

A FORMATIVE AND OUTCOME EVALUATION OF A COMMUNITY BASED
ANTIRETROVIRAL THERAPY ADHERENCE PROGRAMME: THE CASE OF SIZOPHILA,
CAPE TOWN, SOUTH AFRICA

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A dissertation submitted in partial fulfilment of the requirements for the award of the
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COMPULSORY DECLARATION:

This work has not been previously submitted in whole, or in part, for the award of any degree. It is my own work. Each significant contribution to, and quotation in, this research paper from the work, or works of other people has been attributed, cited and referenced.

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EXECUTIVE SUMMARY

This dissertation is informed by a formative and outcome evaluation of the Sizophila programme, a community based antiretroviral therapy (ART) programme. The programme is administered by the Desmond Tutu HIV Foundation, a non-profit organization. The aim of the programme is to enhance ART health outcomes and promote individual wellbeing among people accessing human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) related services in the Hannan-Crusaid Centre. The goal of the evaluation was to assess the Sizophila programme implementation and to determine the impact of the home visit intervention on the medium-term outcomes of HIV viral load suppression and loss to follow-up. The evaluation was primarily for the programme staff.

An implicit Sizophila programme theory was explicated from the programme staff and the evaluator reviewed relevant programme documentation to formulate an explicit programme theory. To assess the plausibility of this theory, social science perspectives based on reviews of empirical evidence of previous research were solicited. The initial Sizophila programme theory was simplistic in assuming a simple cause-effect relationship. The final programme theory recognised that programme interventions function through certain moderators and mediators that can either strengthen or weaken the intervention-outcome effect.

The amended programme theory informed the implementation evaluation questions for the Sizophila programme. In essence, the implementation evaluation focused on 3 domains namely service utilisation, and service delivery and organisational support. The service utilisation questions were answered through secondary data. Service delivery questions were elicited through questionnaires, an interview and secondary data while data on organisational support was obtained through a questionnaire. Results revealed that on the whole, the programme was implemented with fidelity.

An outcome evaluation relied on secondary data to answer questions. The study determined the impact of a home visit on HIV viral load and lost to follow-up outcomes. Therefore, a quasi-experimental retrospective design was used to measure the impact of an initial home visit on the outcomes of focus. The design however, succumbed to

threats to internal validity which were beyond the evaluator's control namely selection bias and attrition.

To assess the impact of the home visit intervention, a logistic regression was used to determine the predictive value of an initial home visit on HIV viral load suppression and lost to follow-up outcomes. Results revealed that the initial home visit had a significant impact on lost to follow-up but not on HIV viral load suppression. The following were specific findings of the outcome evaluation:

- The home visit intervention significantly predicted lost to follow-up ($p = .012$), and accounted for 5.5% of the variance. Patients not receiving the home visit were 2.87 times more likely to be lost to follow-up than those receiving a home visit.
- In addition, a logistic regression determined the predictive value of the home visit on HIV viral load suppression. Results revealed that the initial home visit did not significantly predict HIV viral load suppression ($p = .13$). This was highly attributed to attrition of patients which led to an underpowered study ($1 - \beta$ error prob) = 0.38.

To sum it all up, the Sizophila programme was implemented with fidelity, however attention should be given on data capturing irregularities as these have a potential to obscure the positive effects of a well implemented programme. The outcome evaluation presented mixed results however, due to the limitation noted above, the HIV viral load outcome findings cannot be generalised to a wider population. Consequently, resources permitting, a more rigorous prospective design is recommended for future outcome evaluations.

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CHAPTER ONE

BACKGROUND

Since the emergence of the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) epidemic, more than 60 million people have acquired HIV related illnesses that have claimed nearly 20 million lives (WHO, 2012). The introduction of highly active antiretroviral therapy (HAART) has significantly improved survival rates among people living with HIV/AIDS (PLWHA) (Abaasa et al., 2008). However, the long-term success of HAART has been impeded by the absence of unflinching treatment adherence. Antiretroviral medication potency requires exceptionally high levels of adherence, taking at least 95% of the prescribed dose (Amico, Toro-Alfonso & Fisher, 2005; Mills et al., 2006).

HIV treatment regimens remain complex. This, in conjunction with toxicity concerns, adverse side effects, alterations to day-to-day life and difficulties in maintaining follow-up appointments often presents challenges to long-term adherence (Abaasa et al., 2008). The authors reveal that a suboptimal adherence level is problematic as it results in insufficient drug concentrations to suppress HIV replication. Consequently, this can lead to drug-resistant HIV strains and moderate the role of antiretroviral therapy (ART) in preventing viral replication (Abaasa et al., 2008).

Because enhancing optimal adherence is paramount in maintaining the desired levels of viral suppression, strategies to improve adherence are vital for PLWHA (Rueda et al., 2006). Specifically, community health workers (CHWs) have been identified as important human resources that have the potential to change the delivery of health care services (Schneider, Hlophe & van Rensburg, 2008). The concept of CHWs is not new. It dates back as far as the 1950s when the barefoot doctors and the Co-operative Medical Scheme financed health care in the rural parts of China (Li et al., 2012). Since then, community engagement in health care services has gained popularity in managing chronic conditions such as Tuberculosis (TB) and HIV/AIDS (Simon et al., 2009).

Kenya, Chida, Symes, and Shor-Posner (2011, p. 525) note that “while there is no universal consensus on how to improve medical adherence in HIV-positive populations,

the community health worker model is emerging as an effective strategy to overcome barriers to HAART adherence.” Various researchers have provided evidence for the effectiveness of programmes utilising community care workers in enhancing ART adherence. For instance, Altice, Maru, Bruce, Springer, and Friedland (2007) used directly administered antiretroviral therapy (DAART) to improve adherence. Similarly, ART community based social support interventions proved effective and feasible in rural South Africa (Igumbor, Scheepers, Ebrahim, Jason & Grimwood, 2011).

