programme theory of the adherence club intervention. This facility has retention in care rates of only 63.0% based on the routine monitoring and evaluation data on the adherence club intervention of 2015. Although Facility Y was selected for first phase rollout of the adherence club intervention in 2012 along with other clinics in the health sub-districts, the intervention

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only rolled out in September 2014. Reasons were challenges related to lack of physical space and poor buy-in from the facility health-care providers.

Study setting

Facility Y is a provincial primary health-care facility providing primary health care to the surrounding communities. Staff provide first level and some second level care including a 24-hour emergency service. Housed in a separate building from the main clinic, this is an accredited ART initiation and on-going management site, which operates Mondays to Fridays providing treatment and care services to PLWHA and those infected with tuberculosis (TB). Patients who are co-infected with HIV and TB can easily access both services, as HIV and TB share the same waiting area and are seen by the same counsellors.

Facility Y was one of the facilities selected for the first phase rollout of the adherence club. However, because of a lack of the proper structures such as physical meeting space, the programme could not be implemented at the scheduled time. Following the construction of a makeshift building for club activities, the intervention was initiated at the facility. Though, the programme was poorly implemented because of poor buy-in from the staff members, who failed to identify how the intervention would benefit them and/or improve the overall delivery of ART services to the patients. They perceived the adherence club intervention as extra work in their already busy schedule. Consequently, even when a makeshift building was constructed for the adherence club activities, the programme struggled to function properly.

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When the supervisors identified the problem, a nurse was identified and trained in the implementation and execution of the adherence club programme to champion the intervention at Facility Y. This nurse subsequently ran workshops and meetings with the other ART care providers at the facility expounding on the advantages of the intervention to the patients, the health-care workers themselves and the clinic. This strategy led to an overall improvement of the level of buy-in, uptake and implementation of the adherence club intervention. To date, an estimated 50 clubs with 25-35 patients each have been established at the facility.

Research methods

We combined a retrospective cohort analysis and an explanatory qualitative approach to data collection. The combination of qualitative and quantitative methods allowed us to explore the important contextual elements that influence the implementation of that adherence club

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intervention, the mechanisms that the intervention introduces and the emergent outcome patterns. The multi-method approach also allowed for triangulation. According to McEvoy and Richards, triangulation in realist research ensures confirmation and completeness of information and promotes the use 'abductive inspiration' or *retroduction* to make inferences [29].

Selection of respondents

Regarding the interview process, we applied a purposive sampling approach to select the participants to be interviewed. An adherence club nurse and three lay counsellors were interviewed on the side of the health-care providers, and we conducted interviews with six patients.

Regarding the retrospective cohort arm of the study, our goal was to identify a typical 'mature' adherence club, i.e. a club that reached its maximum capacity of 30-35 patients. First, we selected all the clubs that had opened in 2014. Then, we identified the clubs that had reached their maximum capacity (35 patients per club) in the same year – seven clubs were identified. We then randomly selected two clubs to conduct the survival analysis using the fishbowl method (without replacing). All the patients in the cohort of each of the selected adherence clubs (35 per club) were included in the cohort analysis. Seventy patients made up the cohort for the survival analysis.

Data collection process

We used the two sampled clubs as the focus of data collection for the observation. **Figure 10.2** illustrates the data collection process in the facility.

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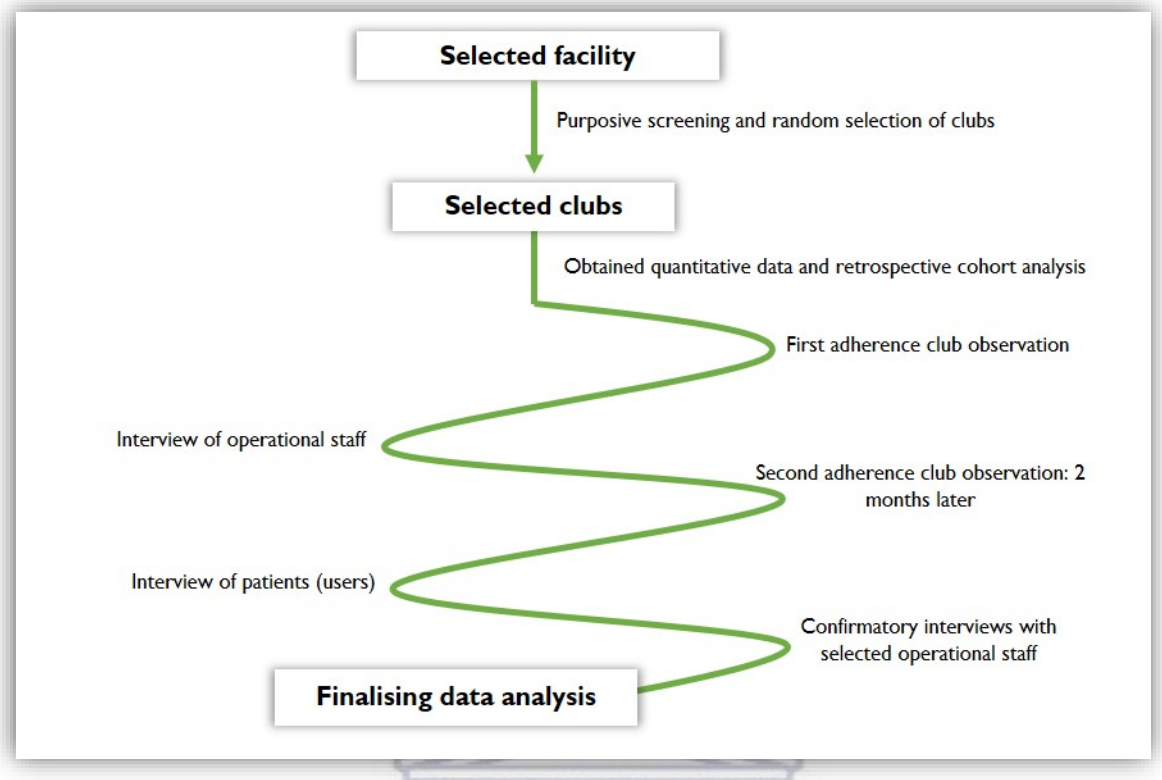

Figure 10.2: Data collection process

The quantitative data were extracted from the adherence club registers at the clinic. In the Western Cape, information relating to retention in care is registered using the modalities outlined in **Table 10.1**.

Table 10.1: Modalities defining adherence club attendance

Recorded Outcome	Outcome Event
DNA	**Did not attend** club session or send a buddy within five days after the club sessions
BTC	**Back to Clinic**- Exiting the club for medical reasons and reinstated in routine standard of care
TFOC	**Transferred out to different club** – Patient is transferred out to another club in the same facility
TFO	**Transfer out** – Patient is leaving the facility completely and will attend a clinic elsewhere
RIP	**Rest in Peace** – Patient has died

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The viral load of the patients is used as a proxy indicator for adherence to medication. Non-adherence was identified as any reading >40 copies/cm^3 and adherence was represented as LDL (lower than detectable reading).

We conducted four non-participant observations of the adherence club meetings [30], where we observed club sessions without interfering in any of the processes. These included two sessions of exclusive medication collection and a blood sample collection plus medication collection. The goal of the non-participant observation was to obtain insights into events and activities and the meanings that the club members attach to the sessions. We captured the dynamics of interactions of the group members with each other and with care providers in our field notes. During each observation session, we took detailed field notes.

After the non-participant observations, we conducted realist interviews – a theory-driven approach to interviewing proposed by Pawson [31] – to uncover the causal relationship of aspects related to the implementation of the adherence club intervention. The investigation looked at the relevant context, generative mechanisms and emerging outcomes in relation to the patients (actors). Pawson [31] advises that in applying the realist interviewing approach, *the researcher's theory is the subject matter of the interview, and the subject is there to confirm or falsify and, above all, to refine that theory*. Pawson [31] suggests that the care providers are versed with issues around the context and outcome of the intervention, while the patients, being the principal actors in the intervention, can provide mechanism related attributes. The patient interviews were conducted after the second non-participant observation. Audio-recorded data from the interview sessions were transcribed verbatim and prepared for analysis. The field notes from the non-participant observations were also developed into transcripts.

The quantitative data were captured and prepared for analysis using Statistical Package for Social Sciences (IBM SPSS) version 24 [32]. The structured observations were documented in the form of jottings and photos, which were later developed into field notes. The audio recorded interviews were transcribed verbatim by a professional transcriber and prepared for analysis. Atlas.ti version 7 was used to manage the data [33].

Data analysis

To identify and describe the outcome patterns of the adherence club intervention regarding retention in care and adherence to medication, we used the Kaplan-Meier method – the probability of surviving in a given time, while considering time in many small intervals [34].

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This method was suitable because it allowed us to estimate the rate at which patients remained in care and the rate at which they maintained a viral load lower than detectable (<40 copies/mm^3 of blood) at every six months intervals, covering a 24-month period. Concerning retention in care, the patients were considered not retained in care if they did not attend a club session or sent a 'buddy' and were sent back to the clinic. Patients were considered censored if they were transferred out to a different club or clinic, or died. For adherence to medication, when a patient was not attending that club for whatever reason, they were considered censored.

The analysis of the qualitative data involved the coding of the realist interview (semi-structured) transcripts. The coding process was done by the first author who has extensive knowledge on the subject matter [35], with a previously validated coding frame that was based on the initial programme theory (**Appendix 1**). After the coding process, we classified the themes as a mechanism, context, actors, intervention and outcomes.

Ethical considerations

This study is part of a larger project "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health-care facilities in the metropolitan area of Western Cape Province, South Africa," which has received ethics clearance from the Higher Degree's Committee of the University of the Western Cape. In addition, we obtained ethical clearance from the Provincial Department of Health of the Western Cape Province. We also obtained permission from the facility heads. Regarding the study participants, we first provided them with an information sheet of the project. This was followed by a verbal explanation of the role of the participant and the significance of their participation. The participants were required to sign an informed consent form. We promised and ensured confidentiality and anonymity by identifying the participants using pseudo names and by password-protecting all files related to the study.

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Results

The findings are presented in relation to the two initial programme theories.

Quantitative findings

Retention in care

The combined retention in care within a 24-month period is 77.8%, with 'Club A' registering a much lower retention in care rate (71.4%) compared to 'Club B' (83.3%) (T**able 10.2)**.

Table 10.2: Retention in care distributions in two adherence clubs at Facility Y

Adherence Club	Total Number	Number of patients not retained in care	Patients retained	
			Number	Percent
Club A	35	10	25	71.4%
Club B	37	6	31	83.8%
Overall	72	16	56	77.8%

The survival distributions of the patients receiving care in the two adherence clubs are shown in **Figure 10.3**. At six months, the retention in care rate of Club A was 91.4% (CI 95 %; 75.8 – 97.8). At 12 months, the retention in care rate dropped to 77.1% (CI 95 %; 59.4 – 89). At 24 months, the rate decreased further to 65.7% (CI 95 %; 47.7 – 80.3). Club B registered better retention in care rates at six, 12 and 24 months with values of 86.5% (CI 95%; 70.4 – 94.9), 83.8% (CI 95%; 67.3 – 93.2) and 81.1% (CI 95%; 64.3 – 91.4), respectively.

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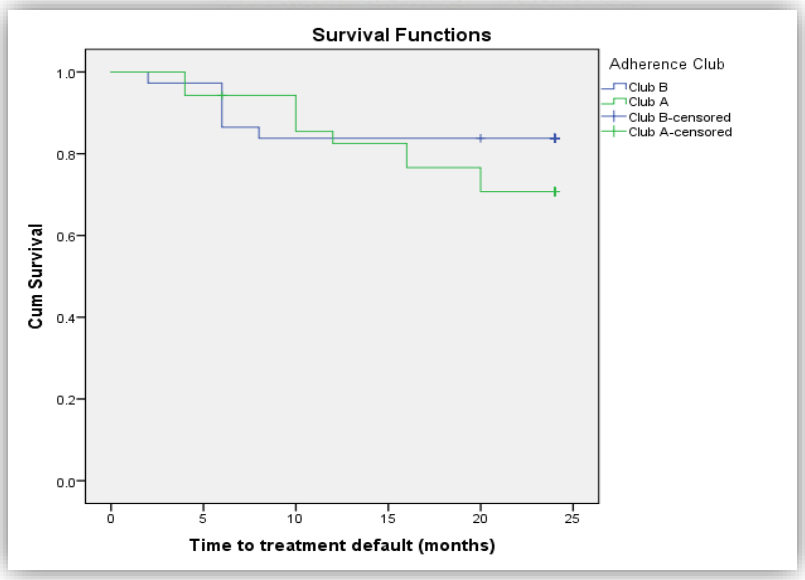

Figure 10.3: Survival distribution of patient retention in care in two adherence clubs at Facility Y

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We further conducted a log-rank test (Mantel-Cox) to determine whether the survival distributions of the two adherence clubs were statistically significantly different. A *p-value* of 0.255 showed that the survival distributions of the two adherence clubs were not statistically different suggesting some level of constancy regarding retaining patients in care within the 24-month period. Nevertheless, Club B showed signs to have stabilised, while a projection of Club A showed that it had the potential of continuously losing patients.

Adherence to medication

Patients in Club B showed better adherence to medication behaviours (89.2%) compared to those in Club A (77.1%). The population-level adherence to medication based on the two sampled clubs was 83.3%.

Table 10.3: Adherence to medication distribution rates in two adherence clubs at Facility Y

Adherence Club	Total Number	Number of patients non-adherent to ART	Adhering patients	
			Number	Percent
Club A	35	8	27	77.1%
Club B	37	4	33	89.2%
Overall	72	12	60	83.3%

Based on **Figure 10.4**, the adherence to medication of the Club A members at 12 and 24 months were 97.1% (CI 95%; 83.3 – 99.9) and 72.0% (CI 95%; 54.0 – 85.2), respectively. At 12 months, Club B members showed a slightly lower adherence rate of 91.7% (CI 95%; 76.7 – 97.8) compared to Club A members, but at 24 months, Club B members showed better retention in care rates 88.4 (CI 95%; 72.7 – 96.0) compared to Club A members.

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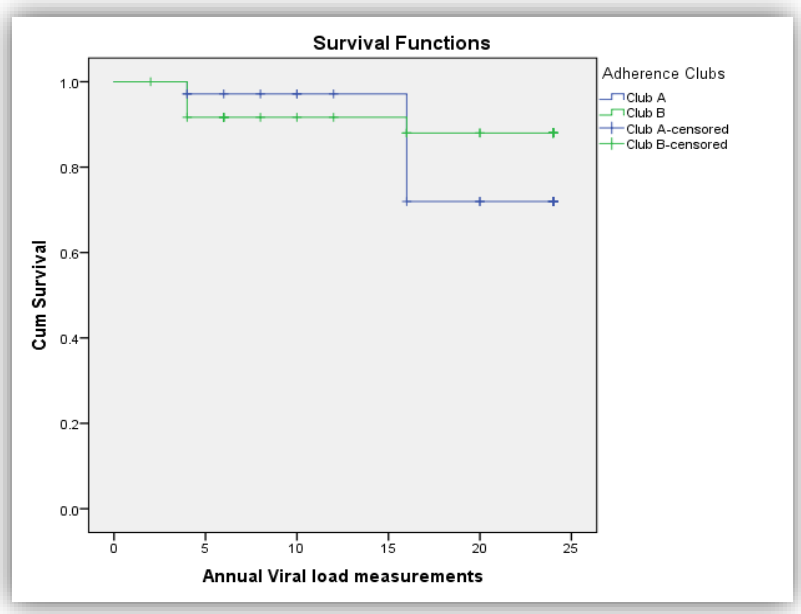

Figure 10.4: The survival distributions of the adherence behaviours of patients in the two adherence clubs at Facility Y

The log-rank test (Mantel-Cox) showed a value of 0.252, which indicates an overall consistency between the two clubs in enhancing adherence to medication among the patients using the intervention.

Qualitative findings

Mechanisms

We identified possible mechanisms from the data, based on the two parts of the initial programme theory. We defined 'mechanism' as a process of how subjects interpret and act upon the intervention (or components of the intervention) [36].

Theory 1

Regarding Theory 1 (**Box 10.1**), we found the following elements in the interviews with the stakeholders.

Motivation

Motivation relates to the motive behind an individual's involvement in an activity. Regarding the adherence club intervention, motivation is "a construct that pertains whenever an activity is

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done to attain some separable outcome" (extrinsic motivation) [37]. In this case, the outcome of interest relates to ease of receiving ART and care services that fit into one's lifestyle. This is especially applicable for patients who are not receiving treatment in the adherence club but are aware of the benefits that the adherence club offers.

> When we prepare them [treatment naïve patients] for ARVs, we tell them 'in six months if your viral load is suppressed then you are going be a VIP which means starting from today you are starting your medication you need to take your medication *very well*. You are not going to come to the clinic monthly. You will come maybe four times but it will be less than five times a year to the clinic, we take blood only once a year.' You know so we are starting to buy them in when we are preparing them. This motivates them to achieve low viral load. [**Counsellor 3**]

> It [the adherence club] is a good *motivation* because number one, the waiting time in this waiting area, in the ARV Unit *is* reduced. [**Nurse 1**]

Perceived benefit

One's attitude towards adopting an intervention is thought to depend on how beneficial the resources of the intervention could be to the individual [38]. The perceived benefit, therefore, relates to the awareness of the positive impact that the resources of the adherence club could have on fitting their ART into their lifestyles. These benefits were related to the prompt service delivery that they received through the adherence club.

> It saves them time to do other things, like go to work or attend school. [**Counsellor 1**]

> You just come straight [directly] into the facility and straight to the Counsellor. You avoid all those waiting periods and medication; you do not have to go to the Pharmacy where you have to sit with the mainstream. Your medication is there [club venue] because our Counsellors collect the medication the day before… As a result, they [Patients] can still go to work …they do not have to sign a day's leave. [**Nurse 1**]

> If you are here and you want to see the doctor, one of the nurses goes inside and speaks to a doctor [on your behalf]. Then, they will just come and fetch you here and then you go straight to the doctor. [**Patient 1**]

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Satisfaction

Satisfaction relates to the fulfilment of the patients' desires, expectations and needs regarding the service delivery offered through the adherence club. According to the providers, the patients' experience with the adherence club care, is that they potentially remain in care and adhere to their medication. This is how some of the patients described the care the experienced in the club.

> Here we are doing everything inside here, so it is nice. *It is very nice*. So, if someone wants to go back to work, she or he can go back to work. So, it is encouraging for the person to take their medication, it is encouraging for the person to come to the clinic. [**Patient 1**]

> Yes, they are doing well. I like it. I appreciate the clubs because, in Zimbabwe, we do not have clubs. Even the way they are talking with us, it is very nice. Sometimes you have a stress to say, 'hey I'm HIV' but the way it is *here* [club], we communicate with other people. So, I like the way they do that. [**Patient 2**]

Bonding and group identifying formation

Bonding is the formation of a close relationship, especially through frequent or constant association. *Open and frequent communication with respect, feelings of warmth, caring and closeness, availability of supportive guidance, … in social systems facilitate bonding and promote healthy intimate relationships* [39]. The literature says that the bonding process can be facilitated by shared common goals and characteristics. The bond formation between the club members is an important mechanism as it fosters sharing among the club patients. This is what some of the participants said about bonding:

> We have 35 patients per club but intimate as well, they are able to form bonds. It is not just anybody, and you know, they know it is *that* group and they try as far as possible to *remain* within that group, because they have that support. [**Nurse 1**]

> Okay, you see here as we are at this club, we are a family now. We did not know each other, but now, as we are here, we know each other… This is my family. Some other people here, they do have families, but they do not tell their families that they have this. [**Patient 1**]

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Perceived social support

Perceived social support speaks to the awareness of the positive impact that the moral, psychological or physical support has on the patients receiving care in the adherence club intervention. The nature of the support received in the adherence club is predominantly peer support. According to Lee and Lok [39], peers can provide companionship, stimulation, physical support, ego support, and intimacy.

> It is a support group. They support each other. They are a family, because some of the patients do not have people to talk to at home, because we always tell them 'when you *here*, it is a free place for everything. [**Counsellor 2**]

> The patients support each other and you can always see them talking to each other. You can see that it is more than just a club or coming to get medication. Sometimes, they would send a message to one of the people in the club, 'please collect my medication, I am unable to come today' or 'I'm working nightshift? You know they [Patients] have their own little thing going, like a bond or something so it is just super awesome. [**Nurse 1**]

> When I am here [in the club], I feel de-stressed (relaxed) like I am staying at home. I think the club is the right thing, because we share some talks, "how is the medication you take?" I prefer the club than to talk with friends [**Patient 1**]

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Knowledge acquisition

Knowledge acquisition is an important cognitive mechanism related to the health talks that are provided by the club facilitators during each club meeting session. We found that the acquisition of knowledge by the patients improves their self-efficacy – the perception of their ability to perform activities related to the self-management of their disease [40].

> In our talks, we talk about condom use, STIs and things that can interact with your medication. We explain that the amount of the virus will go up (in the case of poor adherence) and then you fail from the line [First line] that you are. Then we will have to take you to the other line [Second line], meaning that we have to take you out of the club and then blood and other things will need to start afresh. [**Counsellor 3**]

> In the club, they are open; they always tell us how to take the tablets, what you are supposed to do. Like now, they were telling us that if you have a partner, you must not

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> sleep without a condom. You must always 'condomise'. They were telling us about TB [Tuberculosis], the side effects of drinking alcohol whilst you are on medication and the side effects of smoking cigarettes. [**Patient 3**]

One of the respondents suggested how this education received by the patients translates to understanding.

> When they receive the health talks, at least they will have a clear understanding what to do and how the club will be benefitting them [**Nurse 3**].

Based on our observation of the club sessions, we noticed that the club facilitators also spent some time to remind the patients during the health talk of the rules and regulations guiding the adherence club. They emphasised the behaviours that could potentially lead to the patient being ousted from the club indicating that the rules were being reinforced. One of the counsellors confirmed this observation.

> Yes, the health talks have a very big impact, because it reminds them [patients] of the dos and don'ts because if we do not give the talks, patients will forget the rules. [**Counsellor 1**]

Trust

One of the counsellors explained the unspoken code of conduct or the psychological contract, which exists among the members of the adherence club and the counsellors. That is, club members and counsellors are not meant to disclose the status of patients outside the adherence club meeting or with a non-club member.

> They know that whatever happens here [in the club], it remains here. We do not go and share things that are discussed here in the community. For example, if one of the club members is a friend or a neighbour of whoever, maybe they go to church together. They know that they are not allowed to go and talk 'that we are in the same club'. So, they know that one of the rules is like confidentiality. Whatever happens here, remains here. [**Counsellor 2**]

Perceived barriers

Perceived barriers to leave the club relate to the circumstances that cause patients to be aware of the advantages offered by the adherence club intervention in light of the challenges they face

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in regular clinic care. For instance, in the excerpt that follows, a lay counsellor explained how perceived barriers related to seeking permission from work to pick up their monthly ART from the health-care facility. Patients in ART care could cherish the two-monthly medication pick-up and the quick services offered at the club (nullifying the need for asking permission).