The Sizophila “we shall survive” programme adopted the concept of community based ART adherence counselling in 2002 (Desmond Tutu HIV Foundation (DTHF) Report, 2013). The goal of the programme is to ensure ART success by utilising CHWs to integrate HIV care both within health care facilities and the community. The Sizophila programme is the focus of this evaluation.

For this reason, the evaluation commences with a full description of the programme, including its process and outcome theory. The plausibility of the programme is then assessed by means of a literature review. The suggested alternate programme theory informs the evaluation focus; a formative and outcome evaluation of the Sizophila programme.

Programme Description

The following programme description was obtained from the Desmond Tutu HIV Foundation (DTHF) website (www.desmondtutuhivfoundation.org.za), the programme documents (The Sizophila Adherence Counsellors: Project description, Comprehensive Health Programmes: HIV and TB Projects-2013) and discussions with the Sizophila Programme Manager (Dr R. Kaplan, personal communication, February 21st, 2014).

The Sizophila programme is a civil society-initiated project. The partners include the DTHF, the Western Cape Provincial Department of Health and the Hannan-Crusiad. The main funders include the Western Cape Provincial Department of Health, Crusaid, the United Kingdom charity for AIDS, Heiser Foundation (United States of America), President’s Emergency Plan for AIDS Relief (PEPFAR), Global Fund Grant administered by the Provincial Authority of the Western Cape and Freshlyground Band (South Africa) (DTHF Report, 2013).

Launched in 2002 as a project of the DTHF, the Sizophila ART adherence counselling programme operates from the Hannan-Crusaid Centre in Gugulethu. Gugulethu is a township in Cape Town characterised by widespread poverty and high levels of unemployment (Department of Health of Western Cape, 2003). The district is estimated to have a population of more than 400 000 (DTHF Report, 2013). The majority of the population rely on state-funded health services. The HIV prevalence is estimated at 28%, the highest in Cape Town (Department of Health of Western Cape, 2003).

The programme was initiated in recognition of the devastating impact of HIV/AIDS on individuals, families and communities. The realisation that community support structures coupled with ART were effective in promoting ART health outcomes and improving the quality of life among PLWHA prompted the DTHF to respond to the need to administer ART medication and maintain excellent adherence levels (DTHF Report, 2013). Thus, the following objectives were formulated to inform intervention activities:

1. To support the strategic goals of the department of health with regards to HIV counselling and testing in the health facility and the community,
2. To integrate health care linkages both at health facility and community level,
3. To provide antiretroviral treatment adherence support in the community,
4. To provide HIV/TB prevention and promotion services to TB/HIV patients, and
5. To reduce the incidence of HIV infection in the community.

To roll-out a functional programme, the DTHF sought to employ out-of-job untrained individuals living with HIV and accessing ART in the Hannan-Crusaid centre. These individuals came to be known as Therapeutic counsellors (TCs) and community care workers (CCWs). To date, the DTHF has employed 25 TCs and CCWs (Dr R. Kaplan, personal communication, February 21st, 2014).

Recruitment process

Kaplan, Orrell, Lawn, Bekker, and Wood (2014) note that CCWs or TCs should be able to work in the areas where they live and should know the 'assigned' patients personally. Therefore, to become a Sizophila TC/CCW, a vacancy notice is advertised via posters in

the clinic. Interested candidates apply and undergo interviews. Prospective candidates are eligible for an interview if they satisfy the following selection criteria:

1. Candidates are HIV positive and accessing ART treatment at the centre.
2. Candidates have shown good ART adherence levels.
3. Candidates are willing to work with the community and act as role models.

Successful applicants receive an initial training. Community care workers and TCs undergo a 10 and 20 day training schedule respectively (Dr R. Kaplan, personal communication, February 21st, 2014). This is followed by a 3 month on the job training until deemed 'ready'. Training equips TCs/CCWs with the skills to execute their duties.

In essence, TCs provide pre and post treatment adherence counselling, introduce patients to CCWs, counsel both new and non-adhering patients, provide education on HIV prevention measures and linkages to social services (DTHF Report, 2013). On the other hand, CCWs conduct home assessments and subsequent home visits, track and recall patients who have defaulted ART treatment, conduct random pill checks, and raise HIV campaigns in the community (DTHF Report, 2013). The services offered by TCs and CCWs are interlinked. Both groups emphasise patient education and support.

Target population

The programme aims to provide pre and on-treatment adherence counselling to patients commencing ART treatment. The target population comprise mainly of individuals residing in Gugulethu Township who cannot afford private medical insurance and have been diagnosed with HIV and are eligible to start ART. The target population therefore includes:

- Adults newly diagnosed with HIV,
- HIV positive patients transferred from other clinics to Hannan-Crusaid centre,
- Pregnant women newly diagnosed with HIV (with or without advanced HIV),
- Paediatrics and adolescents newly diagnosed with HIV, and
- Most at risk populations newly diagnosed with HIV.

Programme Impact Theory

Rossi, Lipsey, and Freeman (200, p. 93) defined programme theory as “a set of assumptions about the relationship between the strategy and tactics the program has adopted and the social benefits it is expected to produce.” The programme impact theory explains the causal relationship between inputs and outcomes (Bickman, 1987). This theory focuses on the expected changes the programme will bring about to programme beneficiaries and/or social conditions.

A review of programme records such as the DTHF Sizophila Counselling Business Plan and the Sizophila Project Description document did not reveal any articulated programme theory. In developing a programme theory, it is paramount that an evaluator draws forth and describes an implicit theory before it can be analysed and assessed (Rossi et al., 2004). This entails extracting expectations about programme functions and formulating the anticipated results.

Though not explicitly articulated or illustrated graphically, the Sizophila programme theory was verbally communicated by programme staff (Dr R. Kaplan & Dr L.G. Bekker, personal communication, March 31st, 2014). For this purpose, the evaluator obtained programme goals, functions, components and activities as well as the implicit programme theory. This process gave rise to the Sizophila logic model (Figure 1).

Figure 1 illustrates the Sizophila programme inputs, activities, and outcomes. Based on the model, it is clear that for a programme to function; sufficient resources should be channelled into it. These resources include CCWs and TCs. Activities are intentional processes, tools and actions that form part of the programme implementation (Rossi et al., 2004). The activities that have been adopted for the Sizophila programme are shown in the logic model and will be explained in the process theory.

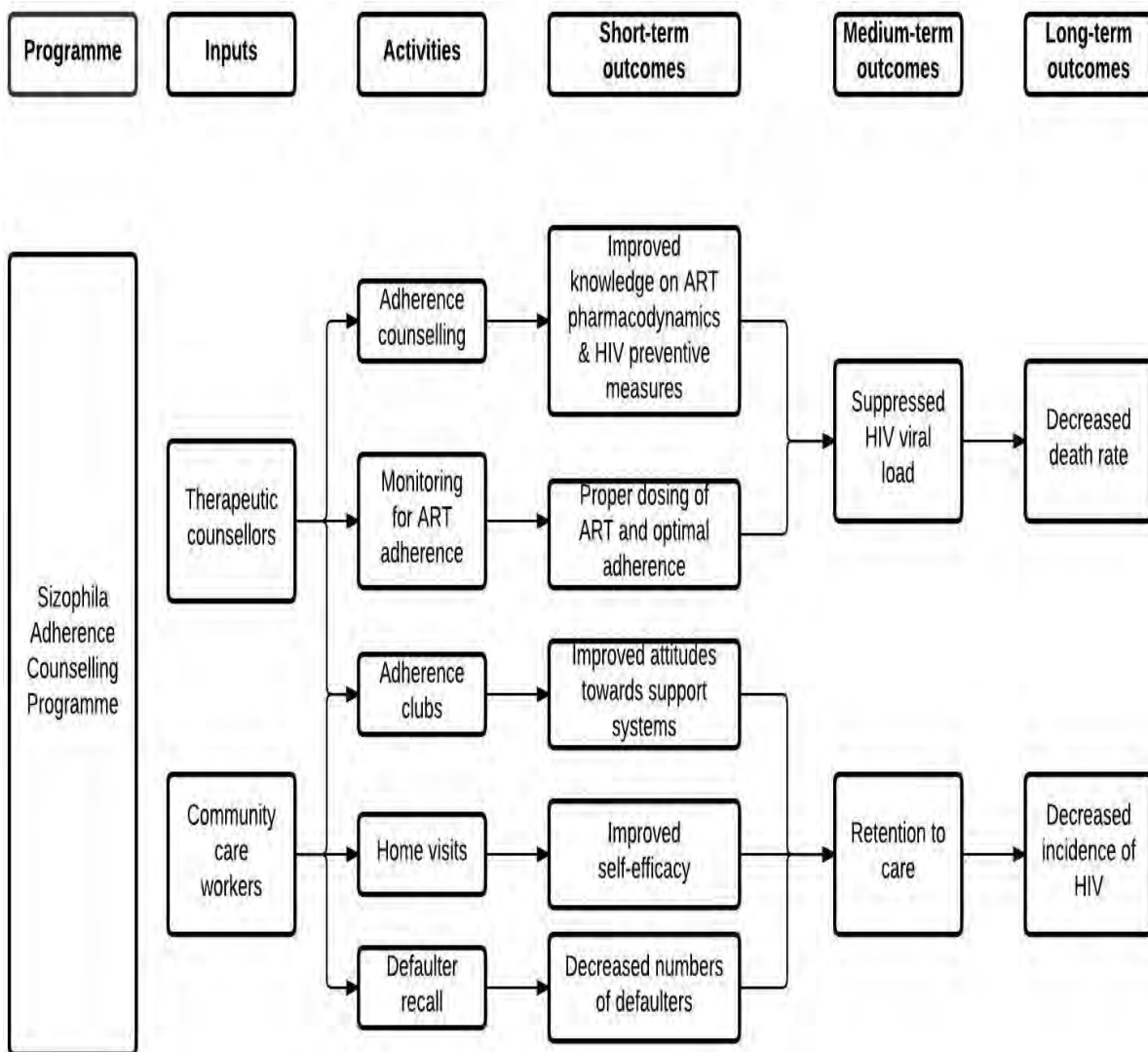


Figure 1. The Logic model for Sizophila adherence counselling programme

The programme activities offered to the beneficiaries will yield the intended outcomes. Outcomes can either be proximal or distal. A distal outcome is achieved within 7-10 years in the life of a programme. The Sizophila impact theory postulates that the activities delivered will lead to the desired outcomes as illustrated in Figure 1.

To accomplish this change process, the programme theory should be explicit about the cause-effect relationship; between the activities and the desired outcomes (Rossi et al., 2004). The ultimate distal outcome envisaged for the Sizophila programme is to decrease the HIV incidence and HIV related death rate in the community.