> When you are in the care of the facility, you only get maybe one month [medication supply]. So, every time you have to ask for a day off, leave, or something for you to get your medication. So [in the club], it is much easier. It saves time and then you do not have to sit in the clinic the *whole day*. [**Counsellor 1**]

The following excerpts outline aspects of the regular ART clinic that patients perceive as barriers to their ART care. Because the adherence club is meant to remove these barriers, it encourages them to remain in ART care under the clubs.

> We also tell them [patients] that they do not need to go fetch their folder, because in this facility, you need to wait in a pre-waiting area, wait for a clerk to come to get your card according to your waiting time. Then you go into the main waiting area and you wait for your folder to be taken out by the clerk. Then, they wait until they get a few folders and then they send you through to our ARV department. Then from here, you have to wait until another clerk puts your ARV stationary into your folder, then wait for a nurse to weigh you, and then wait for a Sister to call you. [**Nurse 1**]

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> And waiting at the aisles is not so nice like here [in the clubs], because then you have to wait for the doctors and you have to wait for everything, your tablets, even to go to the Pharmacy, but here [in the clubs], you can just come and get your medication and weigh and that is it. [**Patient 4**]

A patient also identified the potential of being stigmatised, which is part of the environment of the regular ART clinics as a perceived barrier. This barrier is minimal or absent in the adherence club.

> Therefore, I have to stay stable, because we do not like to stand there in front [in the regular clinic] so that the people are going to judge us. So, I have to take my medication so that the people do not see me there [in the regular clinic]. I must stay here in the club. [**Patient 5**]

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Initial programme theory two

Perceived coercion

Perceived coercion is the awareness of being compelled or pressured to do something. While the club intervention is beneficial to the patients, there are also some managerial benefits, such as decongesting the facility. Thus, the club rules are there to ensure the smooth functioning of the intervention as well as to promote the success of the programme. Nevertheless, some patients might interpret some of the club rules as being coercive.

> One of the rules is that you need to attend your club sessions; you need to be compliant with your dates. If you are unable to come, you send someone, or you can phone, but you have five days' grace period to collect the medication. If you fail to communicate with us or do not collect your tablets within those five days, you are going [to be] returned *back* into the mainstream where you have to go through that *whole* waiting procedure. [**Nurse 1**]

> I know the club [has] got rules and like the one rule. It [club rules] helps a lot because then you must take your medication. It is necessary that you take it [medication]; otherwise, you will go back to where you came [regular ART clinic]. [**Patient 4**]

Our observation revealed that the patients were being reminded of the club rules at every club visit. They are particularly reminded of the circumstances that could lead to being sent back to the main clinic care.

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Fear

Fear relates to the awareness of the dangers of being returned to the mainstream care and experiencing the barriers that the adherence club intervention addressed.

> Another thing is our patients' blood are collected for routine screening once a year. They also know that if their viral load is not lower than detected [supressed], they are placed back into [the] mainstream. Therefore, that is also a way of them also being encouraged to be compliant, taking their medication. [**Nurse 1**]

> So, you do not want to be sent back, because you know you will return to waiting for two hours for tablets. You have to wait there and you go to the Pharmacy, there will be

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a queue. You know that if I miss the appointment with the club, then they might send me back. [**Patient 3**]

Nudging

Nudging is the notion of being guided towards making decisions that are considered beneficial (to the patient) usually by the health-care providers by presenting options in a specific way. By providing restricted options to the patients receiving care in the adherence club programme, they are nudged to acting in a particular way as guided by the resources and principles that are on offer at the adherence club.

> We always tell them that 'Guys, we do not want to lose you. We want you to belong to this club forever'. So, if you think you are at home you are going to do whatever, you cheat, you will not 'condomise' [make use of condoms] as we educate, you stay days without medication, the day will come where your blood will be taken, and then the blood will tell us if you were really cheating at home. So, they are aware that even if they are not with us, they still need to continue to take their medication at home, because the *blood* will … tell us if they still belong to the club. So, they want to belong, because they know if they do not take their medication, they do not use a condom, then something will change, and they will have to go back to the facility care. [**Counsellor 3**]

> They make you come to the clinic, and they make you take your medication, because if you are going back to the main clinic, my dear, you will stay there for the whole day in the main clinic. You come at half past six, you stand in a queue there by the reception, then eight o'clock, they start giving your folders and then from there you go to the scale. [**Patient 1**]

CONTEXT

Context relates to important context conditions relevant to the adherence club, which includes buy-in from health workers**,** clinic organisation, the number of clubs run by the facility, staffing dynamics, availability of resources (including human resources), pre-club preparations (including teamwork) done by the club team and individual patients attributes.

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Buy-in from health workers

Although buy-in could be identified as an important mechanism for the implementation of the adherence club intervention, it also constitutes an important context element for its day-to-day functioning. For instance, a counsellor explained that rather than start the adherence club sessions at 8 am, as it is originally scheduled, they start the club activities at 7 am to allow the patients to finish at the club and still make it to work on time. This is what the counsellor had to say:

> I do not want to lie; they [patients] do not ask a sick note anymore because, at seven o'clock, we sacrifice as the Counsellors. But, because of the clubs, we must be here at half past six, so we start at seven o'clock. They know that after they get their medication, half past seven, we are done! They are going to work. [**Counsellor 2**]

> We have to have buy-in from everybody, so I also had to speak to the pharmacists, telling them, "This is the plan, this is the reason" and tell them how they are going to *benefit* by fewer patients waiting in their waiting area. [**Nurse 1**]

Integrated care

Integrated care means providing services relating to not only ART but also services of other non-communicable chronic diseases, like hypertension, diabetes and epilepsy. Patients having any other illness and who are on ART in the adherence club are also provided with services to manage the concomitant non-communicable chronic diseases. This context encourages the successful implementation of the adherence club regarding patients with comorbidities.

> What we have also done is now all the patients, because we provide a holistic, integrated service in this department, we have made a chronic club [patients with concomitant HIV and non-infectious chronic diseases]. We have three chronic clubs. If you have hypertension or diabetes, then we will put you together in one club. So, we know when *those* patients come, we measure their blood pressures, we will test their sugar levels, and we will send them for their yearly eye testing. We also do their feet exam, so that they are also not disadvantaged. [**Nurse 1**]

Availability of conducive physical space

The availability of appropriate physical space where the adherence club sessions could be conducted is an important context condition. In fact, the lack of a physical structure was one of

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the main reasons why the adherence club programme at Facility Y only commenced in 2014 when a makeshift building was constructed. Some of the providers suggested that having a separate unit to run the adherence club programme is ideal. This was confirmed by the comments of the adherence club nurse.

> We have a separate space at the back for club activities. So, they have got their own privacy and their own space. They have that freedom and it is not with everybody else. [**Nurse 1**]

Availability of a programme champion

A champion is someone who is dedicated to the success of a programme and who closely monitors the implementation and execution of every aspect of the programme. Having a programme champion is identified, therefore, as an important context element for the successful execution of the adherence club intervention. It triggers the required mechanisms to ensure retention in care and adherence to medication. A participant said the following in this regard:

> When I came here, I received training and I wanted to find out more about this club. I received training from an NGO and they told us … what the goal of the club is, what is the aim, and then once I got the buy-in and the training, then I realised the *benefits* of it. I then encouraged my staff and told them "The more patients we put in the club, the fewer patients we have to see." Because the staff is always complaining, 'There are many patients.' They are overworked, they are exhausted, there are staff shortages, their morale is low and it is just too much. So, I said okay, I had several meetings with them. I said, "Guys, we need to pull together, because we are not going to get more staff. The only way to decongest the people waiting in our clinic is to put them in a club, because if they are in the club, we will have fewer people waiting here, fewer people that you have to see." So then, everybody was on board, everybody is excited and then we got a timetable. A planner where we placed dates and encouraged putting patients in and you know, really everybody pulled together. Everybody got a responsibility. We shared responsibilities because, remember, we had 30 patients per clubs at the time. So, everybody was given a responsibility that we need to fill out the clubs, write out the scripts, fewer patients. [**Nurse 1**]

Teamwork

Working as a team is identified as a favourable condition for the successful implementation and execution of the adherence club programme. This is related to the fact that each member of the

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team has a role to play and if any of the team members fail to deliver, then the execution of the intention is affected, which also affects how the users take up the intervention.

> Teamwork is *very important* because if the Sister [Nurse] does not prescribe the medication, you cannot get the medication from Pharmacy, there are going to be delays or *no* medication given. Then the patients have to go sit in that mainstream, then what is the use of the club because then they have to go back to the waiting area. [**Nurse 1**]

OUTCOME

The outcomes that are identified here are based on the findings of quantitative analysis (retrospective cohort analysis – primary outcomes) and emergent outcomes from the interview process that are challenging or complex to measure (these are not part of the primary outcomes of retention in care and adherence to medication). These outcomes include decongesting the health-care facility and reducing the workload of the health-care workers.

Decongestion of the facility

One of the emerging outcomes of the adherence club intervention is that it contributes to decongestion of the health-care facility. One of the participants explained how this is being achieved.

> It [the club] is decongesting because remember, there are 35 patients per club. There are some days that we have two clubs. So, remember, if it is one day, every day 35 patients from the normal waiting area are being removed. So, they receive their medication and their treatment thus decongesting the waiting area… On days that there are two clubs per day, that is 70 patients out of your waiting area. [**Nurse 1**]

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Data synthesis

The data synthesis involved merging the data from the descriptive quantitative arm to the findings obtained from the thematic analysis of the qualitative transcripts in an attempt to refute, confirm or modify the initial programme theories. We formulated the ICAMO matrix following the different modalities of the adherence club intervention. This matrix is outlined in **Table 10.4**.

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Table 10.4: Intervention-context-actor-mechanism-outcome matrix formulated from study findings

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Standard operating protocol - Being reminded of the rules and regulations of the club - HIV policy	- Patient	- Perceived barriers - Perceived coercion - Perceived fear - Reinforcement - nudged	- Nudged to adhere to club appointments
Group dynamics	- Availability of space for meeting - Relationship with other club members	- Patient - Group	- Perceived social support - Bonding and formation of group identity	- Better adherence resulting from developed self-efficacy
Health talks/education	- Good availability of personnel - Effective teamwork	- Patient	- Knowledge acquisition - Reinforcement of club rules and regulations	- Improved self-efficacy
Quick medication access	- Availability of medication - Eligibility criteria - Organisation of pick-up process and club sessions - Buy-in from care providers	- Patient	- Perceived benefit - Motivation - Satisfaction	- Adherence to medication related to medication availability
Prompt continuity of care	- Availability of clinicians - Staffing dynamics - Organisation of club activities - Buy-in from care providers	- Clinicians - Patient	- Trust - Satisfaction	- Retained in care through problem resolution
Club facilitator-Patient relationship	- Staffing dynamics - Teamwork/collaboration - Buy-in from care providers	- Facilitator - Patient	- Trust - Perceived support	- Adherence to medication - Motivation - Retention in care
Overall intervention	- Availability of programme champion - Buy-in from care providers - Preparation and organisation	- Patients - Club teams	- Motivation - Self-efficacy - Satisfaction	- Improved retention in care and adherence to medication

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In constructing the ICAMO matrix, we applied the configurational mapping approach, in which outcomes are considered to follow from the alignment of various interactive components. The retroduction logic informed this process. Retroduction is a form of inference that seeks to identify and verify mechanisms that are theorised to have generated the phenomena under study [41]. First, we paid attention to the outcomes of interest and then identified the mechanism(s) most associated with each outcome. This transfactual thinking approach [42] helped us to identify mechanisms that were associated with the different modalities of the intervention and how these mechanisms relate to the different actors (patients, health professionals). Then, we examined the context in which the mechanisms are contigent to perpetuate the observed outcome as informed by the data. Third, we confirmed each ICAMO chain by applying counterfactual thinking (creating possible alternatives) to trace the various pathways (demi-regularities) [42, 43].

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While having ICAMO links such as in **Table 10.4** is useful, we constructed a configurational map to obtain a bigger picture. According to Byng, Norman and Redfern [44], the bigger picture adds value to understanding the programme theory. The result of this exercise is a framework that summarises how adherence clubs contribute to adherence and retention in care (**Figure 10.5)**.

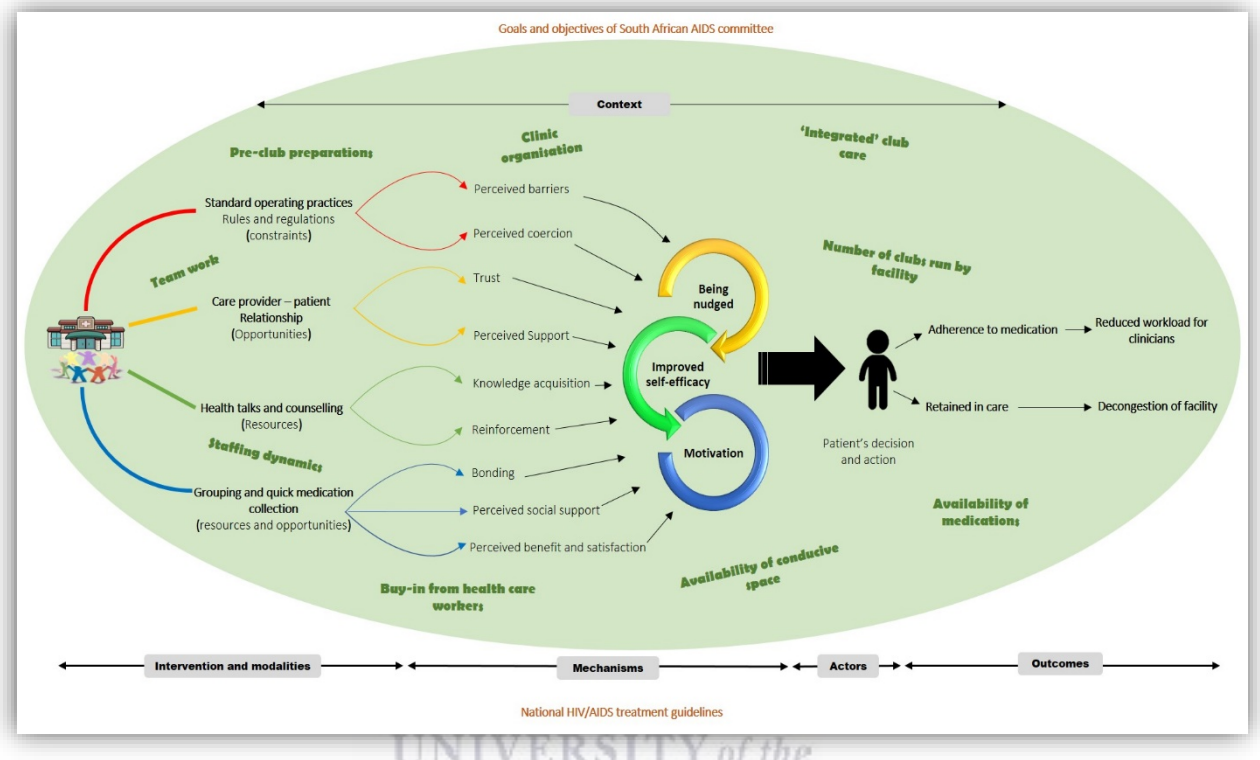

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Figure 10.5: Modified programme theory

Our analysis reveals that the two theories identified as initial programme theories complement each other to provide a full picture of how and why the adherence club intervention works (**Figure 10.5**). This is backed up by the respondents in the realist interviews. Most suggested that a combination of both theories could explain how the club intervention works. They used phrases like: 'It is a combination of *both* your theories…' [Nurse 1] or 'I think both [theories].' [Counsellor 2].

In a next step, we formulate a modified programme theory of the adherence club intervention based on the analysis of the Facility Y data set.

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Box 10.2: A modified programme theory of the adherence club intervention

> Grouping clinically stable patients on antiretroviral therapy **[Actors]** with available resources and buy-in from health-care workers in a convenient space **[Context]** to receive quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required while guided by rules and regulations [**Intervention**], works because their self-efficacy improves and they become motivated and nudged **[Mechanisms]** to remain in care and adhere to medication [**Outcome**].

Discussion

In this study, the aim was to confirm, refute or modify the initial programme theory of the adherence club intervention, which we drafted based on literature reviews and exploratory research. We examined the implementation of the adherence club intervention at Facility Y, chosen as a deviant case – poor performing based on 2014 routine data. Our hypothesis suggested two possible explanations to how and why the adherence club intervention improves retention in care and sustains adherence to medication: by motivating and empowering the patients towards adopting the desired behaviours or by nudging them into doing so.

These study findings showed that the two theories complement each other to explain how and why the intervention works and in what context. While some patients would become motivated and empowered (through improved self-efficacy) to remain in care and adhere to their medication, other would respond more to being told what to do and given directions on how to do it (being nudged). Nevertheless, our study did not explore to what extent these two theories could be combined to explain how and why the adherence club works.

Our findings concerning adherence and retention in care are similar to the results of the study conducted by Luque-Fenandez and colleagues [12], who found good adherence rates of patients who participated in a facility-based adherence club intervention in Khayelitsha, Cape Town. According to these authors, at 12 months, retention on ART was 94%. Another evaluation of the adherence club model revealed that after 12 months in the community adherence club, only 6% of patients were lost to follow-up [13]. Similarly, the good retention in care rates that we found are confirmed by previous studies. This was especially when the programme had a programme champion, and there was buy-in from the health-care workers (2014 onwards).

Although the retention in care and the adherence rates of the patients at the facility seemed to have improved from 2014, as reflected in our current programme theory, it is worth exploring

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why the intervention failed to take off as intended. This could add value to understanding in what context or circumstances the intervention works or not. This follows the notion that programmes are open systems. By open system, realists argue that programmes cannot be fully isolated or kept constant and that they are affected by various conditions such as physical and technological shifts, personnel move and learning, organisational imperative and so on [18]. Such externalities always impact on the delivery of a programme, and this entails that they are never quite implemented in the same way. In some instances, these externalities are introduced in the 'system' to engender a positive impact and are usually changes made to address the challenges that the intervention previously encountered.

The failure of the intervention to kick-off was attributed to poor buy-in from the health-care providers. Buy-in, although considered an important mechanism at the level of implementing the intervention in the facility, nevertheless, buy-in constitutes an important contextual regarding the day-to-day running as it affects the way the intervention is organised and delivered to the patients. Lack of buy-in was identified by the participants of the study as part of the reasons why the intervention was poorly implemented and executed at this facility. For instance, sometimes, the patients would arrive at the club meetings and their medication would not be available. This also related to lack of a pharmacist to dispense and organise the distribution of antiretroviral medication.

Another important context element that was identified as a hindrance to the effective implementation and execution of the adherence club intervention at the Facility Y was the lack of a conducive physical space where the meetings could be conducted. Our interviews revealed that when the intervention was rolled out at the facility, there was no physical space where the patients could meet to conduct the meetings. It took an intervention from the management to provide a makeshift building at the back of the facility for the intervention to be officially implemented. This highlights the important role that context plays in activating the mechanisms that are provided by an intervention. In the absence of a conducive space, the buy-in of the health-care providers became reduced, and they were not motivated to execute the intervention. This, in turn, affected the way the intervention was executed and the way it was received by the patients, thus, impacting of the retention in care and adherence outcomes.

The four important context conditions, lack of buy-in, lack of staff, the absence of a programme champion, and lack of physical space for the club meetings caused the mechanisms that are provided by the adherence club intervention and naturally occurring in the environment not to

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be triggered. Consequently, this led to sustained poor retention in care and suboptimal adherence to medication.

When a nurse was identified and trained to champion the intervention, she exposed the other health-care providers to the benefits of the intervention and headed the implementation. This engendered buy-in from the care workers. Following the buy-in, the pharmacists also reorganised their schedules to prepare medication packages for the club members. Once these elements were put in place, the context conditions of the adherence club changed, and the present conditions were favourable to incite the mechanisms provided by the adherence club intervention to cause the expected outcomes. These improved conditions and performance of the adherence club intervention are reflected in the high retention in care and adherence to medication rates as demonstrated in the retrospective cohort analyses.

Limitations, rigour and trustworthiness

Regarding the retention in care and adherence behaviours of patients in the adherence club, it would have been ideal to obtain the overall rates of the facility. This posed a challenge because the facility actively creates new clubs monthly. This would potentially affect the overall retention in care and adherence rates of patients in the adherence club programme. To this end, we decided to select purposively two adherence clubs that had reached their maximum capacity and to study the rate at which patients drop out of the club for various reasons – default, transferred out of the clinic, lost to follow-up or died.

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To improve the rigour of the study, we adopted the mixed-method approach. The use of a multi-method approach to data collection was not only informed by its ability to improve the *retroductive* inferencing but also to confirm and complement the information required to test the initial programme theory. In addition, we used a variety of participants to promote the triangulation of the information obtained from the participants as it makes it easy for the researchers to verify facts.

Frequent debriefing sessions were held among the authors. These sessions took place in all the phases of this study including the data collection, analysis and synthesis phases. In conducting and reporting the findings of this study, we followed the RAMESES II reporting standards for realist evaluation developed by Wong and colleagues [45].

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Conclusion

A theory-based approach to evaluating the adherence club intervention using the realist evaluation approach requires exploring and making explicit the programme theory that guides the intervention. Through the application of the realist evaluation approach, we sought to identify the context, mechanisms and outcomes related to adherence club intervention in relation to ART-experienced patients described as stable at Facility Y. Based on an initial programme theory that was elicited, we sought to test the hypothesis in a deviant case. Following the data that we obtained, we modified the initial programme theory, which combines the supposedly rival theories to formulate a complementary theory. Further testing of the initial programme theory will be conducted in a crucial case – identified as where the adherence intervention was originally designed and piloted. This would be a step towards obtaining a refined theory of the adherence club intervention.

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CHAPTER ELEVEN

Case Study 3: Testing the initial programme theory at Facility Z

"Patients are not following the [adherence] club rules anymore": A realist case study of the antiretroviral treatment adherence club, South Africa. Qualitative Health Research (Under review)

Abstract

Background: There is growing evidence that differentiated care models employed in the management of HIV patients on antiretroviral therapy (ART) have the potential to improve their adherence to medication and encourage them to remain in care. Although the effectiveness of the adherence club intervention – a type of the differential care model – in enhancing and sustaining ART adherence and retention in care has been established, it is poorly understood *how* this outcome is achieved. In this study, we report on the process of testing the initial programme theory of how, why for whom and under what health system context the adherence club intervention could work (or not) in real life implementation.

Methods: We applied an explanatory theory-building case study approach to testing the initial programme theory of the adherence club intervention. We collected data using a retrospective cohort quantitative design to describe adherence and retention in care behaviours of patients on ART using Kaplan-Meier methods. In conjunction, we employed an explanatory qualitative study design using nonparticipant observations and realist interviews to gain insights into the important mechanisms activated by the adherence club intervention and the relevant context conditions that trigger the different mechanisms to cause the outcomes. We applied the retroduction logic to configure the intervention-context-actor-mechanism-outcome map to formulate generative theories.

Results: If receiving ART in context of limited health talks and counselling, inadequate knowledge of club rules and regulations along with limited resources and integrated care with patients managed for non-infectious diseases of lifestyle, clinically stable adult patients grouped for targeted care are more likely not to attend club sessions and adhere to their medication.

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These patients, who receive quick, uninterrupted supply of antiretroviral medication pick-up become negligent, frustrated and demotivated in a poorly coordinated dysfunctional club.