Process Theory

According to Rossi et al. (2004), process evaluations are designed to assess programme performance, operations, and the execution of intended functions. This type of evaluation examines the degree to which the intended target population receives the programme (coverage), the extent to which the target population receives the intended programme services (service delivery) and the resources available to complete the programme tasks (organisational support) (Rossi et al., 2004). The process theory articulates the link between the programme activities and outcomes. The following section outlines the components of the Sizophila process theory.

Programme resources

As aforementioned, programme resources are vital in achieving the desired outcomes. The process theory begins by articulating the resources available to achieving the intended outcomes. In case of the Sizophila, these include TCs and CCWs.

Programme activities

Clinical services are provided by doctor-nurse- CCW/TC teams. Currently the clinic has about 5000 patients (DTHF Report, 2013). The following section outlines the Sizophila programme activities.

Treatment initiation - the initial home visit

To begin the patient registration process, the CCW completes a Community Care Worker Home Assessment form (CCWHAF) during a pre-treatment home assessment visit. This initial home visit is conducted to assess the patients' social characteristics. In addition, the home visit serves to establish treatment readiness, identify possible and real barriers to ART adherence (Dr R. Kaplan, personal communication, February 21st, 2014).

In as much as the home visit intervention is advocated for, not all patients receive the initial home visit. Approximately 5% of the patients commencing ART treatment decline the home assessment visit. Also, a fairly large number of patients cannot be visited as they reside out of the geographic range prescribed by the CCWs' operating zones (Dr

L.G. Bekker, personal communication, March 31st, 2014). Thus, these patients miss out on the initial and subsequent home visits.

As part of standard of care (SOC), patients are required to attend 3 treatment preparedness sessions. They either choose to attend 3 group counselling sessions or 2 individual counselling sessions and 1 group session. This counselling serves to:

1. Provide ART treatment information, and the importance of adherence,
2. Identify potential barriers to ART adherence,
3. Address potential barriers, and
4. Discuss treatment care plans and schedules.

After the initial household visit, CCWs report the outcome of the visit to a multidisciplinary task team. This team reviews the patient's clinical and non-clinical data to assess ART eligibility (Dr R. Kaplan, personal communication, February 21st, 2014). Where the CCW identifies conditions that are considered less ideal for ART initiation, these are noted by the CCW for intervention.

Adherence counselling

This is an organised approach to enhancing ART medication adherence. The purpose of adherence counselling is to reinforce ART adherence so as to promote favourable health (World Health Organisation (WHO), 2007). Antiretroviral adherence counselling integrates other HIV prevention measures. WHO (2007) note that the objectives of ART adherence counselling include:

1. Providing ART related information and psychosocial support to facilitate decision making processes that are tailored according to individual needs,
2. Support HIV patients in adopting ART adherence and positive living behaviour, and
3. Facilitate unswerving ART treatment adherence practices.

Ongoing home visits

Post ART initiation, new patients receive one home visit per month for the first four months of treatment initiation (Dr R. Kaplan, personal communication, February 21st,

2014). These home visits typically end at 4 months post-ART initiation. However, the continuation of home visits depends on the first HIV viral load quantification result conducted at 4 months after ART initiation. Patients with a suppressed HIV viral load (lower than detectable limits) are deemed 'green alerts', while, those having virologic failure (> 1000 copies/ml) and an unsuppressed viral load at any point after treatment initiation are classified as 'red alerts' (Kaplan et al., 2014). Patients in the red alert category receive extra care. This includes additional adherence counselling sessions, as well as regular home and clinic visits (Kaplan et al., 2014). Patients deemed as green alerts are weaned off TCs' services to adherence clubs.

Pill counts

To monitor adherence, random pill counts are conducted on doses remaining in the container with each visit to the health facility. This data is fed back to patients as adherence counselling aids (Dr R. Kaplan, personal communication, February 21st, 2014).

Adherence clubs

The centre initiated ART adherence clubs in 2012. These clubs are managed by TCs. As indicated earlier, adherence clubs are specifically for green alert patients who have been discharged from TCs' services and down referred in care. Down referral occurs after patients have shown stability and improved care on ART. The primary purpose of adherence clubs is to provide ongoing counselling, social support and retain patients in care (DTHF Report, 2013).

Defaulter recall

This involves the physical tracing of patients who have been missing at the clinic for 12 consecutive weeks from the last facility visit and cannot be classified as deceased or transferred-out (Dr R. Kaplan, personal communication, February 21st, 2014).

The service utilisation plan

This is a depiction of assumptions of how and why the anticipated beneficiaries will be engaged with the programme and how they progress through each point to initiate the

change process documented in the programme impact theory (Rossi et al., 2004). Figure 2 shows a service utilisation flowchart of the Sizophila programme.

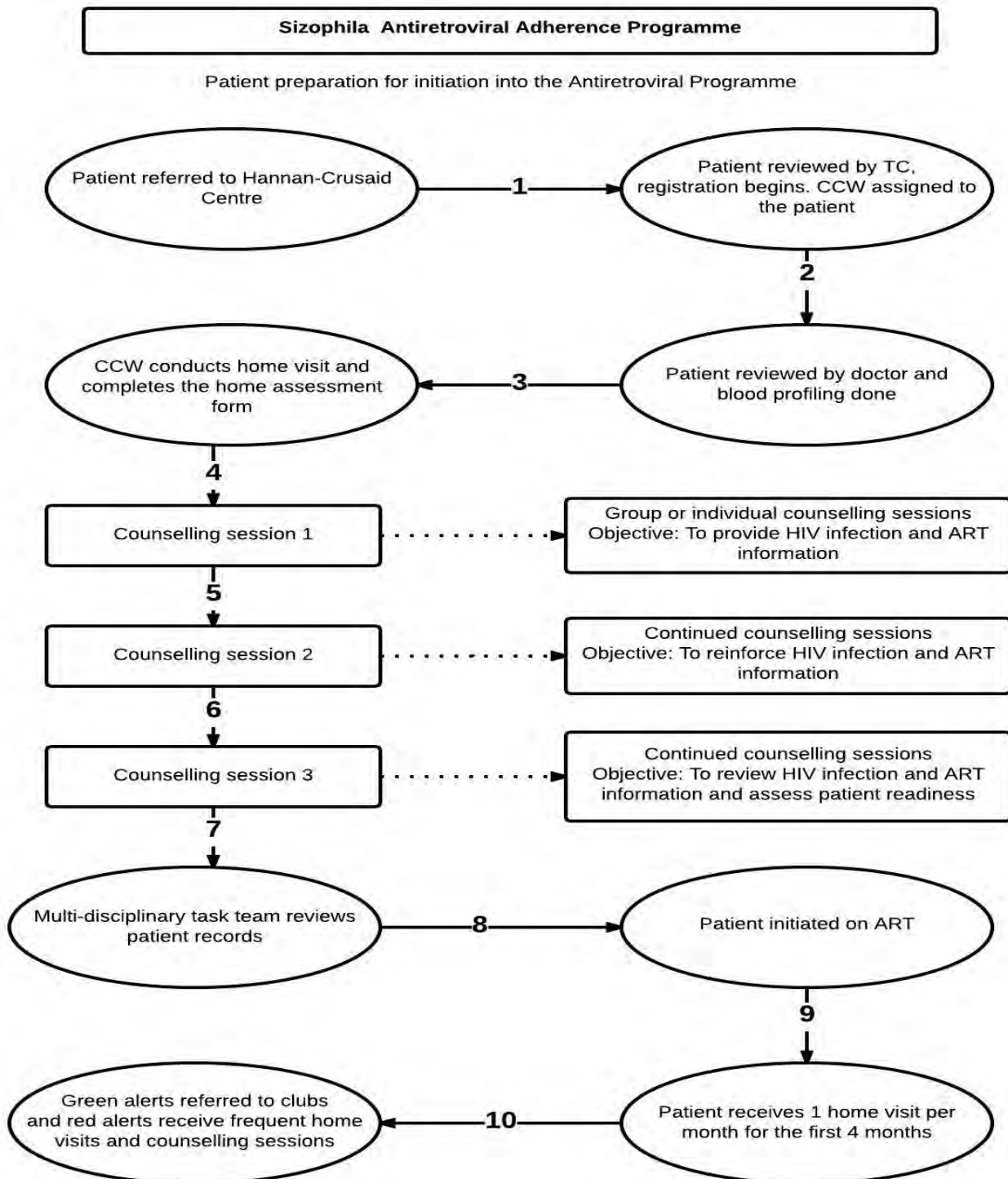


Figure 2. The Sizophila adherence counselling service utilisation

The organisational plan

Another component of the process theory relates to organisational support. The organisational plan articulates the programme functions and activities necessary for the

programme to bring about anticipated social changes (Rossi et al., 2004). The Sizophila organisational plan is depicted in Figure 3. This involves the recruitment and training of TCs and CCWs. Using acquired counselling skills, TCs and CCWs will disseminate the programme activities to the intended target population.

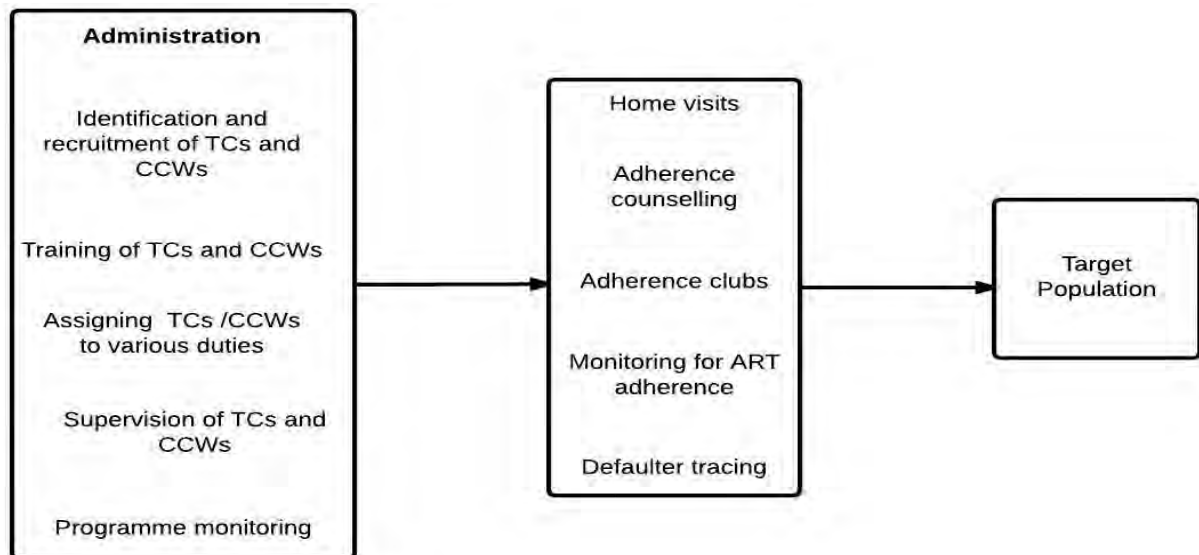


Figure 3. Sizophila organisational plan

After reviewing the programme activities, programme impact theory and the process theory, the evaluator and the stakeholders agreed on a formative evaluation of the Sizophila programme. It is expected that the study will provide Sizophila programme staff with critical information on how best to improve the programme and achieve the intended outcomes. According to Patton (1997), this type of evaluation strives for strengthening or improving a programme by assessing programme delivery, the quality of implementation and the organisational context. A programme theory is vital in guiding evaluators on how best to evaluate a programme (Rossi et al., 2004). Essentially this change-oriented evaluation technique assesses a programme of any discrepancies between the anticipated direction and the outcomes of a programme (Chen, 1990). It provides a platform for assessing the strength and weaknesses of a programme with a goal of programme improvement. As such, this evaluation will focus on assessing the implementation of Sizophila programme activities and the extent to which these activities are implemented. Moreover, evaluation will assess if the implemented programme activities do bring about the desired medium-term outcomes.