Conclusion: Critical health systems conditions that can mitigate enabling mechanisms Operate ART services under conditions of a poorly coordinated 'integrated care' model. These health systems are provided through the adherence club intervention towards achieving sustained retention in care and adherence to medication. This study identified potential mitigating circumstances under which the adherence club programme could be implemented and could inform the rollout and implementation of the adherence club intervention.

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Background

South Africa has an estimated seven million people living with HIV/AIDS (PLWHA) [1] with an estimated 3.5 million (50%) initiated on antiretroviral therapy (ART) as at the end of 2016 [2]. About 85.5% of HIV-positive South African adults had been diagnosed by mid-2015 but only 56.9% of HIV-diagnosed adults were initiated on ART [3]. Retaining most (90%) of those initiated in care and achieving high population-level adherence to ART (90%) is understood to play a strategic role towards ending AIDS by 2030 [4]. Empirical observations have shown that standard clinic ART service delivery models limit capacities to achieve the abovementioned goals. Consequently, differentiated care models such as the adherence club intervention have been implemented in the Western Cape Province, South Africa to enhance efforts towards improving retention in care and adherence to ART.

The adherence club intervention was implemented in the Western Cape Province as a systems improvement intervention to enhance patient retention in care, and their adherence to medication, and decongest congested health facilities [5]. The adherence club intervention is a differentiated care model designed to shift the management of PLWHA with a record of good medication adherence and attendance of clinic appointments (stable patients) for group management – health-care worker managed groups or client-managed groups [6]. These patients are placed in groups of 25–35 patients, who meet bi-monthly at the facility. The adherence club sessions are facilitated by a lay counsellor, who coordinates structured consultations, health talks, group and individual adherence counselling sessions, medication collections ensure a conducive environment for social support [7, 8].

Outcome-based evaluations of the adherence club intervention show that it produces improved rates of retention in care and adherence to medication than the standard clinic ART programme [9–11]. However, there is a limited understanding of how, why and under what health system contexts the adherence club intervention produces the positive effects.

In this study, we aimed to test a hypothesis (the initial programme theory) of the adherence club which we previously formulated with the goal of validating, rejecting or modifying the initial programme theory [8].

Methodological approach

This study is part of a realist evaluation of the adherence club intervention [12]. The realist

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evaluator seeks to understand how, why for who and under what circumstances programmes work by formulating programme theories [13–15] – how programmes achieve their intended outcome(s). The evaluator hypothesises in advance the intervention (or its components), the relevant actors, mechanisms that are likely to operate, the contexts in which they might operate and the outcomes that will be observed if they operate as expected. Realist evaluation essentially involves theory testing and refinement and realist studies, therefore, start with developing an initial programme theory and end with a refined programme theory [16].

The process of eliciting and testing the programme theory of a programme is considered central to the realist evaluation approach. A programme theory consists of a set of statements that describes a particular programme; explains why, how, and under what conditions the programme effects occur; predicts the outcomes of the programme, and specifies the requirements necessary to bring about the desired programme effects [17]. Programme theory testing assesses whether the assumption(s) of how and why the programme is expected to work holds true and under what conditions. If not, why? Therefore, the initial programme theory – theories and ideas that inform the design and implementation of the intervention – guides the assessment of the effectiveness of the intervention and the consistency of the implementation [12].

Pawson and Tilley [14] proposed the context-mechanism-outcome (CMO) heuristic tool to conceptualise the theory building process in realist evaluation. According to van Belle and colleagues [16], "The actors and the interventions are considered to be embedded in a social reality, which influences how the intervention is implemented and how actors respond to it (or not)…" To this end, we used the intervention-context-actor-mechanism-outcome (ICAMO) configuration as a proposed heuristic explanatory tool to construct the theories in the current study [18, 19].

In our previous work, we formulated the initial programme theory of the adherence club intervention. First, we conducted an exploratory qualitative study of programme designers' and managers' assumptions and perspectives of the intervention and a document review of the design, rollout, implementation and outcome of the adherence clubs [20]. We also conducted a systematic review of available studies on group-based ART adherence support models in sub-Saharan Africa [21]. In addition, we carried out a scoping review of social, cognitive and behavioural theories that have been applied to explain adherence to ART [22]. Using the process of configuration mapping, we constructed an ICAMO map representing the initial programme

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theory of the adherence club. Finally, we used the "if…then…because" statements to translate the ICAMO configuration map into testable hypotheses (**Box 11.1**).

Box 11.1: Initial programme theory of the adherence club intervention represented by two tentative theories (hypotheses)

Initial Programme Theory 1

IF adult (18+ years) clinically 'stable' patients with evidence of good clinic attendance are group-managed, receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,

THEN patients are likely to adhere to medication and remain in care,

BECAUSE they develop a group identity, which improves their perceived social, support, satisfaction and trust; and acquire knowledge, which helps them to understand their perceived threat and perceived benefits and improves their self-efficacy. As a result, they become encouraged, empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

Initial Programme Theory 2

IF operational staff receive goals and targets set to continuously enrol patients in the adherence club and strictly monitor their participation through strict standard operating practices (the promise of exclusion in the event of missed appointment and active patient tracing),

THEN patients are likely to adhere to medication and remain in care,

BECAUSE they fear (perceived fear) of losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules. As a result, they become nudged to remain in care and adhere to the treatment, which might decongest the health facility.

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The goal of testing the initial programme theory of the adherence club intervention (an evaluation of the adherence club intervention) was to verify, refute and/or modify the elicited initial programme theory. In this study, we report on the process of testing the initial programme theory of how, why for whom and under what health system context the adherence club intervention could work (or not) in real life implementation.

Research design

Within a realist evaluation, we applied an explanatory theory-building case study approach. We adopted the multiple embedded case study design [23]. Facility Z was considered a unit of analysis, with each of its adherence clubs being sub-units. Koenig [24] confirmed that the case study research design aligns with the realist evaluation approach.

Study setting

Facility Z is a provincial primary health-care facility that provides primary health care to its surrounding communities. Facility Z provides the first level and some second level care from 7

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am to 5 pm from Mondays to Fridays. This facility operates as maternity obstetric unit, mental health services, specialised paediatric services for children up to 5 years old, an outpatient department, pharmacy and dispensary, an antiretroviral clinic, and a chronic diseases of lifestyle (CDL) clinic (including CDL clubs). Furthermore, it is an accredited ART initiation and on-going management site.

The adherence club programme was implemented at Facility Z during the first phase rollout of the programme in 2011. Three offices situated within the main clinic were allocated for the ART programme – for the doctor, nurse and the counsellor(s), respectively. As more patients were recruited into the club programme and new clubs were created, the allocated area could no longer accommodate the programme. In addition, the ART patients complained of possible identification by their neighbours and friends, so they did not feel comfortable.

Because of these challenges, a project was started to build an infectious disease clinic in 2011 to accommodate the ART programme. In 2012, the ART programme was moved to the new building at the back of the main clinic. This building had four rooms for consultations (one doctor and three nurses), two adherence club rooms, and a waiting area and a storeroom and provided an ideal structural environment for operating the adherence club programme.

Following the successes of the adherence club programme and the overall ART programme at Facility Z, the facility was proposed as the pilot site for the integration of chronic care in 2015. This meant that the ART services had to move back to the main clinic to be situated where the other CDL are being managed to form a single Unit. While the ART patients and those with CDL were managed within the same Unit, they were attended to by separate teams of health-care providers with separate treatment management schedules and treatment strategies. The former challenges of lack of space, inconvenience and exposure to inadvertent disclosure when managing ART patients resurfaced, so the management decided to move the 'integrated' services back to the separate building in 2016 where the services currently operate.

Although the two services are organised within the same Unit, they are coordinated separately. On one side, the CDL services operate, and on the other side, the adherence club programme, but the patients share a common waiting area. This means that the building that was occupied by the ART services only is being shared with the CDL Unit. Thus, problems of lack of space and confidentiality are the prevailing conditions.

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Methods

Realist evaluation is compatible with a relatively wide range of research methods. Consequently, it is method neutral (does not specify what methods could be used) but encourages the use of a multi-method evidence base [13]. Many authors have argued for the systematic combination of qualitative and quantitative methods when conducting realist studies [25]. We used qualitative methods to explore implementation features related to the context (non-participatory observations) and the mechanism (in-depth interviews), and quantitative methods to describe and classify the outcomes.

Sampling

For the quantitative phase – retrospective analysis of club registers – we purposively identified the ten clubs that reached maximum capacity (25–35) of the 18 clubs that opened in 2012. Of these ten clubs, we used the fishbowl method of sampling without replacement to obtain two adherence clubs to be included in the analysis. Club A had 26 patients, and Club B had 34 patients, totalling of 60 patients.

Concerning the qualitative phase (interview method), we purposively selected (theoretical sampling) the participants from the health-care providers, patients currently using the adherence club intervention and those who previously were in adherence clubs. Pawson and Tilley [14] suggest that the selection of the potential participants for realist interviews should be based on their contributions toward clarifying the initial programme theory as different respondents might contribute to different components of the initial programme theory [26]. For instance, health-care providers have specific ideas on what is in the intervention that works, the outcomes of the intervention and some awareness of patients for whom the intervention works [14]. Patients, on the other hand, are more likely to illuminate the programme mechanisms [14]. **Table 11.1** shows the number and cadre of the adherence club interventions that were sampled to participate in the study.

Table 11.1: Interview participants

Stakeholder	Number of participants
Doctors	1
Adherence club nurse	2
Adherence club counsellors/club facilitator	2
Patients in clubs	3
Former club patients	2
Total	**10**

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Data collection strategy and processes

The data strategy adopted for the study is outlined in **Figure 11.1**. The data were collected from November 2016 to April 2017.

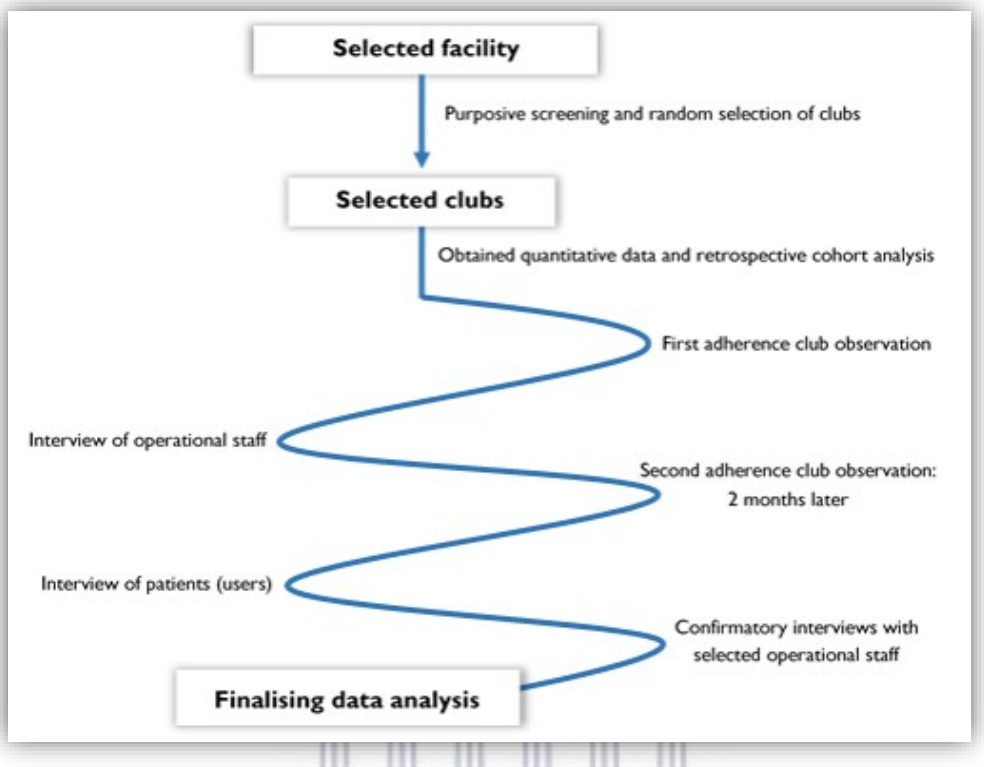

Figure 11.1: Data collection approach adopted

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We started by collecting the quantitative data from the adherence club registers to report on the relevant outcomes and the outcome trends of the adherence club intervention. In **Table 11.2**, the various modalities of retention in care as reported in the club register are described.

Table 11.2: Various outcomes of patients, recorded in the club register

Recorded Outcome	Outcome Event
DNA	**Did not attend** club session or send a buddy within five days after the club sessions
BTC	**Back to Clinic**- Exiting the club for medical reasons and reinstated in routine standard of care
TFOC	**Transferred out to different club** – Patient is transferred out to another club in the same facility
TFO	**Transfer out** – Patient is leaving the facility completely and will attend a clinic elsewhere
RIP	**Rest in Peace** – Patient has died

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In addition, viral load data of the patients attending the adherence club are recorded in the adherence club register. The notation, LDL (lower than detectable) is used to indicate viral repression. Therefore, we used the 'time to first viral rebound (<400 copies/mL)' as an indication of poor adherence to medication.

For the qualitative phase, we applied three data collection methods: nonparticipant observations of adherence club sessions and activities, semi-structured interviews with the clinicians, the facility counsellors, and in-depth interviews with patients using the adherence club interventions. In some instances, we conducted dyadic interviews [27] – where we allowed two participants of the same designation (i.e. counsellors) to interact in response interview questions.

We scheduled the structured observations accordingly to the bi-monthly adherence club scheduled meetings. An observation guide (**Appendix 1**) detailing the interactions, processes, or behaviours to be observed before, during and after the adherence club session was used. We conducted two structured observations per club as illustrated in **Figure 11.1**.

In the interviews, the initial programme theories were presented to the participants, and they were requested to respond to these – confirming, falsifying and above all, refining the initial programme theories [28]. In applying this method, we used a semi-structured interview format guided by an interview guide (**Appendix 2**). As required in realist interviewing, we tailored the interview questions to reflect the knowledge held by the various participants. For the operational staff, our focus was on the implementation and outcomes of the adherence club intervention. The focus of the patient interview was to guide the patients to recount their experiences and reasoning related to their context.

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The quantitative data were captured and prepared for analysis using the Statistical Package for Social Sciences (IBM SPSS) version 24 [29]. The structured observations were documented in the form of jottings and photos, which were later developed into field notes. The audio-recorded interviews were transcribed verbatim by a professional transcriber and prepared for analysis. Atlas.ti version 7 was used to manage the data [30].

Ethical considerations

This study is part of a larger project, "A realist evaluation of the antiretroviral treatment adherence club programme in selected primary health-care facilities in the metropolitan area of Western Cape Province, South Africa." Ethics clearance was received from the University of

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the Western Cape Research Ethics Committee (UWC REC) (Registration No: 15/6/28) [5]. We also obtained ethical clearance from the Provincial Department of Health of the Western Cape Province. In addition, we obtained the permission of the facility head and management prior to data collection processes.

At the level of the study participants, we first provided the interviewed participants with an information sheet of the project. This was followed by a verbal explanation of the role of the participant and the significance of their participation. The participants were required to sign an informed consent form. We promised and ensured confidentiality and anonymity by identifying the participants using pseudo names and by password-protecting all files related to the study.

Data analysis

The quantitative data were analysed using Kaplan-Meier survival analysis [31] to estimate the probability of being retained in care at 12, 24 and 36 months intervals. Participants were considered not retained in the club care if lost to follow-up, sent back to clinic care or died. Time to first viral rebound (<400 copies/mL) was used to assess their adherence behaviour.

Thematic content analysis [32] of the qualitative data was conducted using the ICAMO framework (**Table 11.3**). This process involved identifying what data elements could be categorised as **I**ntervention modality, **C**ontext elements, **A**ctor attributes, and **M**echanisms and **O**utcome patterns through a deductive process guided by the two initial programme theories. The analysis was inductive in the respects that within each category, the actual data was used to derive the subthemes.

Table 11.2: Thematic coding frame

Category	Definition	Coding Rules
Intervention	An intervention is a combination of programme elements or strategies designed to produce behaviour changes or improve health status among individuals or a group	Modalities or programme activities of the adherence club to improve retention in care or improve patients' adherence to antiretroviral therapy
Context	Context refers to salient conditions that are likely to enable or constrain the activation of programme mechanisms.	Components of both the physical and the social environment that favour or disfavour the expected outcomes
Actors	These are the individuals, groups, and institutions who play a role in the implementation and outcomes of an intervention	This was coded as the actions or actual practices of an individual, group or institution.
Mechanisms	This refers to any underlying determinants or social behaviours generated in certain contexts	Any explanation or justification why a service or a resource was used by an actor to achieve an expected outcome, or considered as a constraint

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Outcomes	Immediate outcome	Describes the immediate effect of the adherence club programme activities	Immediate outcome typically refers to changes in knowledge, skills or awareness, as these types of changes typically precede changes in behaviours or practices.
	Intermediate outcome	Intermediate outcomes refer to behavioural changes that follow the immediate knowledge and awareness changes.	Codes here define a move from direct outcomes to intermediate outcomes, identified through the indirect impact of the activity and accountability of the programme.
	Long-term outcome	Refer to change in the medium- and long-term, such as a patient's health status, and impact on community and health system	The codes here represent the further indirect impact of the activity demonstrating the lesser accountability of the programme.

Results

Quantitative findings

The two main outcomes of interest of the adherence club intervention regarding patient care are retention in care and adherence to medication. Although the adherence club intervention is suggested to produce/give rise to health systems benefits such as reducing the workload of the health-care workers and decongesting the local health-care facilities [20]; these outcomes, at this time, could not be explored in the current study.

Retention in care

An overall retention in care rate of 81.7% was achieved by the two selected adherence clubs within 36 months. The retention in care rates of the various Clubs A and B are represented in **Table 11.4**. Although Clubs A and B have different numbers of patients in each club, the retention in care rates of both clubs are comparable (Club A: 80.8% vs. Club B: 82.7%).

Table 11.4: Retention in care distributions in two adherence clubs at Facility Z

Adherence Club	Total Number	Number of patients who dropped out of club	Patients retained	
			Number	Percent
Club A	26	5	21	80.8%
Club B	34	6	28	77.1%
Combined	60	11	49	83.6%

Figure 11.2A shows the rate at which patients dropped out of the sampled adherence clubs. The survival curve suggests that in the first two years in the adherence club, the patients were retained in care in Club A 87.8% (CI 67.9% - 96.6%) and in Club B 97% (CI 83% - 98.8%). However, within the third year, there was a steep drop in the number of patients retained in the clubs. Based on the hazard function graph (**Figure 11.2B**), by the end of the third year, the probability of a patient dropping out of club care is 23% for Club A and 20% for Club B. The

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log-rank test with a p-value of 0.764 (significance at $p < 0.05$) suggests a high level of consistency in the capacity of these two clubs to retain patients in care, as illustrated in the Hazards graph (**Figure 11.2B**). An extrapolation of the graph suggests there is an increased possibility that more patients will be dropping out of the adherence club care at the current state of the intervention implementation.

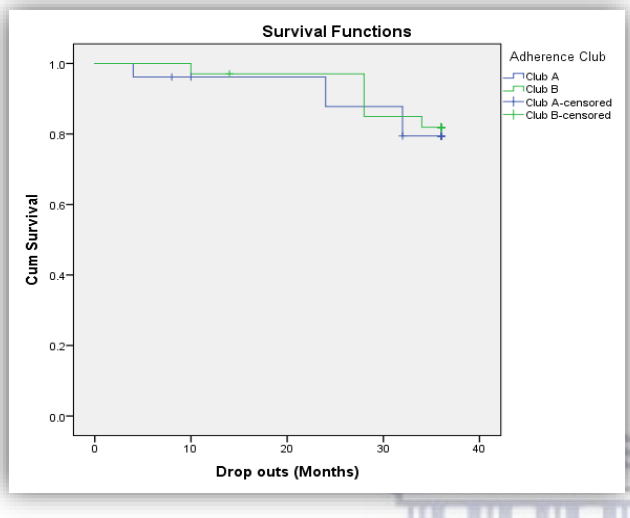

Figure 11.2A

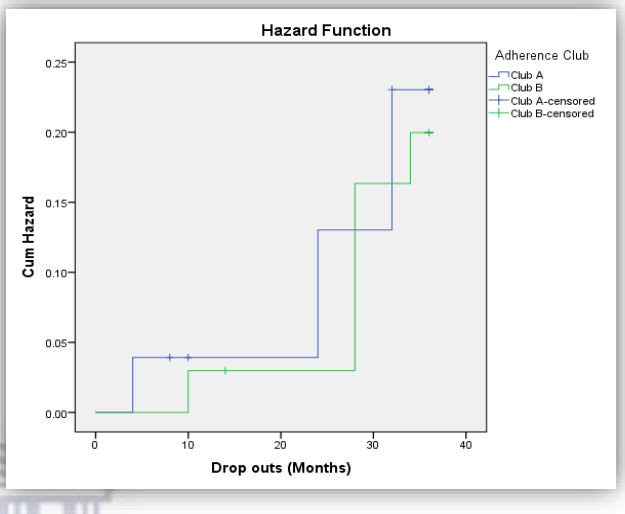

Figure 11.2B

Figure 11.2A&B: Survival distribution and hazard function of patient retention in care in two adherence clubs at Facility Z

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Adherence to medication

Adherence to medication was measured using the viral load of the patients as a proxy. The adherence to medication was measured as time to viral rebound (viral load > 400 copies/mL). Based on the case studies selected a total adherence rate of 96.7% was recorded at the end of 36 months in care. A breakdown of the performance of each of these clubs is shown in **Table 11.5**.

Table 11.5: Adherence behaviour distributions in two adherence clubs at Facility Z

Adherence Club	Total Number	Number of patients' viral rebound (VL> 40 copies/mL)	Patients with suppressed VL	
			Number	Percent
Club A	26	0	26	100.0%
Club B	34	2	32	94.1%
Combined	60	2	58	96.7%

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The values in **Table 11.5** suggest very good adherence rates registered by both clubs. Nevertheless, this should be understood in the context that most of the patients who did not show the propensity to maintain good medication adherence have dropped out of care. The Kaplan-Meier curve (**Figure 11.3**) shows how many of the patients had been censored before the end of the study period. When a person dropped out of care for one reason or another, these patients were considered as censored, so we do not know if the event occurred or not (viral rebound).

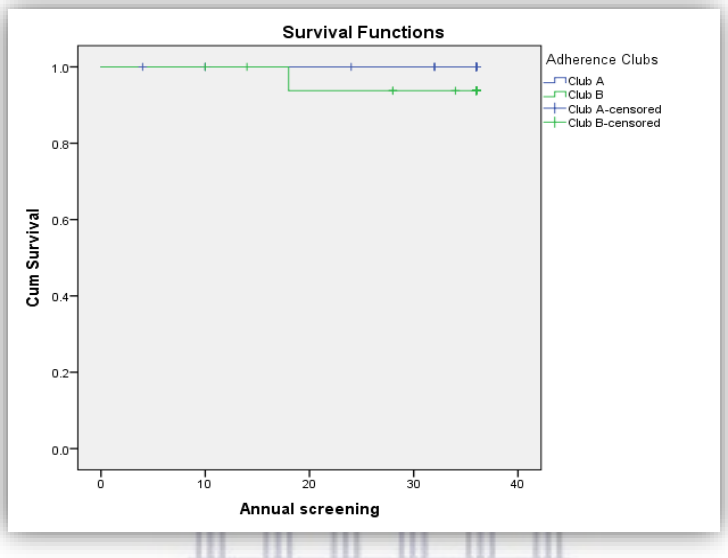

Figure 11.3: Survival distribution of patient medication adherence behaviour in two adherence clubs in Facility Z

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Quantitative Findings

The qualitative data are reported following the initial programme theories (hypotheses).