Assessment of plausibility of programme theory and logic

The specification of the programme model and assessment of how distinct and evaluable the model is; are important elements in determining programme theory plausibility (Bickman, 1987). In essence, a plausibility check contrasts the programme assumptions alongside with what social science research has shown to be effective (Chen, 1990). The goal of this literature review is to assess the plausibility of the Sizophila programme theory. The literature review is in two parts. First, it identifies factors that influence successful implementation of ART adherence programmes mainly because these factors either mediate or moderate the effectiveness of ART adherence programmes. Second, it explores empirical studies linking ART adherence programmes with ART health outcomes.

Search parameters for literature review

A search of online academic databases such as MasterFILE Premier, Academic Premier, SocINDEX and Sage Journals was conducted from the Electronic Library at the University of Cape Town. The constantly changing scope and innovative approaches used in the management of HIV/AIDS necessitated the limiting of articles to those published between 2000 and 2014. Search terms included HIV/AIDS, evaluation of ART programmes, community based HIV care, ART adherence programmes, community health workers, ART adherence support systems and South Africa. In addition, extensive internet searches were also carried out to identify relevant and reputable data sources. Relevant articles were located through broader search engines with search terms mentioned earlier. For the same reason noted above, internet searches were limited to articles published between 2000 and 2014.

Factors affecting ART programme implementation

Most evaluations have reported on outcomes of behaviour change interventions but have either given limited or no evidence regarding programme implementation (Leeman et al., 2010). Brownson et al. (as cited in Leeman et al., 2010) argues that while evidence on efficiency is important, it is equally important to gather evidence on how programmes are implemented and how this differs across contexts. To accomplish this, Carroll et al. (2007) proposes that implementation fidelity can be measured in terms of

participant responsiveness, quality of delivery and programme differentiation. These elements will be used to explain the implementation of ART programmes.

Participant responsiveness

Antiretroviral programmes are commonly implemented with an optimistic approach that participants will fully engage in processes that facilitate the adoption of positive behaviour change skills. However, the failure of participants to partake in such interventions may result in low coverage or failure; consequently, implementation fidelity might be low (Carroll et al., 2007). This view was later confirmed by Leeman et al. (2010) who reported on a synthesis of evidence on implementation of programmes aimed at improving ART adherence in United States. Although interventions varied in length, models and approaches to ART adherence, there was general consensus that interventions that risked confidentiality such as directly observed therapy (DOT) and group interventions had the highest refusal rates (53% and 40% respectively) (Leeman et al., 2010). Reasons for nonattendance included feelings of discomfort and because participants felt asocial to group dynamics (Simoni et al. as cited in Leeman et al., 2010). Moreover, an acceptability study of a DOT programme revealed that only 17% of the participants preferred the DOT programme (Santos et al. as cited by Leeman et al., 2007). Furthermore, participants were willing to partake in the DOT programme if they met with the programme implementer at a location of their choice (Santos et al. as cited by Leeman et al., 2007). The above findings therefore suggests that in general, programmes aimed at group and/or DOT interventions are likely to experience low coverage.

However, it is important to note that these studies were conducted in developed countries. The evidence from these studies might have little relevance to Sub-Saharan Africa as implementation is likely to depend on the context. It is hypothesised that resource-intensive programmes aimed at individuals could be problematic to implement in Sub-Saharan Africa due to large numbers of patients, insufficient resources and the public health approach to treatment (Bärnighausen et al., 2011). For instance, it was revealed that in South Africa personalised individual interventions were only feasible and effective if programmes utilised families or friends (Nachega et al., 2007).

Flexibility of intervention

Flexibility of interventions has been associated with higher rates of attendance. Generally, interventions that allow for adjustment of time and appointment location have been found to be more acceptable than those with fixed appointments (Leeman et al., 2010). Directly observed therapy and telephonic interventions were viewed as more flexible compared to group and individual counselling with predetermined times for sessions (Leeman et al., 2010).

Patient-provider relationship

The strength of the participant-provider relationship is regarded as vital for service utilisation and ART adherence (WHO, 2006). Visnegarwala et al. (2006) and Bontempi et al. (as cited in Leeman et al., 2010) revealed that participants in ART adherence programmes viewed the relationship with an intervener as vital; as interveners provided social support and constructive reinforcement. Leeman et al. (2010) hypothesised that attendance rates are greater if intervener-participant rapport is strong. In fact, Leeman et al. found that strong patient-provider relationships were associated with higher retention rates over time. In essence, interventions tailored at individual education or counselling were reported as having strong relationships. Moreover, to confirm this proposition, Purcell et al. (2007), in an assessment of the efficacy of peer-delivered interventions to promote ART adherence in Mozambique, revealed that attendance and patient retention were higher in participants receiving individual based interventions that enhanced the relationship between the patient and the provider.

Programme differentiation

Dusenbury, Brannigan Falco and Hansen (2011, p. 244) define program differentiation “as identifying unique features of different components or programs so that these components or programs can be reliably differentiated from one another.” Interventions aimed at improving ART adherence have varied depending on the context and audience. Programme implementers in studies by Taiwo et al. (2010) and Cooperman et al. (2012) utilised interventions based on behavioural (enhance ART adherence through direct behaviour modification) and cognitive (affect ART adherence

through education and clarification of concerns) approaches to enhance ART adherence. Also, Kabore et al. (2010) supplemented behavioural and cognitive approaches with biological interventions in which participants received food parcels and nutritional supplements. Some programmes have included affective interventions in which ART adherence was enhanced through emotional support (Bärnighausen et al., 2011).

It appears that most ART programmes utilise cognitive and behavioural approaches to enhancing ART adherence (Visnegarwala et al., 2006; Sarna et al., 2008; Kabore et al., 2010; Taiwo et al., 2010; Cooperman et al., 2012). Vital to these approaches is the dissemination of information and motivation to enhance positive behavioural skills, of which without these aspects, the programmes would probably fail. An added advantage to these approaches is the direct observation of ART ingestion and use of ART monitoring systems such as cues for pill dosage and pill counts (Kipp et al., 2012).

Despite the differences in approaches to ART programme implementation, what has been acknowledged as important is the ability of participants to respond to these interventions (Leeman et al., 2007) and for implementers to effectively implement the interventions (Carroll et al., 2007). The inability of participants to utilise these services and ineffective service delivery might possibly lead to implementation failure.

Quality of delivery

Carroll et al. (2007) suggests that the content of an intervention is its active ingredient as it primarily determines implementation success or failure. Thrasher et al. (as cited in Leeman et al., 2010) assessed the integrity of programme delivery and results revealed that in spite of extensive training and supervision, implementers only satisfied 2 of the 5 criteria benchmarks. In essence, the implementers' weakness lay in using reflective statements and using open-ended questions. Similarly, a study in South Africa evaluated the lay adherence counsellors' fidelity to an evidence-based intervention adopting motivational interviewing techniques (Dewing et al., 2013). Results revealed that counsellors failed to attain proficiency in implementing motivational interviewing (Dewing et al., 2013). Given these findings, the quality of intervention delivery moderates the link between an intervention and implementation fidelity. Carroll et al. noted that the inability to deliver the content of an intervention affects the extent to which full implementation is attained.

Facilitation strategies

Facilitation strategies ensure that programme interventions are delivered in a standardised manner. Williams et al. (2006) facilitated effective programme implementation by pairing nurses and peer educators. These teams were provided with an initial 1 month of training, didactic HIV/AIDS information, substance abuse, and adherence monitoring techniques (William et al., 2006). To ensure fidelity and uniformity in the delivery of the intervention, programme implementers were required to document and keep detailed descriptions of the content and delivery of intervention. In addition, these narratives were reviewed at the conclusion of every visit (Williams et al., 2006). Similarly, Kenya et al. (2013) enhanced implementation fidelity by ensuring that community health workers met with supervisors and discussed cases and recommendations on programme implementation. Although facilitation strategies have been found to enhance implementation fidelity, Carroll et al. (2007) argues that these strategies may not necessarily translate to desired outcomes. This is confirmed by a study conducted by William et al. (2006) which failed to show a significant effect on ART outcomes despite instituting facilitation strategies.

Conclusion

The above literature is valuable in that it draws attention to factors that affect the implementation of ART adherence programmes. These factors have the potential to moderate the relationship between programme interventions and the attainment of ART health outcomes. The Sizophila programme incorporates some of the above mentioned factors such as facilitation strategies and intervention flexibility. The level of adherence/fidelity to programme implementation will primarily determine implementation success or failure.

Empirical evidence linking ART programmes and ART health outcomes

Appendix A shows 20 detailed descriptions of studies linking ART adherence programmes and ART health outcomes. From these articles, 10 were published in the United States of America, 10 in Sub-Saharan Africa of which 4 were in South Africa. Studies utilised terminologies such as patient/treatment advocates, peer supporters

and community counsellors; these are synonymous with the term community care workers.

Type of interventions

Studies reviewed in the literature provided descriptions of interventions used to improve ART health outcomes. Some interventions included DOT (Nachega et al., 2010), peer mentoring (Purcell et al., 2007), home visits (Williams et al., 2006), treatment advocacy (Bogart et al., 2012), motivational interviewing and cognitive-behavioural counselling (Cooperman et al., 2012) and psycho-educative interventions (Tuldra et al., 2000). In essence, these studies sought to establish the potential efficacy of using ART programmes in enhancing ART health outcomes. Programme interventions varied from 4 months to 48 months.

Target population

Five articles targeted specific populations such as women (Visnegarwala et al., 2006) and drug users (Williams et al., 2006; Altice et al., 2007; Purcell et al., 2007; Cooperman et al., 2012). The rest focused on general patients.

Type of study and sample size

Eleven studies were randomised control trials (RCTs). Other studies utilised cross-sectional designs, qualitative designs, case studies with participant observations, prospective cohort and community based participatory research. The sample size ranged from 9 to 966 participants.

Efficacy of ART adherence programmes

Most of the studies reviewed (17 out of 20) revealed that ART adherence programmes contributed significantly to the attainment of ART health outcomes. Typically, the majority of the studies reported viral load suppression (Sarna et al., 2008; Taiwo et al., 2010; van Loggerenberg et al., 2014), retention to care (Visnegarwala et al., 2006), high adherence levels (Williams et al., 2006; Pearson et al., 2007; Sarna et al., 2008) and increased CD4 counts (Coetzee et al., 2004; Kabore et al., 2010).