MECHANISM

Mechanisms related to initial programme one

This initial theory relates to how clinically stable patients receiving care in the adherence club programme perceive, interpret and act on the resources and opportunities offered by the club intervention. The mechanisms include perceived stigma, frustration (related to disrupted group dynamics), perceived (lack of) social support from group members, perceived (lack of) support from care providers, encouragement/discouragement, lack of learning/knowledge acquisition, perceived benefit and confusion.

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Perceived stigma

Because of sharing the same treatment space with other CDL patients, the study participants suggested that the attendance of club activities presented an opportunity for the ART patients of being identified by someone from their community, who is not HIV-positive. This could lead to them being stigmatised in the community.

> Sometimes you come for your club date for pick-up, there are social issues with HIV, which we cannot even run away from like stigma. [**Counsellor 2**]

> The [club] patients also were complaining about them [patients with other chronic conditions] coming inside the place where they [club patients] are being stigmatised. They say they are being stigmatised because outside the building, there were other people, their neighbours, their families and whoever, so it was difficult for them to talk even when the room door was closed. [**Nurse 2**]

Frustration (related to disrupted group dynamics)

The adherence club teams adopted a model of splitting the adherence club groups into those who were employed and unemployed merging them with similar groups in another adherence club to form a new 'club.' Thereby space issues could be resolved, and potential inadvertent status disclosure to other non-HIV positive patients averted. Those who were employed were given the morning timeslots and those unemployed the eleven o'clock timeslot. Breaking up the groups led to frustration, as one of the participants commented:

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> The patients are coming a long way with each other. When they come, they share their experiences with each other. Sometimes the patients start the discussions because they are used to one another. So now when we split them, then that one feels, 'No! I do not want to be separated from my club. I want my club.' [**Nurse 1**]

Perceived (lack of) social support from group members

Patient interaction is identified as a pivotal element of the adherence club intervention. With lack of conducive space to conduct the club activities as dictated by the current conditions of 'integration', patients do not get the time or space to interact with each other as they could when they had a designated conducive space in 2014. This has reduced the social support that patients used to get from each other. Some participants commented on this:

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> This one can be shy, this one would say I have a pimple there, then its starts from there, you saying things, which are real and then the other one would say! I also have this thing; I did not know it is caused by HIV. **[Nurse 1]**

A patient who had experienced the adherence club programme when patients could gather as a group and at its current state where there is no conducive meeting area, identified the important role of group sharing and social support and the consequences of the absence of 'gathering as a club'.

> Especially for me, what was very important is when you have a problem; you will be thinking that problem is just affecting you. However, once you come to the club, you can hear many of the people also have the same problem. You will be sharing that problem. At the end of the day, you have a good point on how to solve the problem. That is why I liked the club… Now, we do not have time to share problems together as a club. It already affects us, which if we can be together like before, we can share our problems… Sometimes you can see someone who has a problem you once has, but because we do not have time to chat together, it is difficult just to approach them. [**Patient 2**]

Perceived (lack of) support from care providers

In this theme, we identify from the data instances pointing to supportive health-care providers and instances where the health-care providers could not provide the support that patients needed because of the circumstances dictating the execution of the adherence club intervention. Regarding perceived support, the health-care providers cited an instance where they had to go out of their way to preserve the medication of patients who communicate with them to ensure that the medication is not sent back to the clinic after the five-day grace period.

> They arrange with us if someone will not be able to make it. Today, I have four patients who have told me on WhatsApp or called that they will not make it today. They are going to come by that day so I have to take the medication [for safe keep] before it goes to the pharmacy. [**Counsellor 2**]

Respondents also recounted instances where social support to patients was not possible due to the prevailing circumstances.

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> We do not have time to share our problems. If you try to ask a nurse, 'I have got this problem, this and this' they will say, 'No, you can see all those people, they need my help so now. I do not have time to help you' and which is true. [**Patient 2**]

> The patients have their own things that they want to ask, maybe to the nurse…but when you come here, everybody [non-HIV-positive patients] is standing here you cannot even ask what you wanted. [**Nurse 2**]

Encouragement (discouragement)

When the adherence club used to work smoothly, and the patients had time to consult with the club facilitators and other health-care providers, a patient recounted that they used to get encouragement from the health-care providers.

> Even the sisters they will encourage you about food, this and that, all those things they talk when you came to club. [**Patient 3**]

With some important aspects of the adherence club intervention not being effectuated because of the implementation conditions, another patient stated that she is now discouraged from attending the club sessions (knowing that she can always come and pick up her medication when she wants).

> If I want to squeeze and come on my date, I can do it. But because there is no more club [sitting as a group], that the means I have no reason to attend. [**Patient 5**]

Perceived benefit

The benefit of the adherence club intervention regarding the patient relates to the quick collection/pick-up of their medication packages. In fact, this is the only aspect of the adherence club intervention that is functional and accommodates the absence of a clubroom and the presence of patients with CDL. Two patients recounted how this aspect of the adherence club is beneficial to them.

> Yes, I like it [the adherence club] because you can come and get your medication in time, then you can eventually go to work. When you are not in the club, you have to stay for the whole in the queue, maybe you will go home past four o'clock. [**Patient 2**]

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> It is easier for me. Like, I am working, my boss does not give us enough time to come and when we come, we must sit all day. Then he will complain why we sit so long, so it is easier when I just come [to] pick up [my medication] and go. [**Patient 5**]

Confusion

One of the club patients recounted how confusing they got when they were trying to locate where the adherence club session was taking place because of the displacements that they experienced related to the service integration.

> You go to your normal place, room 14 there is no one there, and the door is locked. You wait and look out for the other people. Then, there is this system of integration where people will collect their folders and take their folders to the big weighing room for the normal patient. There, they are being tossed up and down, and not even asked. If our blood pressures could be tested in the morning, you will see that it will be high. There is no direction, there is no movement, and people are standing there not knowing what to do. [**Patient 3**]

Initial programme theory two

The second initial programme theory of the adherence club intervention relates to the role of the rules and regulations of the adherence clubs in driving the behaviours of the patients using the club intervention to enhance and sustain retention of patients in care and their adherence to medication. Themes identified from the data are poor understanding/knowledge of the club rules, perception (or absence) of being punished and negligence (laxity).

Poor understanding/knowledge of club rules

Following the adherence to club rules and regulations – attending every club session and maintaining good medication adherence – is an important step that guarantees a patient stays in the adherence club to benefit from its rewards. Some of the health-care providers indicated that not having a conducive environment to deliver the club activities deprive them of the chance to make newly recruited club patients understand the club rules and the consequences of not following the club rules and regulations.

> Like a new club is starting today. We need to do everything with that patient on that first day, telling the patient about adherence, informing them of the processes, the club rules, and all those stuff. You need to tell the patients those things. Then, where is space?

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> What we do [is that] we just register the patient, and it is not nice to work like that. [**Counsellor 1**]

Another counsellor suggested that because the patients do not understand or know the club rules, it is difficult for them to follow the club rules.

> Yes, patients are not following the club rules anymore… because now, that patient will come as a new patient, the patient just knows that she must get a packet [medication] here. She does not know that she has a five-day grace period, she does not know all those stuff, and so [if she does not follow the rules] we send her back to the clinic. Now she is back from clinic care; changing clubs. [**Counsellor 2**]

Perceived absence of feeling of being punished

The second initial programme theory of the adherence club suggests that when patients perceive they are being punished by removing them from the adherence club intervention to clinic care – characterised by long waiting times – they tend to adhere to their medication and attend club appointments. The following quotes from the participants suggest that the leniency showed by the health-care providers to put patients out of the club when they fail to adhere to the club rules and regulations takes away the fear factor associated with returning to the main clinic care scheme. Thus, reducing the effectiveness of the adherence club intervention.

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> Are you taking your medication or not? To assess the patient for adherence, you need to ask this question to the patients. Then you can see deep down, this one [patient] is not taking the tablets. This one was cheating. This one was changing times and all those things, and then if the viral load keeps on going up, although the patient is on the second line, then you do a pill count. You take the treatment and give the patient weekly supplies. The patient must come back to you after the week's supply. The patient will take the medication. When you repeat the viral load, it will be low because it is tiring to come to the clinic [frequently], and the patient does not have anywhere to hide… [**Counsellor 2**]

> After one month, they come the following month. We send them now to the floor, go get your folder, from the folder, you go via preparation room, from the preparation, you go to the doctor or to the sister [nurse]…whoever sees you there, then no punishment for that patient. Is only that one-day punishment for visiting wrongly, the patient will come back and will be given another two months' supply of medication and same club visit date. That patient is still now in the club, so you do not know when you book the patient out or when you do not. That is why we say they [clinicians] do not follow a proper structure of the club

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> because it was precisely said, 'After five days, if the patient does not come, book the patient out.' So now, the patient takes one month, two months and comes back, and on their return, they remain [are kept] in the club. [**Counsellor 1**]

Negligence (laxity)

Negligence follows from the lack of knowledge of the club rules and the lack of enforcement of the rules on the part of the health-care provider. These conditions instil laxity in the patients, as they do not perceive any threat of being returned from the adherence club intervention. This is what a participant had to say:

> You can see even me; my date was on Thursday the 7th September 2017. However, because there is nothing to rush for, I am only coming today [Tuesday, 19 September 2017]. [**Patient 4**]

During our observation, we saw and interviewed patients who failed to attend their club appointment coming weeks later. They were simply asked to go to the pharmacy to check if their medication was still there. If not, they were sent to see a clinician, who prescribed a month's supply and then told to attend their next club appointment.

CONTEXT

In realist evaluation, 'context' relates to the circumstances in which the programme is implemented and it is considered as the features of the organisation, staffing, history, and so on that are necessary for the programme to 'fire' the mechanism or that prevent the intended mechanisms from firing. Contextual conditions were identified to influence the implementation and execution of the adherence club intervention. These were integration of HIV treatment with other CDL, the unconducive environment, the lack of resources, poor adherence club programme coordination, experimenting various execution models, and presence of non-HIV-positive patients.

Integration of HIV treatment with other chronic diseases of lifestyle

Previously, the adherence club programme had a designated building at the back of the main clinic building. From 2015, there was a pilot of the 'service integration' project, whereby ART patients and those with other CDL were managed in an 'integrated' fashion – at the same Unit. One of the participants described the nature of the service integration:

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> That is now the aim and the purpose [of the service integration] to mix the club. However, we are not mixed yet, but we are all gathering in this one waiting area. So those people [the other health-care providers] are busy with the chronic [CDL] people that side and we are busy with the HIV people this side [**Counsellor 2**]

Figure 11.4: Picture of waiting area shared by ART patients and those with CDL

The 'integration' of these services, nevertheless, seems to impact, especially in a negative manner on the implementation of the adherence club programme. This is what a participant said regarding the effects of the service integration:

> When we were there [in the facility], we were still separated from the other people [those with CDL], because we are using the same waiting room of near the two rooms. A normal, person could see why these people are sitting in their own space. So, it is already telling somebody, something is wrong with these people. [**Counsellor 1**]

Unconducive environment

Reports from the participants indicated that previously, the adherence club programme operated in a separate building, with designated spaces to operate two club sessions concurrently. Nevertheless, with the introduction of the notion of 'integration', the area is shared with services pertaining to other CDL making it less convenient for the execution of club activities.

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> The way the clubs used to run when we were inside this building before [separate designated building for adherence club activities], we could do all sorts of things with the patients… especially health education, HIV and AIDs education. We could run the clubs very smoothly on a daily basis, also having one-on-one talks with the patients. It was all about HIV we could talk about it all the time. Then we were moved inside the building, inside the facility then by going inside the facility, the challenge[s] that we had was, we only got a small room to work in. [**Nurse 1**]

Following the service integration, aspects of the adherence club programme became disorganised making the environment within which the activities of the club were held unconducive to the health-care providers and the patients. This could be identified from the experiences of the following participants:

> When we started this thing [integration], we thought HIV would be at the back because the room is there, and then, people with other chronic conditions would be from that black bunk up there but on the first day, we were shocked, because those people occupied the entire space. We did not know where to go, so we called the [facility] manager. 'Can you see what happening?' Because what they said was, it must be back-to-back. This one [group] must face this side and those [the other group] must face that side. It might happen that we [ART services] are quick and that side [CDL services] is slow and the patients with CDL are asking. What is happening that side? (Adherence club). [**Doctor 1**]

> Every time we are in the room, we need to close the door and then, there is not enough ventilation and the room was packed because it was just one small room. So, we have been working like that for quite a long time. Until we were sent out again to return to the same building and there we found another challenge where we only got this small room for our activities (**Figure 11.4**). [**Counsellor 1**]

Lack of resources

Some of the health-care providers working on the adherence club cited the lack of resources as challenges they face in the delivery of adherence club services.

> You see, so we have been doing that [running the clubs] all along, but we do not have the proper space, proper things to run the place you know! [**Nurse 1**]

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We came to find out that there are no clubrooms available, only this room and this waiting area here is available for us. We cannot do much in this waiting area because… we are together with other chronic illness people here inside. [**Counsellor 1**]

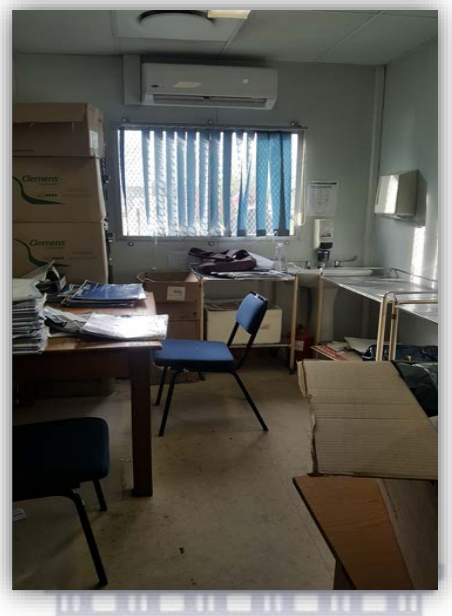

Figure 11.5: Tiny room allocated for adherence club activities. Measures about 3 m in length by 2 m in width

Poor adherence club programme coordination

Reports from the adherence club implementers indicate challenges regarding the coordination and execution of the adherence club activities; conditions that could influence the uptake of the intervention by the patients. They mentioned irregularities and confusion during the scripting of the patients for medication and in deciding when a patient should be sent out of club care as some of the issues facing the delivery of the club intervention:

So, when it is scripting time, she [Nurse] will do the scripting for all the clubs. Then we have the challenge whereby the clinicians inside, they would send the patient to book for a club, but then the nurse has already scripted for the club patients. [**Counsellor 1**]

When the patient has high blood pressure and diabetes, the clinician will ask the patient to go back to the clinic [back-to-regular clinic care]. The next two months or a month later, the patient will come for another check-up, then, if their blood pressure is normal – stable, they will be sent back to the club – another club, but you [the counsellor] have already taken that patient from the club. This renders the [club] registers dirty [untidy]. [**Nurse 2**].

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Experimenting various execution models

Another contextual condition influencing the execution of the adherence is the experimentation of different implementation models of the adherence club intervention. These changes were related to the frequent changes in the environment and the timeslots. While the changes in the environment were related to the introduction of the 'integrated' care model, the changes in the timeslots were an attempt to resolve the issues of space and potential stigma from the non-HIV-positive patients. A participant outlined these changes:

> Then we also tried the structure whereby, we select those unemployed ones and the one ones who are employed we give them one slot and the others but still it did not work. People they were used to coming at eight o'clock and then, we eventually, we found people were not coming even at that eleven [o'clock] nor in the afternoon. So, the structures were not working for the timeslots. You see, so we left the timeslots and came back to eight o'clock because no one wants to come at eleven o'clock at the hospital either. [**Counsellor 2**]

Presence of non-HIV-positive patients

The presence of non-HIV-infected patients close to where the adherence club patients were receiving care affected the outcomes of the adherence club intervention. With the two services taking place concurrently, there is not enough space to accommodate both services while ensuring patient confidentiality. The size of the adherence clubroom being small means that 25–30 patients cannot all fit inside for the club activities to be properly conducted. This means that some aspects of the adherence club, such as health talks, counselling and instructing the club rules, which can compromise the confidentiality of the club patients are omitted, and only the sealed medication of the patients distributed.

> That side [CDL services] is usually slower and the patients there are asking why. We want to go to that door. It is faster there. How do you tell them what is in that door? [Adherence club office]. [**Counsellor 1**]

At some point, the adherence club team attempted to change the adherence club times to later in the morning so that the patients could come when those with CDL had finished their session, but the health-care providers reported that this strategy did not work. This is what they had to say:

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> We cannot do those stuff anymore [health talks, counselling and club rule instructions] because if we do, we are disclosing the status of our patients. They [clinic management] have been trying to tell us to change our timeslots. We told them that we cannot change the timeslots because these people are working people, they have jobs, they have careers, they go to school so they are just interested to come and get their meds, stay for that hour and go. They are only prepared to stay that hour because we used to tell them that the club is from eight to nine. We tried it [changing the timeslots] for the first and second months. We asked the patients to come on their usually two month's basis, but it still did not work. [**Nurse 1**]

OUTCOME

The term 'outcome' includes short-, medium- and long-term changes, intended and unintended changes resulting from the implementation of the adherence club intervention. For the patients using the adherence club, this change could be sustained retention in care and adherence behaviour and a change in the experiences of the patients in the programme. Outcomes identified from the qualitative data analysis include inadvertent status disclosure, poor club attendance, poor retention in care and poor adherence to medication.

Inadvertent status disclosure

Some of the study participants suggested that the proximity of non-HIV-positive patients to where HIV-treatment and care services are taking place could lead to inadvertent disclosure of their HIV status, which could lead to perceived stigma. The words of this participant capture this.

> Nobody knows that I am HIV positive except my husband. If other people see me outside and we are chatting about HIV and AIDS, they will really know I am HIV positive. Once am walking outside, they will start gossiping about me. She is HIV positive. [**Patient 4**]

Poor club attendance

Because of the prevailing conditions under which the adherence clubs are being delivered, and the absence of some of its key components, patients have been prompted not to honour their club appointments. This can be confirmed by a nurse and a patient.

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> You remember I said there is a five-day grace, now we get patients they stay longer than that five days, after one month, they come the following month. [**Nurse 1**]

> You can see even me, my date was on Thursday, I was supposed to come on the 7th, on Thursday but because [now there is] nothing to rush for, because all along we were rushing for the club, you see? So now, I just give myself any time that I can just come for my medication. [**Patient 2**]

Poor retention in care

According to some health-care providers, the repercussion of the integration of services for patients with CDL along with those on ART can be seen in the poor retention in care of those receiving care in the adherence clubs. This is what a club facilitator had to say:

> We saw a drop in the [Club] attendance. People did not come, some came later [after club hours] if they came. One or two will come even not at that eleven o'clock slot that we gave them, so we did not actually know what we are doing. [**Counsellor 2**]

Poor adherence to medication

Health care providers working on the adherence club also suggested that the poor execution of the adherence club intervention owing to the 'integration' of other services into the programme affects the adherence behaviour of patients in the adherence club.

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> When you do not have health talks, people will take advantage. How? When they come in here, you just give them their treatment then you go, you do not know whether they are taking [their medication] or not because there is no space where you can monitor. Unless after one year, we monitor them, annually. Yes, and then, you could see this patient was not taking treatment for… some time. [**Nurse 2**]

Data synthesis

After we distilled the various aspects of the implementation of the adherence club intervention at Facility Z according to the elements of the ICAMO heuristic tool, our next task was to conceptualise the links between the different elements. This will help us to compare and contrast the theory obtained by the initial programme theory towards confirming, refuting and modifying the initial programme theory [26].

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In testing the initial programme theory of the intervention as directed by the data attributed to the intervention, context, actor, mechanism, and outcome collected from the implementation site, the realist work at a level of abstraction where we consider the *main* mechanisms generating the *main* patterns of outcomes (retroduction).

Our data synthesis followed two steps. First, we constructed an ICAMO matrix table (**Table 11.6**). The construction of the ICAMO matrix table followed the process of *retroduction* – a form of inference that seeks to identify and verify mechanisms that are theorised to have generated the phenomena [33]. In our retroductive inferencing, we applied the 'configurational' approach to causality, a logic in which outcomes are considered to follow from the alignment, within a case, of a specific combination of attributes [13].

Table 11.6: An ICAMO matrix to identify and align the elements of the ICAMO heuristic tool

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Integration of HIV treatment with other chronic diseases of lifestyle - Unconducive environment - Lack of resources - Presence of non-HIV positive patients	- Patient	- Perceived stigma - Poor knowledge of club rules and regulations - Perceived absence of punitive measures	- Inadvertent disclosure of HIV status - Poor attendance of club appointments
Group dynamics	- Unconducive environment - Lack of resources - Experimenting various execution models	- Patient - Group	- Perceived lack of social support - Feeling of frustration related to loss of group dynamics	- Reduced adherence related to constant changes and disruptions in group dynamics
Health talks/education	- Lack of resources - Presence of non-HIV positive patients - Unconducive environment	- Patient	- Lack of knowledge acquisition	- Reduced self-efficacy leading to poor retention in care and medication adherence - Inadvertent disclosure of HIV status
Quick medication access	- Unconducive environment - Lack of resources - Experimenting various execution models	- Patient	- Perceived benefit - Perceived stigma	- Adherence to medication related to medication availability - Poor adherence resulting from poor club attendance
Prompt continuity of care	- Poor adherence club programme coordination and execution	- Clinicians - Patient	- Role confusion - dissatisfaction	- Reduced rate of retention in care
Club facilitator-patient relationship	- Unconducive environment - Lack of health talks and counselling sessions	- Facilitator - Patient	- Trust - Perceived lack of support	- Poor adherence to medication - Poor retention in care
Overall intervention	- Unconducive environment - Lack of resources - Experimenting various execution models - Presence of non-HIV positive patients - Experimenting various execution models - Poor adherence club programme coordination	- Patients - Club teams	- Demotivation - Frustration - Confusion	- Reduced attendance of club sessions - Poor retention in care - Reduced medication adherence rates

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After obtaining conjectured ICAMO configurations, the second step of the data synthesis was the construction of the configuration map (**Figure 11.6**). Following the matrix table, we applied counterfactual thinking (testing possible alternative explanations) to argue towards *transfactual* (mechanism-centred) conditions [33]. We applied the retroduction logic to configure the elements of the realist heuristic tool (configurational mapping) – assuming the outcomes to follow from the alignment of mechanisms fired in particular contexts – to construct the programme theory. By counterfactual thinking, after formulating the possible ICAMO links, we examined each possible alternative configuration (explanation).

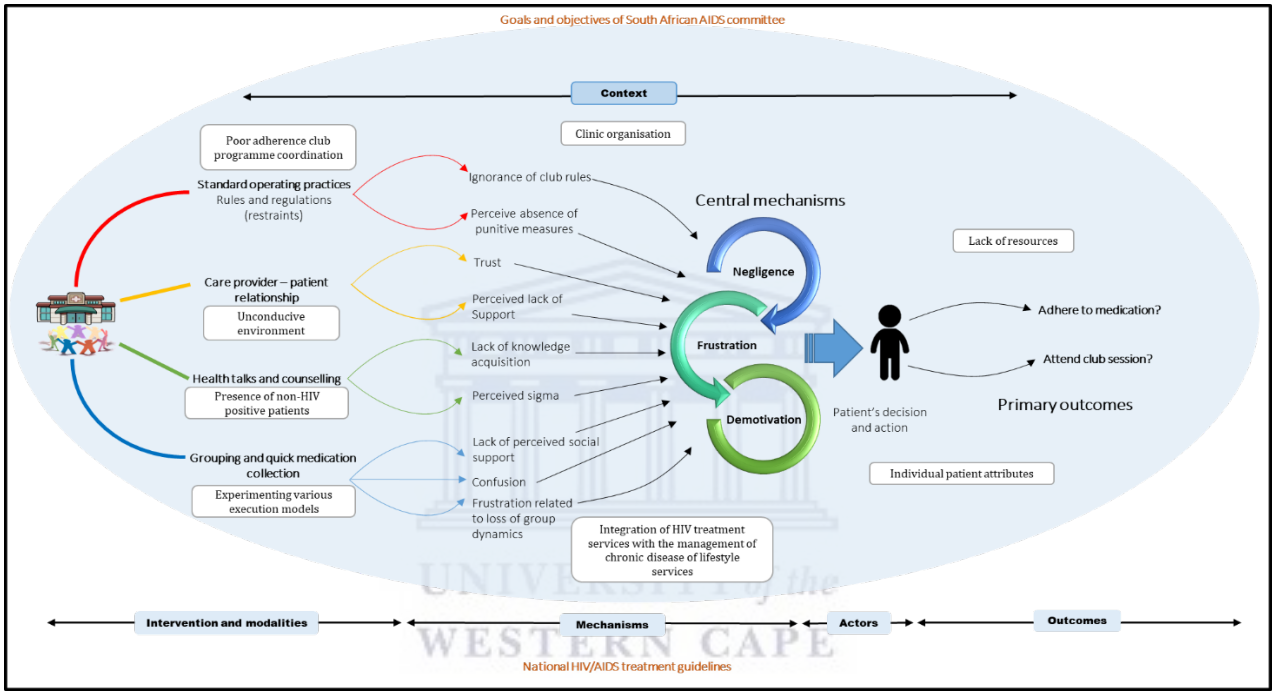

Figure 11.6: A configurational map of the adherence club programme theory based on case study data

Finally, using the "if…, then…, because …" statement [34], we constructed a programme theory of the adherence club intervention based on the data obtained in the case study (**Box 11.2**).

Box 11.2: Modified programme theory of the adherence club based on the case study data

Grouping clinically stable patients [**Actors**] receiving quick uninterrupted supply of antiretroviral medication with limited health talks and counselling, inadequate knowledge of the club rules and regulations [**Intervention**] within the context of limited resources (non-conducive clubroom) and integrated care with other patients managed for non-infectious diseases of lifestyle and poorly coordinated club execution [**Context**], then patients are likely to not attend club sessions and adhere to their medication [**Outcome**] because they become negligent, frustrated and demotivated [**Mechanisms**].

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Discussion

The objective of this study was to test the initial programme theory of the adherence club intervention in a real-life implementation condition to ultimately refute, concur, or modify the initial programme theory. The move from the initial programme theory to obtain a causal theory (theory of what happens in practice) is based on data from studying various aspects of the programme in an implementation scenario. The data obtained from this facility, while it does not exactly match the hypothesised theory, provided very important aspects of the implementation of the adherence club intervention to modify the initial programme theory.

The adherence club intervention comprises four service modalities; quick medication collection, targeted health education and counselling (group-based and individual-based), social environment for sharing, and fast-tracked clinician visits. These treatment modalities are knit together by club rules and regulations. The findings in this study revealed that owing to the circumstances under which the adherence intervention is implemented at Facility Z, only the quick medication collection aspect and fast-tracked clinician visits are effectively implemented. Even the rules that are meant to govern operating the clubs are not adequately applied, and the patients are not fully briefed about the terms and conditions of the adherence club intervention.

According to Pawson and Sridharan [35], realist hypotheses attempt to differentiate programme actors and their circumstances (normally abbreviated as 'contexts') regarding how they might respond to the adherence club programme mechanism. The 'integrated' care model, adopted by Facility Z, presents a unique context for the patients using the adherence club intervention regarding the programme mechanisms activated by the intervention. Based on the data, the 'integration' presents a different prevailing context within which the adherence club intervention is implemented, characterised by the unconducive environment, lack of resources (adherence club meeting room), the presence of non-HIV-positive patients, different execution models, and poor adherence club programme coordination. While the context is supposed to provide the 'ideal' conditions to bring the mechanisms into action [14], these mentioned conditions seemed to undermine those mechanisms provided by the adherence club intervention.

The retention in care findings reflected the changes that the adherence club programme had undergone. Within the first two years when the programme operated in a separate section, with all the intervention modalities appropriately delivered, the combined retention rates of the two

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sampled clubs 83.6% (95% CI, 85.1-92.5) resembled those reported elsewhere 89.3% (95% CI, 87.1-91.4) at 24 months [11].

In the third, year, the retention in care rate dropped sharply, with an estimated 23% hazard of a patient dropping out of the adherence club programme. This apparent drop in the capacity of the adherence club intervention to retain patients in care reflects the notion of 'integration' that was adopted by the facility. Although the adherence to medication figures remained high (combined retention in care 96.7%), this is because those patients who responded positively to the changes in the context and did not adhere to their medication had already dropped out of care. Thus, they were already censored when calculating the adherence in care behaviours.

The findings of this study suggest that the prevailing context conditions undermined the mechanisms offered by the adherence club intervention. This is evident in the challenges related to retaining patients in care and getting the patients to adhere to their medication. We had previously tested the initial programme theory in two cases. While these cases could be identified to have presented prevailing conditions that enabled the adherence club mechanisms to produce the intended outcomes (sustained retention in care adherence to medication), investigating the adherence club intervention under conditions that potentially mitigate the programme mechanisms is important in eliciting a middle-range theory of the adherence club intervention. Through cross-case analysis, we would identify those conditions that could 'enable' or 'disable' the adherence club mechanisms to describe how, why for whom and under what circumstances the adherence club works (or not).

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Limitations, rigour and trustworthiness

Regarding the retention in care and adherence behaviours of patients in the adherence club, it would have been ideal to obtain the overall rates of the facility. This posed a challenge because the facility is actively creating more clubs monthly, which would potentially affect the overall retention in care and adherence rates of patients in the adherence club programme.

To this end, we decided to select, purposively, two adherence clubs that had reached their maximum capacity and to study the rate at which patients drop out of the club for various reasons – default, transferred out of the clinic, lost to follow-up or died. Another reason that we purposively selected the clubs is related to the untidy nature of the adherence club register. This follows the poor execution of the adherence club rules, whereby, patients would be returned to

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another adherence club when they show signs of good adherence after being dropped from the club.

To improve the rigour of the study, we adopted the mixed-method approach. The use of a multi-method approach for data collection was not only informed by their ability to improve abductive inspiration but also to confirm and complement the information required to modifying, refuting and/or verifying the initial programme theory. In addition, we used a variety of participants to promote the triangulation of the information obtained from them as it enables the researchers to verify facts.

Finally, in conducting and reporting the study, we followed the guidelines for reporting realist evaluation studies developed by Wong and colleagues [36].

Conclusion

The role of context in defining the outcome of health-care interventions has been highlighted by implementation scientists and realist evaluators. The findings of this study revealed the prevailing implementation context of the adherence club intervention as presented by an 'integrated' model of managing patients with HIV and people with chronic non-communicable diseases. These findings highlight potential conditions that can mitigate the adherence club intervention mechanisms towards achieving the intended outcome of the intervention. These conditions could serve towards developing a middle-range theory explaining how, why, for whom and under what health system conditions the adherence club intervention works (or not).

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SECTION IV

CROSS-CASE ANALYSIS AND REFINED THEORY

Overview

The cross-case analysis represents Phase 3 of the realist evaluation. This phase entails comparing the context-specific generative theories (ICAMO configurations) that were obtained based on the testing of the initial programme theory in the three contrastive sites. We reviewed and compared the results of the individual case studies to see how the initial programme theory can or needs to be modified. The process of moving from the specifics of individual cases to a theory that is more abstract is known as analytical generalisation and is outlined in this chapter. This phase is illustrated by the blue circle on the realist evaluation cycle in Figure IV.I.

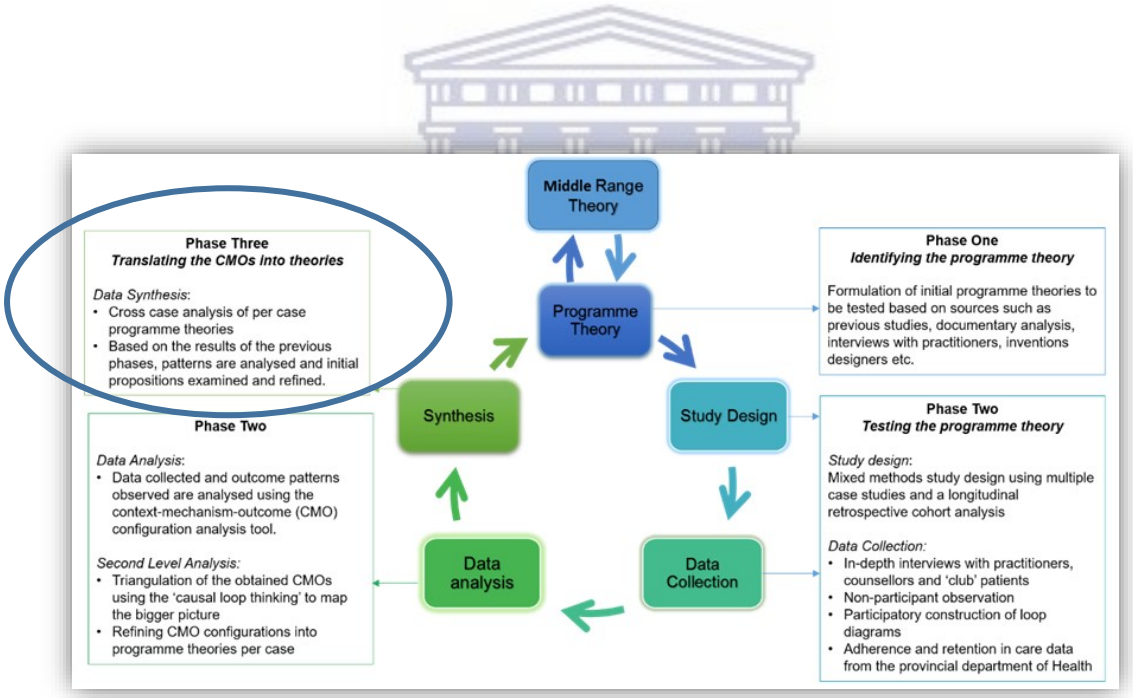

Figure IV.I: Identifying Phase 3 on the realist evaluation cycle

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CHAPTER TWELVE

Synthesising the findings of the three case studies towards formulating a refined theory of the adherence club intervention

Unearthing a refined programme theory of the adherence club intervention: A cross-case realist synthesis. Social Sciences and Medicine (Under Review)

Abstract

Poor retention in care and suboptimal adherence to antiretroviral treatment (ART) undermine its successful rollout in South Africa. This has consequences on managing the estimated seven million people living with HIV in the country. The adherence club intervention was designed as a systems improvement programme to enhance the retention in care of patients on ART and their adherence to medication. Although empirical evidence suggests that the adherence club model is more effective in retaining people living with HIV on ART care and sustaining medication adherence compared to standard clinic care, it is poorly understood exactly how and why it works, and under what health system contexts. Embedded within a realist evaluation study, we elicited an initial programme theory of the adherence club intervention and tested the initial programme theory in three contrastive sites. In this article, we report on the refined programme theory that was developed from the synthesis of the case-specific theories that were obtained from three case studies. To this end, we did a cross-case analysis, to delineate the combination of the intervention, context and mechanism components of the three cases to explain the outcomes of the adherence club intervention. Reproductive inferencing guided our analysis within the configurational mapping of the elements of the intervention-context-actor-mechanism-outcome realist heuristic tool. Through the cross-case analysis, we formulated a general theory identifying the contextual factors and the mechanisms underlying patients' practices required to retain them in care and enhance adherence to medication. This theoretical perspective is critical for understanding whether, how and why the adherence club intervention has been successful in a particular context, and under what context conditions it can be scaled up or replicated.

Introduction

South Africa has the largest HIV-treatment programme in the world, accounting for 20% of

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people on antiretroviral therapy globally [1]. There is growing evidence that differentiated care models employed in the management of HIV have the potential to improve and sustain adherence to medication and retention in care of PLWHA [2,3]. With an estimated 7.1 million people living with HIV in South Africa as at 2017 [4], differentiated care models have been identified, which could make a substantial contribution towards the management of large HIV-patient cohorts.

The adherence club intervention [5–7], a type of a differentiated care model, is implemented in Western Cape Province, South Africa to address challenges of poor retention in care – attending scheduled clinical visits – and suboptimal adherence to ART – taking medication as prescribed. The adherence club intervention is an ancillary ART service delivery model designed to streamline ART delivery for stable adult (18+ years), treatment-experienced patients, with good clinic attendance records and good medication adherence (evidenced by the two most recent consecutive viral loads undetectable (<400 copies/mL)) [8]. Through group consultations, convenient medication pick-up processes, facilitated access to a clinician when needed, the adherence club provides ART patients with the required clinic care and drastically reduces their waiting times [5–7].

The adherence club programme shows potential to relieve clinic congestion and improve retention in care and treatment adherence in the context of the rapidly growing HIV-patient populations on ART [3,9–11]. Although empirical evidence suggests that the adherence club model is more effective in retaining people living with HIV on ART and sustaining medication adherence compared to standard clinic care, it is poorly understood exactly how and why it works. To this end, a realist evaluation was conducted [7]. In this article, we report on the process of synthesising the findings obtained from three case studies to formulate a refined theory of which intervention modalities of the adherence club intervention work, for whom, in what circumstances, in what respects and why?

Methodological approach

Realist evaluation is a theory-driven approach to programme evaluation [12,13], which strives to answer the question what works, for whom and under what circumstances [14,15] to explain how and why programmes, policies and interventions work (or not) [16]. For an intervention to work, it must influence the reasoning (mechanism) of the targeted actors to cause them to adopt an intended behaviour that in a specific context will lead to a specific outcome. Therefore,

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realists assume that an outcome (O) is generated by a mechanism (M) being triggered in context (C) through an actor (A) when an intervention (I) is implemented (**Figure 12.1**). This conceptualisation captures how, why, for whom and in what circumstances programmes work. Formulating realist theories is, therefore, achieved through the formation of Intervention-context-actor-mechanism-outcome (ICAMO) configurations [17,18].

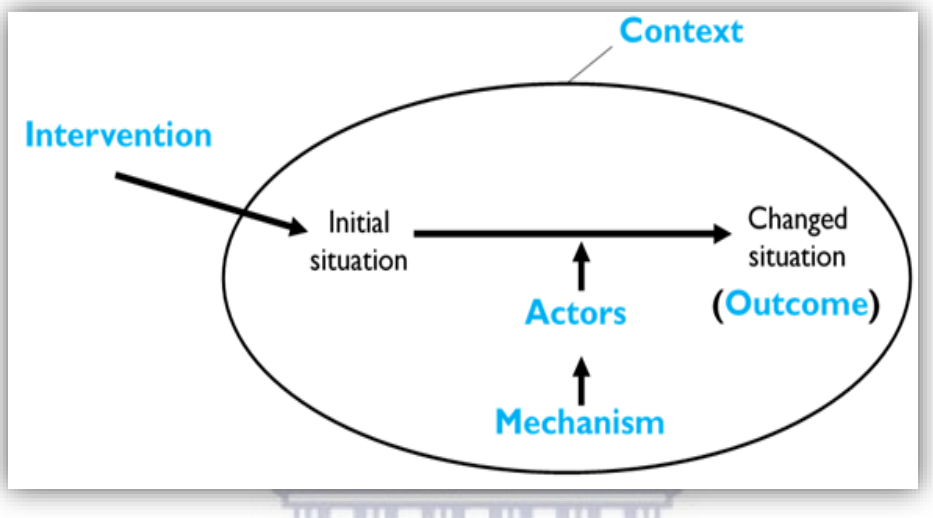

Figure 12.1: A generative configuration of realist theories

Realist evaluators go into the evaluation process with some expectations, guided by the initial programme theory. During the evaluation, some expectations are confirmed, and some might prove to be misguided. The end product of the analysis is expected to improve the picture of the programme efficacy and inefficacy [19]. Three principal phases are, therefore, identified when conducting a realist evaluation inquiry. 1) Eliciting the initial programme theory; 2) testing the initial programme theory in contrastive sites; and 3) building a more refined programme theory based on the findings from the contrastive case studies (**Figure 12.2**).

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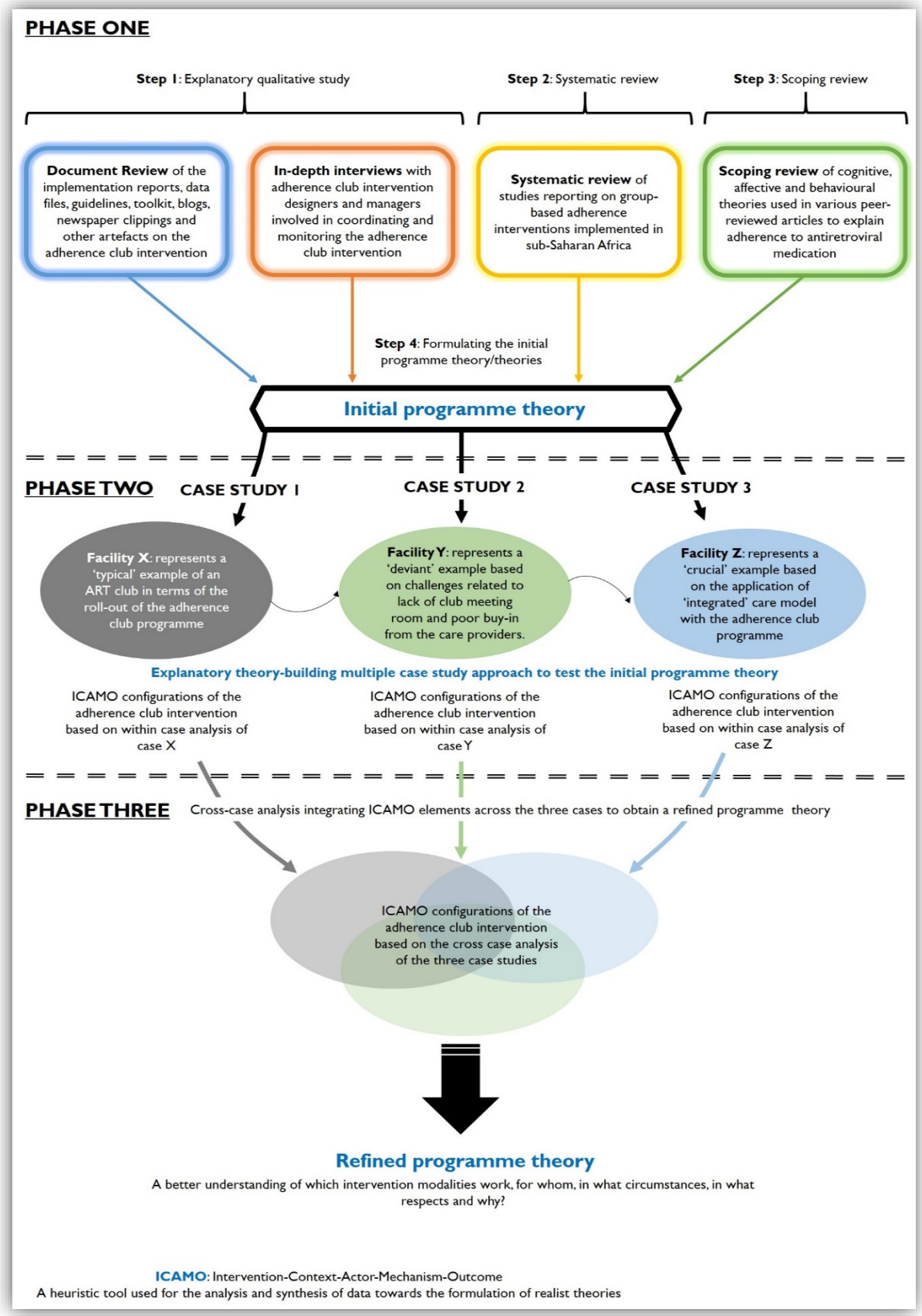

Figure 12.2: Three phases of realist evaluation inquiry

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In the first phase of this work, we formulated the initial programme theory of the adherence club intervention [20]. We first conducted an exploratory qualitative study of programme designers' and managers' assumptions and perspectives of the intervention and carried out a document review of the design, rollout, implementation and outcome of the adherence clubs [21]. We also conducted a systematic review of available studies on group-based ART adherence support models in sub-Saharan Africa to tease out their underlining theories [22]. In addition, we carried out a scoping review of social, cognitive and behavioural theories that have been applied to explain adherence to ART [23]. Using the process of configuration mapping, we constructed an ICAMO map representing the initial programme theory of the adherence club, through the process of retroduction – mechanism centred logic and analysis. Finally, we used the "if…then…because" statements to translate the ICAMO configuration map into testable hypothesis [20] (**Box 12.1**). Formulating the initial programme theory signifies the end of the first phase of the evaluation.

Box 12.1: Initial programme theories of the adherence club intervention

Initial Programme Theory 1

IF adult (18+ years) clinically 'stable' patients with evidence of good clinic attendance are group-managed, receive quick symptom checks, quick access to medication, consistent counselling and social support from the peer counsellor,
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they develop a group identity, which improves their perceived social, support, satisfaction and trust; and acquire knowledge, which helps them to understand their perceived threat and perceived benefits and improves their self-efficacy. As a result, they become encouraged, empowered and motivated, thus, more likely to remain in care and adhere to the treatment.

Initial Programme Theory 2

IF operational staff receive goals and targets set to continuously enrol patients in the adherence club and strictly monitor their participation through strict standard operating practices (the promise of exclusion in the event of missed appointment and active patient tracing),
THEN patients are likely to adhere to medication and remain in care,
BECAUSE they fear (perceived fear) losing the benefits (easy access to medication, peer support, reduced waiting times, and two-month ART collection) of the club system and they are coerced through adhesive club rules. As a result, they become nudged to remain in care and adhere to the treatment, which might decongest the health facility.

In the second phase, we applied an explanatory theory-building multiple case study approach [24] to test the initial programme theory in three contrastive sites described as typical, deviant or crucial [25]. Each site or facility was considered a unit of analysis, and each pair of adherence

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clubs being sub-units, which are embedded in the cases. Within each case, we tested the initial programme theory for its adequacy. We obtained modified versions of the initial programme theory explicating how and why the adherence club intervention works within that case (or not).

The third phase involves refining the programme theory based on the theories developed from the case studies, which is the focus of this paper. Therefore, in this paper, we report on the cross-case analysis towards developing a more refined programme theory of how and why the adherence club intervention works and under what health systems context.

Study design

In this study, we applied a cross-case study design. Cross-case analysis is a research method that facilitates the comparison of commonalities and difference in the events, activities, and processes through identified units of analyses [26]. Thus, it enabled us to delineate the combination of the intervention, context and mechanism components to explain the outcomes of the adherence club intervention. Using this method helped us to construct an explanation as to why one case was different or the same as others and to further examine the initial programme theory.

The confirmatory theory testing approach was applied. This approach uses predominantly hypothetico-deductive forms of reasoning, which entails moving from a theoretical concept (initial programme theory) to empirical testing of hypotheses [27]. In this approach, the researcher enters the research situation with an *a priori* theory and the purpose of the data collection is to 'confirm' or 'disconfirm' or modify the theory.

Case selection

A maximum variation case selection approach was adopted [24]. This is an exploratory sampling strategy to identify the typical cases that are subsequently selected. Our aim of selecting cases with varying characteristics was to predict contrasting results to increase the degree of certainty of the results. Our case selection was, therefore, purposive and based on the 2014 routine data on the retention in care rates of clinics in the Western Cape Province. We classified 'good' retention in care as values above 80%. A value between 70% and 80% was considered 'average' and any value below 70% described as 'poor' retention in care. Case X had a retention in care rate of 70%, Case Y, 63.0% and Case Z, 81.7%. Based on these values,

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we labelled our cases as typical, deviant and crucial, respectively [25]. In **Table 12.1** the characteristics of the facilities selected for the case studies in 2014 are shown.

Table 13: Characteristics of facilities selected for case studies

Characteristics	Case X 'Typical'	Case Y 'Deviant'	Case Z 'Crucial'
Adult patients on ARVs in August 2014	2561	1501	1486
Number of ACs	39	2	20
Official starting date of AC	2012	2014	2012
Number of patients in adherence club care	1309	35	480
Number of ART staff	11	09	08
Implementation context	rollout	rollout	rollout
Predominant catchment population	Coloured	Black	Coloured

Data congregation

Three case studies were conducted. We employed the explanatory theory-building approach to testing the initial programme theory of the adherence club intervention in each of the cases. The result of this process was three ICAMO prototypes explaining how, why and in what circumstances the adherence club intervention works (or not) within each of the facilities.

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Case study 1: Case X

Case X, where the initial programme theory was tested first, represents a 'typical' case regarding the implementation of the adherence club because it was among the facilities recruited for first phase rollout in 2012. Since its inception, the adherence club programme at Case X facility has shown steady growth at a reasonable pace.

At this facility, the adherence club programme operates in a separate Unit within the main clinic. The dedicated staff consist of receptionists (2), a data clerk (1), counsellors (3), nurses (3) and doctors (used to be 2 in 2014 but 1 since 2016). The adherence club programme grew steadily with no noticeable disruptions regarding the organisation and how it operates. The adherence club Unit has offices allocated to all the above-mentioned staff including a big area dedicated to the adherence club activities. With all the necessary facilities available and with buy-in from the health-care providers, the adherence club programme progressed steadily and was identified

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through the theory obtained after testing the initial programme theory as a positive case.

The ICAMO configurations obtained below (**Table 12.2**) are based on qualitative and quantitative data collected to identify and describe the mechanism, context, actors and outcome. (This process is described in detail in the case study, Chapter 9).

Table 12.4: Intervention-Context-Actor-Mechanism-Outcome configurations of Case X

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Standard operating protocol - HIV policy	- Patient	- Perceived barriers - Perceived threat - Nudged	- Adhering to club appointments
Grouping patients	- Availability of space for meeting - Longevity of patient the club - Relationship with other club members	- Patient - Group	- Perceived social support - Positive group dynamics	- Better adherence resulting from developed self-efficacy
Health talks/education	- Availability of personnel	- Patient	- Knowledge acquisition	- Improved self-efficacy
Quick medication access	- Availability of medication - Proper preparation for club session	- Patient	- Perceived benefit - Motivation - Satisfaction	- Adherence to medication related to medication access
Prompt continuity of care	- Availability of clinicians - Staffing dynamics - Organisation of club activities	- Clinicians - Patient	- trust	- Retained in care through problem resolution
Club facilitator-patient relationship	- Staffing dynamics - Teamwork/collaboration	- Facilitator - Patient	- Trust - Perceived support	- Adherence to medication - Retention in care
Overall intervention	- Buy-in from care providers - Preparation and organisation	- Patients - Club teams	- Motivation - Self-efficacy - Satisfaction (with care)	- Improved retention in care and adherence to medication

Case study 2: Case Y

Case two was identified as a 'deviant' case, because of two reasons. First, the retention in care rates of patients on ART at this facility was very low compared to the other facilities in the district. Second, while the initial implementation of the adherence club programme at the facility was scheduled for the first phase rollout in 2012 along with the other facilities, adherence clubs were only implemented officially in 2014. Two factors were responsible for the delayed implementation of the programme at the facility, these were lack of a 'dedicated venue' as meeting place for the club members and adherence counselling offices and poor buy-in from the facility health-care workers. Regarding staffing, this facility had a dedicated club doctor, two

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nurses, three counsellors and an admin clerk and data clerk. The counsellors also counselled patients with TB.

In 2015, a nurse was identified from another facility and trained in the various aspects of the implantation of the adherence club. She championed the implementation of the programme by heading the coordination of the club activities and education the other health-care providers to get their buy-in. Once these two components were secured, the adherence club programme in facility Y started performing well and was thus identified through the data analysis as a positive case – confirming the initial programme theory (**Table 12.3**).

Table 151: Intervention-Context-Actor-Mechanism-Outcome configurations of Case Y

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Standard operating protocol - Being reminded of the rules and regulations of the club - HIV policy	- Patient	- Perceived barriers - Perceived coercion - Perceived fear - Reinforcement - nudged	- Nudged to adhere to club appointments
Group dynamics	- Availability of space for meeting - Longevity of patient the club - Relationship with other club members	- Patient - Group	- Perceived social support - Bonding and formation of group identity	- Better adherence resulting from developed self-efficacy
Health talks/education	- Availability of personnel - Team work	- Patient	- Knowledge acquisition - Reinforcement of club rules and regulations	- Improved self-efficacy
Quick medication access	- Availability of medication - Organisation of pick-up process and club sessions - Buy-in from care providers	- Patient	- Perceived benefit - Motivation - Satisfaction	- Adherence to medication related to medication availability
Prompt continuity of care	- Availability of clinicians - Staffing dynamics - Organisation of club activities - Buy-in from care providers	- Clinicians - Patient	- Trust - Satisfaction	- Retained in care through problem resolution
Club facilitator-patient relationship	- Staffing dynamics - Teamwork/collaboratio n - Buy-in from care providers	- Facilitator - Patient	- Trust - Perceived support	- Adherence to medication - Motivation - Retention in care
Overall intervention	- Availability of programme champion - Buy-in from care providers - Preparation and organisation	- Patients - Club teams	- Motivation - Self-efficacy - Satisfaction	- Improved retention in care and adherence to medication

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Case study 3: Case Z

Case Z was considered a 'critical' case because, at the time of case selection (2014), the facility showed good retention in care rates for their overall ART programme. Following the successes of the adherence club programme and the overall ART programme at Case Z facility, this site was proposed for piloting the integration of chronic care in 2015. This meant that the ART services had to move back to the main clinic to be situated where the other chronic conditions such as diabetes, hypertension, arthritis and epilepsy were managed. Although the ART patients and those managed for chronic care were being managed within the same Unit, separate teams of health-care providers managed them using separate treatment management schedules and treatment strategies. Regarding staffing, the facility had a dedicated doctor, two nurses, two counsellors, and a data clerk. Nevertheless, the facility faced challenges of lack of space, inconvenience and exposure to inadvertent disclosure when managing ART patients resurfaced, so the management decided to move the 'integrated' services back to the separate building in 2016 where the services currently operate.

Although ART and other chronic care services are organised within the same Unit, they are coordinated separately. On one side of the building the non-chronic care services are conducted, and on the other side the adherence club programme, but the patients share a common waiting area. So, the building that was once dedicated exclusively to ART services is being shared with the other chronic care services Unit; thus, space and confidentiality problems are the prevailing conditions. In **Table 12.4** the ICAMO matrix obtained after data analysis at case Z facility is shown.

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Table 12.4: Intervention-Context-Actor-Mechanism-Outcome configurations: Case Z

Intervention modalities	Context	Actor	Mechanism	Outcome
Club rules and regulation	- Integration of HIV treatment with other chronic diseases of lifestyle - Unconducive environment - Lack of resources - Presence of non-HIV positive patients	- Patient	- Perceived stigma - Poor knowledge of club rules and regulations - Perceived absence of punitive measures	- Inadvertent disclosure of HIV status - Poor attendance of club appointments
Group dynamics	- Unconducive environment - Lack of resources - Experimenting various execution models	- Patient - Group	- Perceived lack of social support - Feeling of frustration related to loss of group dynamics	- Reduced adherence related to constant changes and disruptions in group dynamics
Health talks/education	- Lack of resources - Presence of non-HIV positive patients - Unconducive environment	- Patient	- Lack of knowledge acquisition	- Reduced self-efficacy leading to poor retention in care and medication adherence - Inadvertent disclosure of HIV status

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Quick medication access	- Unconducive environment - Lack of resources - Experimenting various execution models	- Patient	- Perceived benefit - Perceived stigma	- Adherence to medication related to medication availability - Poor adherence resulting from poor club attendance
Prompt continuity of care	- Poor adherence club programme coordination and execution	- Clinicians - Patient	- Role confusion - dissatisfaction	- Reduced rate of retention in care
Club facilitator-patient relationship	- Unconducive environment - Lack of health talks and counselling sessions	- Facilitator - Patient	- Trust - Perceived lack of support	- Poor adherence to medication - Poor retention in care
Overall intervention	- Unconducive environment - Lack of resources - Experimenting various execution models - Presence of non-HIV positive patients - Experimenting various execution models - Poor adherence club programme coordination	- Patients - Club teams	- Demotivation - Frustration - Confusion	- Reduced attendance of club sessions - Poor retention in care - Reduced medication adherence rates

Data analysis

The process of synthesising the findings of the three case studies followed a confirmatory theory building approach. Confirmatory theory building approaches, especially when applied within realist studies, use a retroductive (or abductive) form of reasoning as the central approach to inference making [27]. This allowed us to move from descriptions of the concrete to the abstract, and back to the concrete [15]. After obtaining the modified programme theories from the three contrastive sites, we applied an analytical process that involved the identification of ICAMO components across the three cases and linked them to formulate a refined theory of the initial programme theory. This process involved the application of various analytic techniques, retroduction (mechanism-centred theorising), counterfactual thinking (comparison of theories) and abstractions (analytical generalisation), and concretisation of the theorised mechanisms in different situations of configurational thinking.

Our analysis was guided by retroductive inferencing within the configurational mapping – a logic in which outcomes are considered to follow from the alignment, within a case, of a specific combination of attributes – of the elements of the realist heuristic tool [16]. The conjectured ICAMO configurations, of each of the three cases, were compared and contrasted in the search for general models (**Figure 12.3**).

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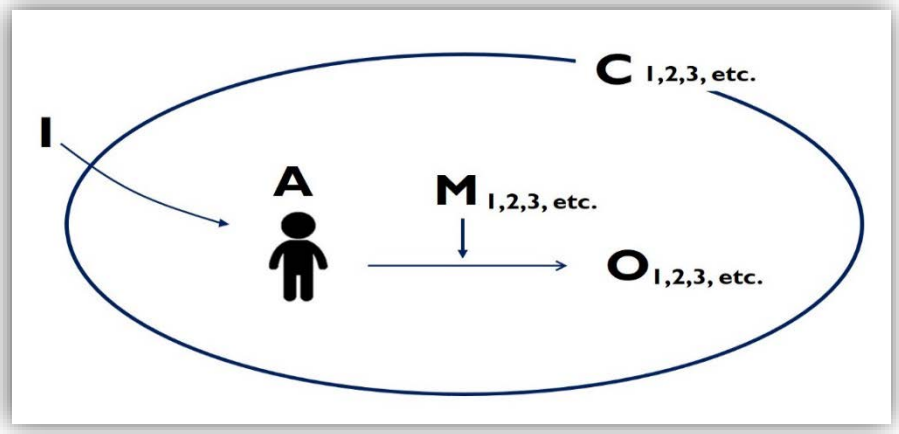

Figure 12.3: Comparing various contexts to develop a refined ICAMO configuration

Comparison and contrasting were done by linking each active mechanism identified as being associated with a positive outcome (M-O links), then we looked for the context in which the mechanism was contingent. The ICAMO prototype from the negative case was used to adjust (confirm) certain links to develop ICAMOs based on failed outcome scenarios, and as a reason to abandon certain ICAMO configuration chains [28]. According to Mingers [29] the interplay between positive or counteracting mechanisms determines whether events occur or not. Comparing the negative and positive cases also provided evidence for adjusting the ICAMO configurations as in some cases, the negative ones enforced the construction of positive ones. This was achieved by identifying the association of the failed outcomes with 'missing mechanisms' and 'negative contexts'. The process required the application of counterfactual thinking (testing possible alternative explanations) to argue towards *transfactual* (mechanism-centred) conditions [27]. In applying this counterfactual [and transfactual] thinking, we constructed ICAMO maps (**Figures 12.4-12.9**) of each of the modalities of the adherence club intervention based on the ICAMO heuristic tool to obtain a configurational causality representation of each intervention modality.

Results

Our analysis followed the five modalities associated with the adherence club intervention, i.e. the club rules and regulations, the grouping of the patients, quick medication pick-up, prompt continuity of care, facilitator-patient relationship and the overall adherence club intervention. After refining the ICAMO configurations related to each of the adherence club intervention modalities, we used the '**if…then…because**' phraseology to explain the conceptualisation of

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the configurations. The 'if…then…because' phraseology follows that: ***if*** certain resources (information, material, opportunities, and sometimes constraints) are provided, ***then*** they will trigger the actors reasoning to a sufficient extent that a change to healthier behaviour will follow [19].

Club rules and regulations

The adherence club intervention has rules and regulations that govern its functioning. During the introductory visit to the club, patients are provided with the rules and regulations governing the adherence club and its activities, and reminded of these on every adherence club visit. For this intervention to work, users (patients) are meant to abide by the rules and regulations of the adherence club. In this way, the rules and regulations introduce a new set of mechanism(s) within the social context of the ART programme.

According to the club rules and regulations, club membership can be terminated if the patient has a viral load above 400 copies/mL or significantly abnormally low CD4 count <200 cells/mm^3, and when they develop an active TB infection. These are considered as proxies for non-adherence to medication. When a patient fails to attend mandatory club sessions regularly or when s/he fails to send a 'treatment buddy' to collect their medication from the club facilitator or club nurse within five days (grace period), they are also returned to the main clinic care.

Based on our findings, these rules and regulations introduce mechanisms such as fear (related to losing on the benefits of the club), feelings of being threatened (as they are constantly being reminded of these rules) and feelings of being nudged (told what to do in a positive reinforcing manner) (**Figure 12.4**).

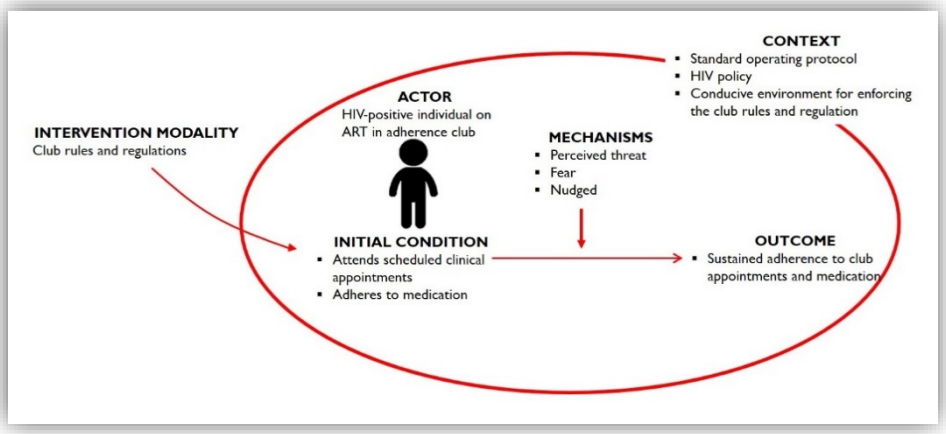

Figure 12.4: Refined ICAMO configuration in relation to the adherence club rules and regulations

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Based on our refined ICAMO configuration in relation to the club rules and regulations, it can be theorised that ***if*** the standard operating rules and regulations of the adherence are applied in the context of the standard operating protocol and HIV policy within a conducive adherence club environment, ***then*** patients are likely to remain in care and adhere to their medication, ***because*** they perceive being threatened, feel nudged or are afraid of losing the club benefits.

Group formation

The notion of grouping patients with similar clinical characteristics and needs is one of the critical aspects of the adherence club intervention. According to the adherence club programme designers and health managers, grouping patients together for ART stimulates the formation of relationships formed among the group members in addition to providing easy access to ARV medication.

The grouping of patients with a common goal and sharing 'similar' experiences engender a new set of mechanisms. Prominent mechanisms provided by the grouping of patients together for targeted care include bonding, which leads to a positive group dynamics and social support. In **Figure 12.5**, the refined ICAMO configuration that was obtained from the cross-case analysis of the three case studies is shown.

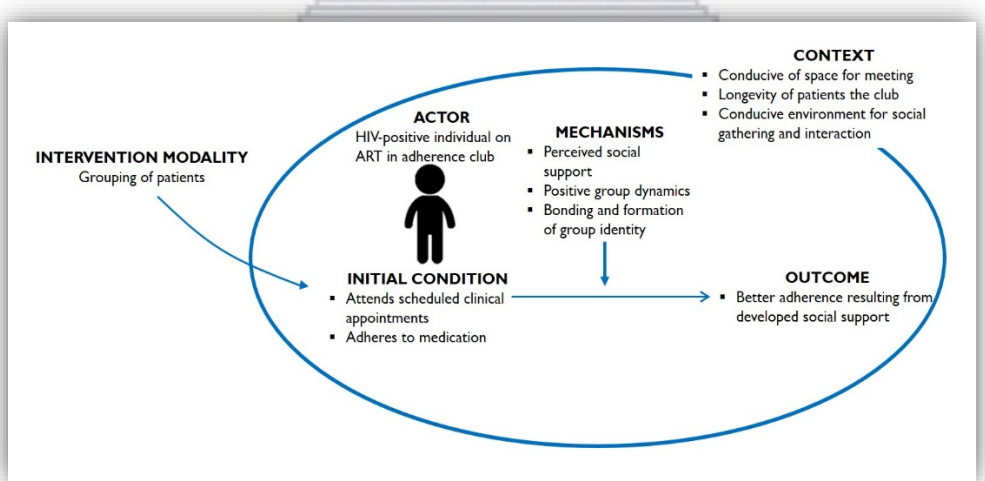

Figure 12.5: Refined ICAMO configuration in relation to the aspect of grouping the patients

Based on this refined ICAMO configuration, the following explanation could be drawn. ***If*** patients are grouped together for targeted ART care in a comfortable meeting space and conducive social environment (away from non-HIV-positive patients), ***then*** they are likely to

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remain in care and adherence to their medication ***because*** they bond with each other and provide social support to one another.

Health talks/counselling

Health talks and counselling are among the major secondary activities that take place when patients meet bi-monthly for their medication refill in an adherence club. The club facilitator gives health education talks to the assembled group on relevant topics. These topics most often focus on the challenges that patients face with taking their medication. This opportunity is also used to dispel any doubts, rumours and myths that the patients might have regarding their treatment. The patients are also counselled on the importance of sustained adherence to their medication, and the effects of not taking their treatment as prescribed.

The adherence club health talks and counselling induce distinct sets of mechanism(s) to enhance the treatment and care of patients on ART. Identifiable mechanisms related to health talks and counselling include knowledge acquisition, motivation and empowerment. These mechanisms often translate to a further mechanism, self-efficacy – one's perception of one's ability to accomplish a task. In **Figure 12.6** the generative configuration of health talk/counselling provided as part of the adherence club activities is illustrated.

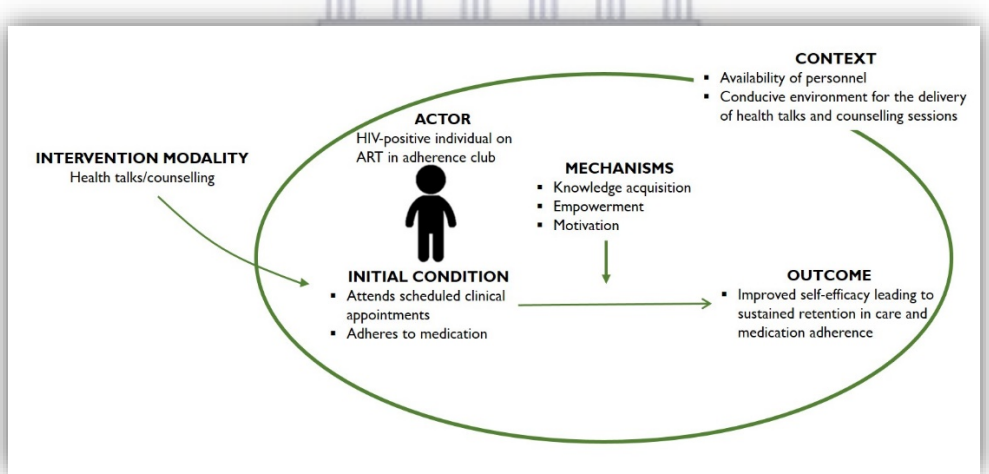

Figure 12.6: Refined ICAMO configuration in relation to the adherence club rules and regulations

The ICAMO configuration obtained from the synthesis offers the following description. ***If*** grouped patients on ART continuously receive health education and counselling within a conducive environment with available health personnel, ***then*** they are likely to remain in care

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and continue to adhere to their medication, ***because*** they acquire the right knowledge about their condition, and they become motivated and empowered.

Quick medication pick-up

Quick medication pick-up is a modality of the adherence club intervention that was designed to address the challenge of long waiting times at the clinic when patients come to pick up their medication. The medication is either packed by a CDU or the clinic pharmacy or made available to the club facilitators to dispense to the patients when they arrive for their club session. In addition to the quick access to their medication when they arrive at the clinic, the widely spaced appointment schedules (two months) of the adherence club sessions allow patients to get up to two month's supply of their medication.

Providing medication to patients through the adherence club with less frequent visits to the clinic introduces mechanisms such as perceived benefit, motivation and satisfaction. How these generative mechanisms produce the intended outcomes of the adherence club intervention is illustrated in **Figure 12.7**.

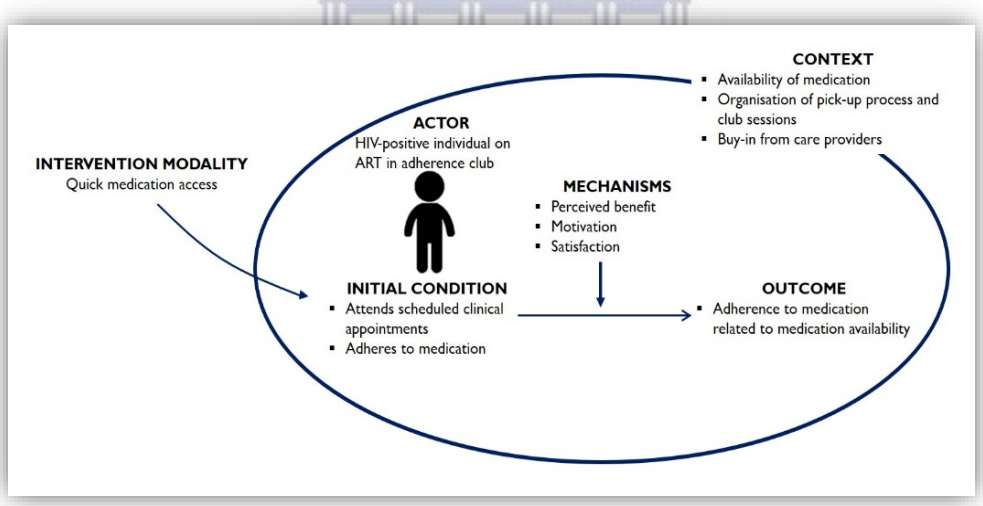

Figure 12.7: Generative configuration of mechanisms provided by quick medication access

A refined ICAMO configuration of the quick medication pick-up modality of the adherence club suggests the following theory. ***If*** patients on ART receive quick medication pick-up, ***then*** they are likely to adhere to their medication and remain in care, ***because*** of their perceived benefit, motivation and satisfaction (related to carrying on with other daily activities such as going to work).

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Club facilitator-patient relationship

The adherence club uses the lowest cadre of the health-care providers to run the activities of the club. The person to do this is usually a peer of the adherence club members with the lowest level of specialisation. The adherence club facilitator prepares and runs the club sessions, makes sure pre-packed medications are available and distributes them to patients, fills in the club register and provides peer education and counselling to the club patients. Therefore, a healthy relationship between the peer club facilitator and the patients presents different sets of social mechanisms to enforce the workings of the clubs. These social mechanisms are 'trust' and 'perceived support'. The generative power of these mechanisms is modelled in the configurational map (**Figure 12.8**).

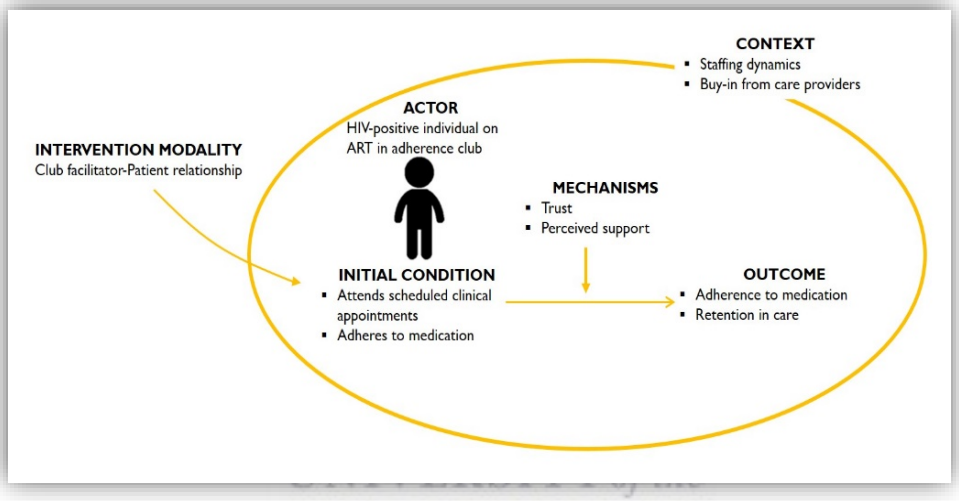

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Figure 12.8: Generative configurations of the mechanisms of the facilitator-patient relationship

Although this is not in a strict sense a modality of the adherence club, the relationship shared between the club facilitator and the patients or a group of patients introduces a possible supportive reason of how and why the adherence club works. The refined ICAMO configuration associated with this relation suggests that ***if*** patients receiving ART share a healthy relationship with the club facilitator, ***then*** they are likely to remain in care and adhere to their medication ***because*** they trust the club facilitator and they perceive that the facilitator provides them with social support towards managing their disease.

Overall intervention

Byng and colleagues [28] argue that while it is important to have the ICAMO configurations of the different units of the programme, policy or intervention, it adds value to see how these units

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come together as a whole. They suggested constructing a configurational map to represent the bigger picture. This was achieved by distilling three major mechanisms from the mechanisms identified from the data through the process of abstraction and accentuation (highlighting the most prominent mechanisms) [30]. This follows the logic that certain mechanisms dominate others and occur more frequently, and thus become apparent at the level of the actual phenomena in the form of partial regularities, or demi-regularities. The following mechanisms, motivation, empowerment and being nudged were identified. These mechanisms were used to construct a configurational map for the adherence club intervention as an entire intervention with its various modalities as illustrated in **Figure 12.9**.

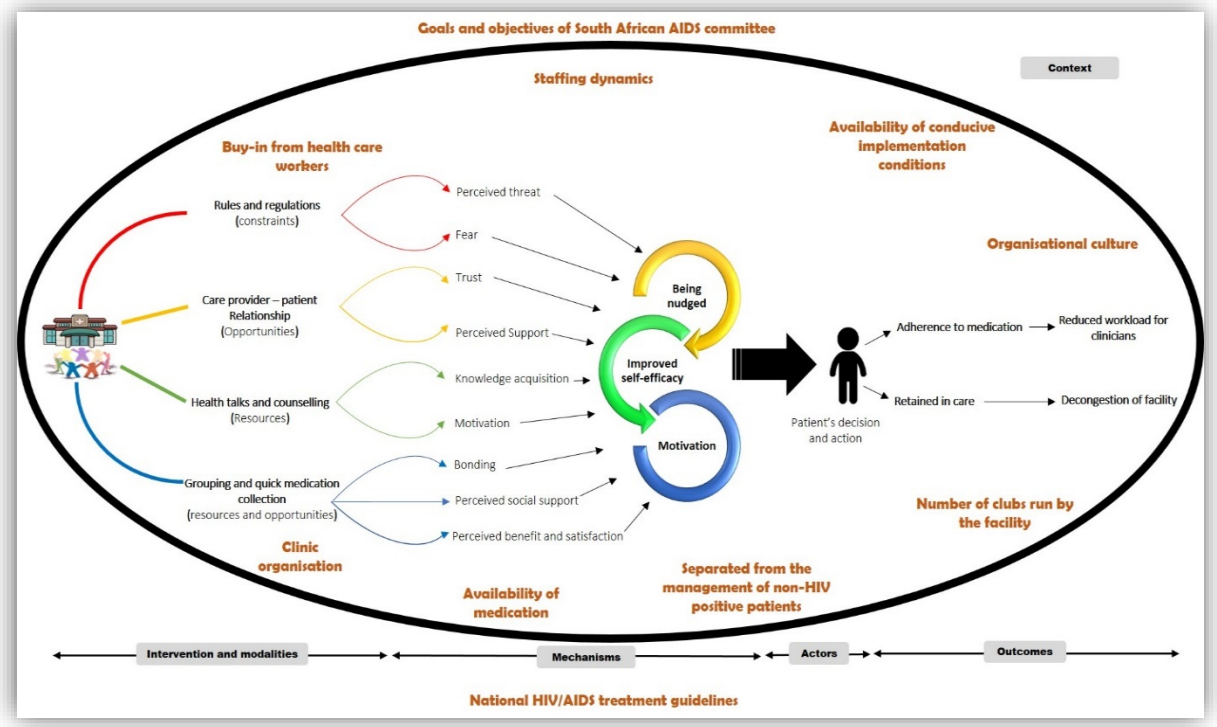

Figure 12.9: Generative configuration of the adherence club modalities

While constructing the bigger picture of how and why the adherence club intervention works, we started off by showing how the different components or modalities of the adherence club intervention affect the actors (patients). Then we show how these actors assimilate the impact of the intervention components and through their reasoning, adopt actions and interactions that generate the intended outcomes of the adherence club intervention. Hedström and Swedberg [30] describe this approach as micro-macro mechanism model. Based on this generative configuration of the adherence club modalities we could be teased out the following refined theory (**Box 12.2**).

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Box 12.2: Refined programme theory of the adherence club intervention

> Grouping clinically stable patients on antiretroviral therapy **[Actors]** with available resources and buy-in from health-care workers in a convenient space **[Context]** to receive quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required while guided by rules and regulations **[Intervention]**, works because their self-efficacy improves and they become motivated and nudged **[Mechanisms]** to remain in care and adhere to medication **[Outcome]**.

It must be acknowledged that for adherence-enhancing interventions to work, the user plays a critical role. Although the treatment and care of ART patients is based on the partnership between the patients and the health-care providers, the major responsibility of the self-care lies with the patients. This responsibility relates to adopting and making use of the resources, opportunities and constraints provided by the adherence-enhancing intervention. Therefore, the participation of the patients is important to obtaining the requisite outcome of the intervention.

Discussion

In this paper, we aimed to compare different contexts (settings) within which the adherence club has been implemented in the search for a general model explicating how, why and under what circumstances the adherence club intervention works. A confirmatory cross-case analysis was adopted to obtain a refined programme theory. The three case studies were useful in formulating a more refined programme theory of the adherence club intervention. While our initial programme theory (**Box 12.1**) suggested that the two theories could independently explain how and why the adherence club intervention works and under what circumstances, testing it in the different case studies illustrated that these two theories operate conjointly to provide a comprehensive explanation, rather than independently or in parallel.

Two of the three case studies (Cases X and Y) were positive cases (confirming the hypotheses of the initial programme theory). That is most of the mechanisms that were hypothesised to operate to 'cause' the outcomes were confined within the context of these cases. Case Z was identified as a negative case but it confirmed the initial programme theory in the sense that the absence of the ideal condition(s) identified in the initial programme theory to facilitate the implementation of the adherence club intervention and activate the adherence club programme mechanisms were absent. In fact, the prevailing circumstances had mitigating effects on the implementation of the adherence club programme and deactivated the club intervention

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mechanisms. This led to a decline in the intended outcomes (poor attendance of club activities and suboptimal adherence to medication) in Case Z.

The transition from case-specific ICAMO configurations to cross-case configurations then to the refined programme theory describes a shift from the specific to more generalizable theory. This process describes the notion of 'cumulation' labelled by Pawson and Tilley [15] that focuses on traversing between the initial programme theory and the theories formulated in the empirical case studies to a refined theory. The process of moving from the specifics of individual cases to a theory that is more abstract is known as the analytical generalisation and is outlined in **Figure 12.10**.

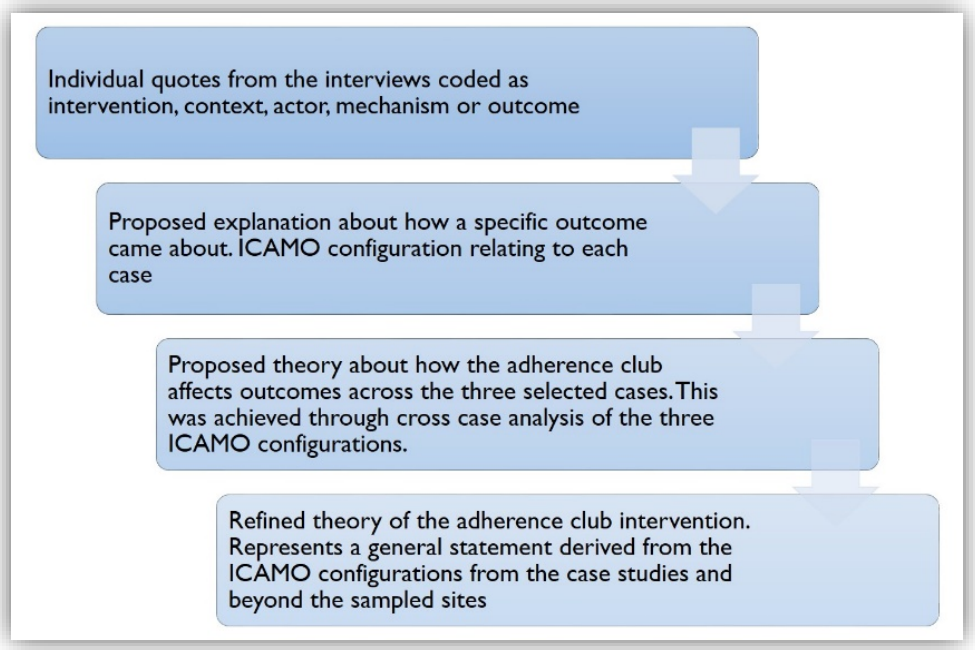

Figure 12.10: Application of the analytical generalisation to refine programme theory

Although we obtained a general statement based on the derived ICAMO configurations of how, why, for whom and under what circumstances the adherence club intervention works, we realised in a meeting with the adherence club designers and managers that different patients respond to different aspects or components of the adherence club intervention. For instance, the adherence club has five components of care embedded, with rules and regulations governing the implementation of these treatment and management components. The discussion elucidated that some patients respond better to being nudged through rules and regulations that underpin the

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functioning of the adherence club rather than being motivated and empowered into remaining in care and adhering to medication through the quick medication pick-up, health education, counselling, and group dynamics. Similarly, in another differentiated HIV-care model, Community ART Groups, implemented in Tete, Mozambique, it was found that the group members were bound by a 'Code of conduct' which offered a social control of how the groups functioned [31].

Similarly, different patients will respond to different intervention modalities provided by that club intervention based on their circumstances and what constitutes a barrier to them. For instance, a qualitative evaluation of the Medication Adherence Club intervention in Kenya showed that patients preferred the intervention to the standard treatment scheme because the clubs provided quick access to medication and they had a reduced number of clinic visits which saved them time and money [32].

Patients using the adherence club intervention in another study identified the quick access to their medication as the main benefit of the adherence club intervention [33]. The authors did not report any evidence of social support taking place among the club members. However, other studies conducted by Dudhai and Kagee [33], and Rasschaert et al. [34] indicated that the patients most valued social support among the members of a group-based adherence intervention.

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In a study conducted by Whiteside and Roots [35] to evaluate what works in another differentiated care programme, they identified that the health talk provided to patients and the relationship between the health-care providers and the users were most important to the patients. The authors explained that the health talk enhanced treatment uptake and literacy and the real-time interactions between the patients and care supporters were central to the intervention. They suggested further that the 'relationship' provided a conducive psychological environment in which patients received support and encouragement when they experienced stigma, medication side effects and other obstacles to adherence [35].

We believe that because the adherence club intervention has many treatment and care modalities incorporated, there is a chance that it could address the challenges of a wider range of patients using the intervention to enhance their adherence to medication and sustain the attendance of clinic appointments. This assertion is supported by evidence comparing the effectiveness of interventions with multiple strategies (two or more) to single strategies [36]. The findings

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showed that interventions with multiple components are more effective than those with a single component.

Nevertheless, measuring the effectiveness of complex interventions using outcome-based approaches such as randomised controlled trials poses serious challenges [37]. This is because multi-strategy interventions for the most part are complex – having more than one possible outcome, sensitive to context, their implementation depends on the flexibility in tailoring the intervention permitted, and they usually have long causal chains linking intervention with its outcome(s). To this end, theory-driven approaches to evaluation, such as realist evaluation, have been proposed as alternative methodological approaches that could capture the complexity of these multi-component interventions [38,39].

Theory-driven evaluations essentially start by developing testable hypotheses of the programme, intervention or policy and testing these hypotheses in identified cases leads to case-specific theories that provide propositions that can be tested and refined [40]. The theories obtained from realist evaluation contribute to "Theories of the Middle Range" as defined by Merton [40]. Such middle-range theories are situated at the level of abstraction that is optimal to be 'useful' and 'testable'. *Middle-range theory involves abstraction, of course, but they are close enough to observed data to be incorporated in propositions that permit empirical testing* [41]. Middle range theories provide explanations that are sufficiently general to explain outcomes across settings and social activities [15].

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Limitations, rigour and trustworthiness

As we moved toward obtaining the refined theory, we recognised that the chances of losing the validity of the data increased. To ensure our data informed our final theory, we referred to the original transcripts to ensure that the ICAMO configurations retained the validity of the interview data. In addition, we organised a feedback meeting with the adherence club programme designers and management at the end of the first two phases (**Figure 12.1**). These feedback sessions were very informative and ensured that we were capturing and representing their ideas appropriately.

Throughout the evaluation (Phases 1 to 3), we systematically applied the configurational approach towards constructing the ICAMO heuristic tool to represent the theories that emanated from the data at various steps and phases. The use of a systematic approach to determine

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ICAMO configurations worked across all cases and strengthened the cross-case analysis and synthesis.

In a few instances, some of the explanations developed during the hypothesis development phase seemed to be supported by common sense, but these remained in the early stages because we could not find sufficient data to construct ICAMO configurations supporting the arguments. Consequently, we abandoned these explanations.

The use of positive and negative cases to conduct the cross-case analysis towards formulating the general theory did not only allow us to identify similarities and differences in the cases but to go beyond in supporting or refuting the initial programme theory.

In conducting this study as well as the case studies assembled from the study, we applied all the principles stipulated in the RAMSES II guideline for conducting realist evaluation [12].

Conclusion

In this study, we set out to conduct a comparative case-study analysis to obtain a more generalizable knowledge about how, why, for whom and under what health systems context the adherence club intervention works or fails to work. Using data from three contrastive sites that have implemented the adherence club intervention, we formulated generative statements using the ICAMO heuristic tool to represent theories from each of the cases. Through cross-case analysis, we formulated a general theory identifying the contextual factors and the mechanisms underlying patients' practices required to retain them in care and enhance adherence to medication. This theoretical understanding is critical for understanding whether the adherence club intervention has been successful in a particular context, and also whether and under what context conditions it can be scaled up or replicated.

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CHAPTER THIRTEEN

CONCLUSIONS AND RECOMMENDATIONS

Why, how, for whom and under what health systems conditions does the adherence club intervention works: Implications for the rollout and implementation of differentiated antiretroviral care models

Introduction

According to UNAIDS, there were 7.1 million PLWHA in South Africa, among whom about 56% were accessing ART in 2016 [1]. South Africa is considered to have the largest HIV-treatment programme in the world [2], accounting for approximately 20% of people on ART globally [1]. The UNAIDS 2017 report also estimated that among those living with HIV, 45% had suppressed viral loads translating to 80% of those who are accessing ART. These figures suggest that retention in ART care and adherence to HIV medication remain critical issues to be addressed by the South African health system.

While standard treatment and care schemes show potential to retain patients in ART care, their success is undermined by congested health-care facilities, long waiting times and shortages of health-care providers [3]. To this end, differentiated models of HIV treatment and care have been implemented in various parts of sub-Saharan Africa, including South Africa. These differentiated care models are ancillary to the mainstream ART care delivery schemes, and they streamline ART service delivery by adapting the care components to the needs of a targeted group [4]. Differentiated care models usually adopt a multifaceted approach towards enhancing patients' adherence and retention in care behaviours by embedding various strategies including providing minimal clinical screening, quick ARV refills, adherence support and defaulter tracing, strict monitoring of attendance and problem solving, and encouraging self-efficacy and mutual support within a single model [5]. The preponderance of the evidence supporting the effectiveness of differentiated care models [6–8] has led to its inclusion in the new WHO operational guidelines for managing HIV and AIDS [9].

The adherence club intervention is one of such differentiated care models that is implemented in the Western Cape Province, South Africa [10, 11]. This model of ART care delivery is aimed

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at ‘stable’ adult (18+ years) patients on ART and delivers scheduled bi-monthly clinical screening, quick ARV refills, adherence support through counselling and health talks, and mutual support by grouping the patients in ‘clubs’.

Several studies provide evidence of the effectiveness of the adherence club intervention in improving retention in care and enhancing adherence to medication using effect size computations [12–15]. Nevertheless, effect sizes do not provide policymakers and programme implementers with information on how an intervention might be replicated in their specific contexts, or whether trial outcomes will be reproduced in pragmatic conditions [16].

Complex interventions – having more than one possible outcome, are sensitive to context, and having long causal chains linking intervention with its outcome(s) – such as the adherence club intervention usually undergo some tailoring when rolled out in different contexts. Capturing what is delivered in practice, with close reference to the theory of the intervention can enable evaluators to distinguish between adaptations to make the intervention fit different contexts and changes that undermine intervention fidelity and realised outcomes [16]. Regarding the adherence club intervention, we elicited the following programme theory to illustrate the how, why, for whom and under what circumstances it would work (or not) (**Box 13.1**).

Box 13.1: Elicited adherence club programme theory

Grouping clinically stable patients on antiretroviral therapy with available resources and buy-in from health-care workers in a convenient space to receive quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required while guided by rules and regulations, works because their self-efficacy improves and they become motivated and nudged to remain in care and adhere to medication.

Eliciting the programme theory by identifying and elucidating the mechanisms through which the adherence club interventions bring about changes in the retention in care and adherence behaviour of club members are crucial to understanding how and why the effects of the intervention occurred and how these effects might be replicated in other settings [17]. In this paper, we explain how, why and under what health systems context the adherence club intervention works (or not) from our realist evaluation of the adherence club intervention [18]. We also discuss possible implications of our formulation of the adherence club’s programme theory to the rollout of the adherence club programme in other settings.

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Summary of findings

How does the adherence club work?

The adherence club intervention is a multi-faceted or multi-strategy intervention. The various strategies incorporated in the adherence club intervention are designed to improve retention in care and medication adherence by removing some of the mechanisms that were introduced by negative circumstances. These intervention modalities counteract these 'negative' mechanisms by introducing mechanisms that are likely to generate good retention in care and adherence club behaviours. In **Table 13.1**, common barriers to medication adherence and retention in care [19] and the various strategies incorporated in the adherence club intervention to address the related barriers are illustrated.

Table 13.1: Classic barriers to retention in care and adherence to medication and associated intervention modalities and mechanisms they provide

Category	Barriers	Adherence club modality	Mechanisms introduced
Individual-related factors	• Age (being younger) • Depression (Mental health) • Forgetfulness • Substance abuse • Poor self-efficacy • Low health literacy • Perceived wellness	• Health education, counselling and peer support.	• Lack of knowledge acquisition • Motivation • Empowerment • Perceived social support
Medication-related factors	• Medication side effects • Medication dosing (Complex regimen) • Treatment fatigue	• Health education and counselling	• Lack of knowledge acquisition • Motivation • Empowerment
Health system factors	• Access to ART (Medication stock outs) • Relationship with health-care providers • Staff shortages • Long waiting times • Poor services delivery	• Quick ART pickup and bi-monthly medication schedules	• Perceived benefit • Satisfaction • Motivation
Socio-economic Factors	• Poverty • Lack of family support • Food insecurity • Stigma and discrimination • Transportation challenges	• Quick ART pickup and bi-monthly medication schedules • Social support	• Perceived benefit • Satisfaction • Motivation • Perceived social support • Group identity
Socio-cultural factors	• Alternative treatment • Male dominance and gender-based violence • Religious beliefs	• Health education • Counselling and peer support	• Perceived benefit • Satisfaction • Motivation • Perceived social support

Based on **Table 13.1**, we inference that the adherence club intervention works by replacing the existing mechanisms (inducted by various barriers) with mechanisms introduced through the adherence club intervention modalities. In addition, the use of a multi-strategy approach

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provides the patients using the adherence club intervention the opportunity to respond to the strategies that address their unique challenges. Furthermore, the synergistic effect of all the strategies could foster the effectiveness of the intervention, as patients may face different challenges at different points on their treatment journey.

Why does the adherence club work?

In the realist logic, programmes, intervention and policies work by causing the relevant actors to reason and, consequently, act in a particular way based on the resources, constraints or opportunities they offer. Pawson and Tilley [20] refer to the reasoning that relevant actors apply to the resources, constraints and opportunities as the mechanism by which an intervention works. In **Table 13.1** the various mechanisms that were uncovered in our study in relation to the various strategies are outlined.

Based on our study findings, the adherence club intervention sustains adherence to medication and retention in care because it improves the *self-efficacy* of the stable patients on ART through perceived social support, improved problem-solving skills, and health education. Additionally, these patients become *motivated* through the satisfaction of quick health-care services, counselling and health talks and *nudged* through the adherence club rules to remain in care and adhere to their medication.

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For whom does the adherence club intervention work?

The question 'for whom?' regarding the adherence club intervention covers a wide range of patient characteristics. For this reason, it is advised that while designing differentiated care models, considerations should be made regarding the characteristics of the patient population targeted – patient centred care. The adherence club intervention target 'stable' patients, described as patients older than the age of 18, have been on ART for a year or more, show evidence of good adherence to medication (two consecutive virological suppression) and good clinic attendance record (evidenced by clinic attendance card).

The reasoning behind using people who are treatment-experienced relates to enhancing their adherence to medication which is different from establishing medication adherence behaviours. Establishing medication adherence behaviours is done when the patient is initially initiated in care. This is done through intensive counselling sessions and stringent adherence monitoring

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such as pill-counting. These modalities are reduced or absent in the adherence club intervention because it is assumed that the patients have gained enough knowledge and experience over the stipulated 12 months to enable them to self-manage their disease and fitting their treatment into their lifestyle. The adherence club intervention, therefore, offers ancillary services to remove to health systems and individual barriers to retention in care and adherence to medication.

In what context does the adherence club work?

In our study, we emphasise at the relevant health systems context that influences the rollout, execution and uptake by the relevant actors of the adherence club intervention in whole or in part. According to our findings, the mechanisms provided by the various intervention modalities of the adherence club are contingent on several contextual conditions for the intended outcome behaviour to be observed. In other words, for the adherence club intervention to work (achieve its intended outcomes), a few health-care conditions must be met. These are, availability of and collaboration among the adherence club team members, the adherence club unit should be separated from Units managing other non-HIV-positive patients, there should be a conducive environment where patients could meet, and there should be adequate availability of resources especially the ARV medication.

Implications, recommendations and knowledge contribution

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Implications for the rollout and implementation of the adherence club

In response to the concurrent high incidences of non-communicable chronic diseases (diabetes, hypertension, epilepsy, etc.) and HIV in South Africa, the NDoH introduced an ICDM model [21]. This model of care advocates for the rationalisation of the frequency of clinical consultations, the facility visits for collection of repeat prescriptions and counselling sessions (plus health education).

Proponents of this type of integration argue that it has the potential to reduce the stigma and discrimination behaviours associated with HIV and to enhance the utilisation of scare human resources [22]. Our study findings (**Case study 3**) indicated that if 'integration' as proposed by the ICDM model is not properly executed, the promise of reduced stigma and discrimination and efficient use of human resources are undermined. For instance, at one facility (**Chapter 11**),

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ART patients AND those receiving treatment for chronic non-communicable diseases (diabetes, hypertension, epilepsy, rheumatoid arthritis etc.) are managed as a Unit (**Chronic Care Unit**) sharing the same space. However, they do not attend the same 'club' and do not have synchronised schedules. Thus, they do not use the same health-care providers.

Our findings (**Chapter 11**) showed that the retention in care and adherence to medication behaviours of patients using the adherence care intervention dropped at the identified facility when *an* 'integrated' care model was introduced compared to when the adherence club was operated as a standalone programme. Our findings suggest that the 'integrated model that was practiced at the facility constituted a barrier to the successful implementation and execution of the adherence club intervention. This finding suggests that adherence club intervention works better when operated as a standalone unit rather than under the 'integrated' care model.

Another important health systems context that our study unveiled as pertinent for the successful implementation of the adherence club intervention is having a conducive meeting space. According to the identified generative mechanisms, (**Chapters 9 and 10**) patients interact with each other and provide social support to each other as they bond within the group. This bonding and consequent social support can only be possible if there is an allocated meeting space, where these grouped patients could sit and interact with one another. A spacious room that allows them to sit together and share their experiences with each other enhances retention in care and adherence to medication. We posit then that it is imperative for facilities that seek to implement the adherence club intervention, to arrange for a spacious environment for the club sessions to be conducted.

A 'club team' ideally runs the adherence club programme. This team includes a club manager, a club facilitator, a professional nurse, a pharmacist and a data clerk [23]. The club facilitator is responsible for executing and coordinating the day-to-day activities of the adherence club. According to the adherence club manual, the club facilitator should be a lay counsellor or a community health worker. The use of this cadre of health-care providers to coordinate operating the adherence club intervention follows the notion of task-shifting to improve the efficient use of health-care providers.

Although a plethora of studies has supported efficient use of lay counsellors and health-care workers for the management of HIV-positive individuals on ART [24], our findings revealed that if nurses and doctors do not systematically support this cadre, their work could be

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undermined, leading to poor outcomes [25]. We recommend that the uptake and implementation of the adherence club intervention should ensure that the club facilitators should be fully supported by nurses, with direct access to physicians and that the activities of these club teams should be well-coordinated from its facility base.

Buy-in from the health-care providers was unearthed as one of the health system contexts within which the adherence club intervention could thrive and excel [26]. In one facility (**Case study 3**), our findings indicated that the adherence club intervention did not have full buy-in from the health-care providers at the beginning of its implementation, which was slow and poorly executed. The identification of an adherence club programme champion and training were some of the strategies employed to resolve the issue of poor buy-in. Since then, the performance of the facility about retaining patients in care and enhancing their adherence to medication was greatly improved. The implication of this is that having a programme champion, who would drive the implementation and overall coordination of the programme goes a long way towards improving buy-in from the health-care providers. In turn, this improves the implementation and correct execution of the adherence club activities.

Implications for practice

The adherence club programme is rapidly expanding in the Western Cape Province [27]. Following this expansion, various out-of-clinic adaptations of the intervention are being considered. For instance, community-based adherence club models (hosted within a community centre, church hall or non-governmental organisation) [13] and home-based models (hosted in the home of a club member) [28] have been piloted with promising results to improve HIV-service decentralisation.

The subsequent rollout and expansion of such models will also require that the fundamental conditions that made the adherence club intervention to work should be considered. For instance, there should be a conducive environment for the patients to meet, discuss, and conduct the club activities. To this end, meeting at patients' homes should be considered to reduce the number of patients per club to maybe 15 to accommodate them in residences where there is less space [23].

In these out-of-clinic models, the health-care providers travel to the hosting facility with the necessary resources (medication and blood sample collection arsenal) to coordinate the club activities. In situations such as these, when a patient requires further consultation with a

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clinician, they need to go to the clinic because in most instances clinicians do not travel with the club facilitators. Our study findings indicated that a nurse should be considered to travel with the 'club team' to provide the continuous support that the club facilitators might need and to provide the clinical support if patients require any. Alternatively, a referral slip should be given to the club entitling them to have their blood drawn or see a clinician immediately without queuing at the reception.

When clubs are first started at the facility, considerations should be made to facilitate their decentralisation in the various community 'spaces'. The most important of these is to designate a facility club with a specific catchment area. All club members for that club should reside in the specified geographical location. This will ensure that the entire club can be relocated to a community space.

Contributions to the differentiated care movement

Differentiated models of ART could focus on individual patients or a group (group-based ART care). Most individual-focused models of ART and care focus on providing psychological support, adherence monitoring, and equally address household dynamics potentially impacting on patient adherence. While group-based care models offer psychological support and ensure easy access to medication and adherence monitoring, they also create a conducive atmosphere for peer-support among the group members. Duncombe and colleagues [29] designed a framework that captures the various service-delivery structures that differentiated models could take based on service intensity of four delivery components, type of services delivered, the location of service delivery, the cadres of health-service providers involved, and frequency of health services.

Our study elicited the theory relating to how each of these components works to obtain the designated effect of retaining patients in care and adherence to medication. The circumstances under which these HIV-care modalities are most effective were specifically identified. For instance, requesting patients to attend bi-monthly health-care clinical visits instead of monthly visits incites satisfaction and trust in the health-care system and prompts them to remain in care and, consequently, adhere to their medication. Understanding how and why each of these components works could shed light on possible ways to combine them to obtain maximum benefit for the patient and the health system.s

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Although there is a wealth of evidence suggesting that differentiated care models have the potential to improve access to ART, retention in care and adherence to medication, challenges remain regarding conceptualising and implementing differentiated care models [30]. Our theory-based understanding provides valuable implementation insights of how the different components of differentiated care models work and under what conditions (or not). However, questions remain relating to the differentiated care modules based on the four modalities. More research and targeted evaluations are needed to inform rollout of the various combinations of differentiated care models.

National policy implications

In 2016, the Department of Health of South Africa sent out a circular to the national, provincial and district HAST Managers entitled "Implementation of the Universal test and treat strategy for HIV positive patients and differentiated care for stable patients" [31]. In this circular the government's intention to roll out differentiated care models nationwide is detailed. According to the information in the circular, the application of the differentiated care model is primarily to decongest the health-care facilities [31]. This is to be achieved by 'rewarding' adherent and stable 'chronic' patients with a quicker service and the flexibility to choose their preferred medication collection service (client-centred focus) through three options that are reflected in the adherence policy and service delivery guidelines:

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1. Spaced and fast lane appointment system (also known as ICDM)
2. Adherence clubs and
3. Central Chronic Medication Dispensing and Distribution (CCMDD).

Our study elicited theories of how, why and under what circumstances each of these adherence-enhancing options works (or not). Understanding the theory that underpins how each of these models works could be beneficial in deciding which model is appropriate for which patient based on their circumstances.

Conclusion

The adherence club intervention shows great potential for retention in care among patients and enhancing sustained adherence to medication. The adherence club intervention works by grouping 'stable' patients on ART in context of the available resources, buy-in from health-care

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workers and convenient space to receive a quick and uninterrupted supply of medication, health talks, counselling, immediate access to a clinician when required, while guided by rules and regulations. In this way, patients' self-efficacy improves and they become motivated and nudged to remain in care and adhere to medication.

The successful implementation and rollout of the adherence club intervention are contingent on some important health system conditions. Prominent among these conditions are the separation of the adherence club programme from other HIV-negative patients as much as possible, availability of convenient space for the adherence club meetings, the continuous support of the adherence club facilitators by clinicians and buy-in from the health-care facility health workers.

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AFTERWORD

Reflections on the study

In this section, a reflection on the study based on what was proposed to be done and what was actually done and what prompted the changes (or adjustments) that were made is discussed. The study plan is outlined in the study protocol [1].

First, we planed to test the formulated initial programme theory in five facilities (Chapter 3 p. 45) but ended up using three facilities. Our decision to use three of the five facilities was because we considered that the three facilities provided us with enough variation in context to allow us to obtain a refined programme theory of the adherence club intervention. We do not, therefore, argue that the refined theory is of the 'middle range' - theories that provide explanations that are sufficiently general to explain outcomes across settings and social activities [2]. We belief that futher testing of the refined programme theory in other contests could lead us to a middle range theory of how, why, for whom and under what health system context the adherence club intervention works.

Secondly, we proposed to use the context-mechanism-outcome (CMO) heuristic tool to elicit and test the initial programme theory. This is based on the proposition of Pawson and Tilley [3]. Nevertheless, while elicting the initial programme theory of the adherence club intervention, we realised that different actors had different roles to play and the programme had different meaning to the different actors (stakeholders) [4]. For instance, the focus of the adhrence club managers and implementers was to decongest the health care facility and reduce the workload of the health care providers and that of the patients is remaining in care and adhering to their medication (thus staying healthy). Owing to the different perspectives of the actors, we decided that in conceptualising our theories, it would make sense to indicate who actor the theory related to and what aspects of the intervention the theory is situated. This confirms tha argument that "actors and interventions are considered to be embedded in a social realist, which influences how the intervention is implemented and how the actors respond to it (or not)" [5]. To this end, we configured our theories using the Intervention-context-actor-mechanism-outcome (ICAMO) heuristic tool for analysis.

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Following from point two, we realised that formulating the initial programme theory and testing them based on the three main groups of actors (patients, health care workers and management) would take much more time. Consequently, our focus on the theory development was limited to the patients level. Our decision was informed by the fact that although the treatment and care of ART patients is based on the partnership between the patients and the health-care providers, the major responsibility of the self-care lies with the patients. This responsibility relates to adopting and making use of the resources, opportunities and constraints provided by the adherence-enhancing intervention. Because patients experience the coal phase of the intervention, their participation is important to obtaining the requisite outcome of the intervention and whether or not the intervention works.

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END

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APPENDICES

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OFFICE OF THE DEAN
DEPARTMENT OF RESEARCH DEVELOPMENT

28 September 2015

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Mr CF Mukumbang (School of Public Health)

Research Project:	A realist evaluation of the antiretroviral treatment-adherence club programme in the Cape Metropole area of the Western Cape Province, South Africa.
Registration no:	15/6/28

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

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REFERENCE: **WC_2015RP36_356**
ENQUIRIES: Ms Charlene Roderick

University of the Western Cape

Robert Sobukwe Road

Bellville

7535

For attention: **Mr Ferdinand Mukumbang**

Re: A REALIST EVALUATION OF THE ANTIRETROVIRAL TREATMENT-ADHERENCE CLUB PROGRAMME IN THE CAPE METROPOLE AREA OF THE WESTERN CAPE PROVINCE, SOUTH AFRICA.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries in accessing the following sites:

Heideveld CDC	**Anthea Abrahams**	**Contact No: 021 637 6686**
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Vanguard CDC	**Luntu Mbanga**	**Contact No: 021 695 8244**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (annexure 9) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

A T HAWKRIDGE

DR A HAWKRIDGE
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 9/3/2016.

CC **P OLCKERS** — **DIRECTOR: KLIPFONTEIN/ MITCHELLS PLAIN**
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BMJ Open

Realist evaluation of the antiretroviral treatment adherence club programme in selected primary healthcare facilities in the metropolitan area of Western Cape Province, South Africa: a study protocol

Ferdinand C Mukumbang,[1] Sara Van Belle,[2,3] Bruno Marchal,[1,2] Brian Van Wyk[1]

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ABSTRACT

Introduction: Suboptimal retention in care and poor treatment adherence are key challenges to antiretroviral therapy (ART) in sub-Saharan Africa. Community-based approaches to HIV service delivery are recommended to improve patient retention in care and ART adherence. The implementation of the adherence clubs in the Western Cape province of South Africa was with variable success in terms of implementation and outcomes. The need for operational guidelines for its implementation has been identified. Therefore, understanding the contexts and mechanisms for successful implementation of the adherence clubs is crucial to inform the roll-out to the rest of South Africa. The protocol outlines an evaluation of adherence club intervention in selected primary healthcare facilities in the metropolitan area of the Western Cape Province, using the realist approach.

Methods and analysis: In the first phase, an exploratory study design will be used. Document review and key informant interviews will be used to elicit the programme theory. In phase two, a multiple case study design will be used to describe the adherence clubs in five contrastive sites. Semistructured interviews will be conducted with purposively selected programme implementers and members of the clubs to assess the context and mechanisms of the adherence clubs. For the programme's primary outcomes, a longitudinal retrospective cohort analysis will be conducted using routine patient data. Data analysis will involve classifying emerging themes using the context-mechanism-outcome (CMO) configuration, and refining the primary CMO configurations to conjectured CMO configurations. Finally, we will compare the conjectured CMO configurations from the cases with the initial programme theory. The final CMOs obtained will be translated into middle range theories.

Ethics and dissemination: The study will be conducted according to the principles of the declaration of Helsinki (1964). Ethics clearance was obtained from the University of the Western Cape. Dissemination will be done through publications and curation.

Strengths and limitations of this study

- Antiretroviral treatment adherence clubs, aiming at engaging patients and staff in a long-term relationship to improve adherence to treatment, have proven to be effective in pilot settings in South Africa.
- Realist evaluation is a methodological approach that allows one to explore how and in which conditions such adherence clubs can be scaled up.
- This paper presents the research protocol of a realist research programme that will assess the implementation and effects of facility-based adherence clubs in the Metro area of the Western Cape Province (South Africa).
- Through empirical research in five settings, we will develop a programme theory that explains how adherence clubs lead to higher retention in care and better treatment adherence of HIV patients.
- Applying a realist evaluation approach can be challenging, and this study will contribute to methodological development by operationalising methods to use the Context-Mechanism-Outcome configuration in the analysis of multiple cases.

INTRODUCTION

South Africa is home to the largest number (6.8 million) of people living with HIV/AIDS (PLWHA) in the world.[1] The South African government consequently embarked on the fight against the AIDS pandemic through various programmes. As a result, an estimated 3.1 million (32.2%) PLWHA in South Africa have been initiated on antiretroviral therapy (ART) as of April 2015,[2] representing the largest ART programme in the world.[3] The challenge that the South African ART programme now faces is retaining these patients in care and ensuring that they continue to adhere to their ART medication. In early 2011, the adherence club model was

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RESEARCH ARTICLE

Towards Developing an Initial Programme Theory: Programme Designers and Managers Assumptions on the Antiretroviral Treatment Adherence Club Programme in Primary Health Care Facilities in the Metropolitan Area of Western Cape Province, South Africa

Ferdinand C. Mukumbang[1,2]*, Sara van Belle[2,3], Bruno Marchal[1,2], Brian van Wyk[1]

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Abstract

Background

The antiretroviral adherence club intervention was rolled out in primary health care facilities in the Western Cape province of South Africa to relieve clinic congestion, and improve retention in care, and treatment adherence in the face of growing patient loads. We adopted the realist evaluation approach to evaluate what aspects of antiretroviral club intervention works, for what sections of the patient population, and under which community and health systems contexts, to inform guidelines for scaling up of the intervention. In this article, we report on a step towards the development of a programme theory—the assumptions of programme designers and health service managers with regard to how and why the adherence club intervention is expected to achieve its goals and perceptions on how it has done so (or not).

Methods

We adopted an exploratory qualitative research design. We conducted a document review of 12 documents on the design and implementation of the adherence club intervention, and key informant interviews with 12 purposively selected programme designers and managers. Thematic content analysis was used to identify themes attributed to the programme actors, context, mechanisms, and outcomes. Using the context-mechanism-outcome configurational tool, we provided an explanatory focus of how the adherence club intervention is roll-out and works guided by the realist perspective.

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Implementation Science

SYSTEMATIC REVIEW Open Access

An exploration of group-based HIV/AIDS treatment and care models in Sub-Saharan Africa using a realist evaluation (Intervention-Context-Actor-Mechanism-Outcome) heuristic tool: a systematic review

Ferdinand C. Mukumbang[1,2*], Sara Van Belle[2], Bruno Marchal[1,2] and Brian van Wyk[1]

Abstract

Introduction: It is increasingly acknowledged that differentiated care models hold potential to manage large volumes of patients on antiretroviral therapy (ART). Various group-based models of ART service delivery aimed at decongesting local health facilities, encouraging patient retention in care, and enhancing adherence to medication have been implemented across sub-Saharan Africa. Evidence from the literature suggests that these models of ART service delivery are more effective than corresponding facility-based care and superior to individual-based models. Nevertheless, there is little understanding of how these care models work to achieve their intended outcomes. The aim of this study was to review the theories explicating *how* and *why* group-based ART models work using a realist evaluation framework.

Methods: A systematic review of the literature on group-based ART support models in sub-Saharan Africa was conducted. We searched the Google Scholar and PubMed databases and supplemented these with a reference chase of the identified articles. We applied a theory-driven approach—narrative synthesis—to synthesise the data. Data were analysed using the thematic content analysis method and synthesised according to aspects of the Intervention-Context-Actor-Mechanism-Outcome heuristic-analytic tool—a realist evaluation theory building tool.

Results: Twelve articles reporting primary studies on group-based models of ART service delivery were included in the review. The six studies that employed a quantitative study design failed to identify aspects of the context and mechanisms that work to trigger the outcomes of group-based models. While the other four studies that applied a qualitative and the two using a mixed methods design identified some of the aspects of the context and mechanisms that could trigger the outcomes of group-based ART models, these studies did not explain the relationship(s) between the theory elements and how they interact to produce the outcome(s).

(Continued on next page)

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BMC Public Health

RESEARCH ARTICLE Open Access

Exploring 'generative mechanisms' of the antiretroviral adherence club intervention using the realist approach: a scoping review of research-based antiretroviral treatment adherence theories

Ferdinand C. Mukumbang[1,2*], Sara Van Belle[2,3], Bruno Marchal[1,2] and Brian van Wyk[1]

Abstract

Background: Poor retention in care and non-adherence to antiretroviral therapy (ART) continue to undermine the success of HIV treatment and care programmes across the world. There is a growing recognition that multifaceted interventions – application of two or more adherence-enhancing strategies – may be useful to improve ART adherence and retention in care among people living with HIV/AIDS. Empirical evidence shows that multifaceted interventions produce better results than interventions based on a singular perspective. Nevertheless, the bundle of mechanisms by which multifaceted interventions promote ART adherence are poorly understood. In this paper, we reviewed theories on ART adherence to identify candidate/potential mechanisms by which the adherence club intervention works.

Methods: We searched five electronic databases (PubMed, EBSCOhost, CINAHL, PsycARTICLES and Google Scholar) using Medical Subject Headings (MeSH) terms. A manual search of citations from the reference list of the studies identified from the electronic databases was also done. Twenty-six articles that adopted a theory-guided inquiry of antiretroviral adherence behaviour were included for the review. Eleven cognitive and behavioural theories underpinning these studies were explored. We examined each theory for possible 'generative causality' using the realist evaluation heuristic (Context-Mechanism-Outcome) configuration, then, we selected candidate mechanisms thematically.

Results: We identified three major sets of theories: Information-Motivation-Behaviour, Social Action Theory and Health Behaviour Model, which explain ART adherence. Although they show potential in explaining adherence bebahiours, they fall short in explaining exactly why and how the various elements they outline combine to explain positive or negative outcomes. Candidate mechanisms indentified were motivation, self-efficacy, perceived social support, empowerment, perceived threat, perceived benefits and perceived barriers. Although these candidate mechanisms have been distilled from theories employed to explore adherence to ART in various studies, the theories by themselves do not provide an explanatory model of adherence based on the realist logic.

(Continued on next page)

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