These studies demonstrate that behavioural and cognitive learning processes are vital in achieving the desired ART health outcomes. Channelling specific interventions has proved vital in maintaining optimal levels of adherence (Tuldra et al., 2000; Amico et al., 2005). The authors suggest that information communication, motivation and change in attitudes and behaviours are important elements of ART adherence. Amico et al. (2005, p. 662) revealed that “Adherence-related information, a prerequisite of adequate adherence encompasses accurate information concerning one’s specific regimen, about how to utilize ART, about the requirements for adequate adherence, about specific side effects associated with one’s regimen, and information about potential drug interactions.” These sentiments have been echoed by Schneider, Kaplan, Greenfield, Li, and Wilson (2004) who noted that ART information dissemination enhanced optimal adherence.

The success of ART adherence programmes can also be explained by theories of human behaviours. Bandura, (1991) noted that a theory of human behaviour explains how human and cognitive behaviour is acquired along with how individuals motivate and regulate their behaviour in everyday life. Social modelling has the power to change human behaviour as it exhibit strong motivational effects (Bandura, 1991). The author suggests that good behaviour acts as social prompts that initiates, directs and aids modelled behaviour. In essence, the achievement of personal and programmatic goals is facilitated by interdependence efforts in which knowledge, skills and resources pooling act in concert to shape personal wellbeing (Bandura, 1991).

Tuldra et al. (2000) utilised a psycho-educative intervention adapted from Bandura’s self-efficacy theory. In essence, the intervention was mainly aimed at improving participants’ knowledge and cues to self-medication to improve self-efficacy. Tuldra et al. (2000) demonstrated that interventions aimed at health promotion go beyond biomedical interventions. Addressing adherence issues from a holistic perspective ensured that individuals were better equipped to deal with both social and health ills.

It appears that selecting an adherence model is context specific; it includes factors such as patient accessibility and circumstances, type and duration of intervention. These factors primarily determine the model to be applied. The use of cognitive and behavioural interventions can be observed in the Sizophila programme model.

Programme implementers utilise ART adherence monitoring systems (pill counts), cues for remembering dosing times and group/individual patient education to enhance ART adherence. In addition, programme implementers conduct home visits to identify barriers and/ or facilitators to ART adherence. Despite the differences in approaches to ART adherence, all models share a common goal of enhancing optimal ART adherence.

As aforementioned, 3 studies found no significant virologic outcomes between the treatment and the intervention group (Williams et al., 2006; Purcell et al., 2007; Nachega et al., 2010). These studies share a common attribute; they were all RCTs. Nevertheless, they differed in participant and intervention characteristics and duration. For instance, Williams et al., (2006) conducted a study on participants with a history of substance abuse. Participants in the treatment group received home visits for one year while the comparison group received SOC. Although participants in the treatment group showed greater adherence levels, the two groups did not differ in HIV viral load or CD4 cell count level (Williams et al., 2006). This was attributed to the fact that during enrolment most of the participants- just above half had already reached a ceiling effect (suppressed viral loads) at baseline thus restricting room for improvement. In addition, HIV clinical practices improved during the course of the intervention, thus, potentially weakening the impact of the intervention (Williams et al., 2006). Moreover, a compensatory element was observed in the control group. Participants exhibited enthusiasm in regularly scheduled interviews with professionals. These interviews were believed to improve self-awareness and adherence (Williams et al., 2006).

Purcell et al. (2007) compared peer mentoring interventions based on social learning theory, information, motivation and behaviour and social identity models against video discussion interventions among drug users over a period of 5 weeks. Both interventions were well received and there were no observable differences between the two groups. This was attributed to the method of delivery. Participants were not receptive to social group processes. In fact, individual sessions were well received and most attended (Purcell et al., 2007). The failure of the design to recognise individual features in addressing sexual issues was noted as potential hindrance to achieving the desired outcomes. In addition, the authors attribute this finding to lack of adequate time to build individual skills to affect behaviour change.

Nachega et al. (2010) utilised a DOT strategy to promote ART among new patients accessing HAART in Cape Town. The authors attributed the failure to show an effect to implementing a programme in a context with already high ART adherence levels. This proved futile suggesting that the intervention was probably not necessary.

Fisher et al. (2006) revealed that although the consequences of non-adherence and the effectiveness of adherence programmes are well documented, the conceptualisation of factors affecting ART adherence are lacking especially in social science or medical literature. In addition, Donaldson (2007) notes that social programmes, particularly those targeted at health behaviours are often implicitly stated focusing mainly on the intended outcomes. Implicit impact theories restrict the ability to detect or measure the bridging variables on which the outcomes are based on (Rossi et al., 2004). More so, if the process theory is poorly articulated; it might be difficult to account for the failure to produce the intended outcomes (Carroll et al., 2007). For this reason, a more detailed analysis of the assumptions that are ingrained in the programme theory is necessitated.

Critiquing the programme theory

In determining programme theory plausibility, it is important to consider various viewpoints regarding the logic of the programme. Therefore, it is essential to examine the perspectives of critics who query the association between programme activities and the intended outcomes. Consequently, these viewpoints will be utilised in critiquing the Sizophila programme theory.

One of the prominent critics of programme theory, Donaldson (2007) suggests that many health behaviour programmes are informed by a variety of multiple component interventions. These programmes are hypothesised to have multiple mediator and moderator variables. The recent model by Fisher et al. (2006), the information–motivation–behavioural skills model (IMB model) (Appendix B) incorporated constructs from earlier models or theories such as the health belief model, theory of reasoned action and theory of planned behaviour to explain ART adherence. Fisher et al. (2006) argues that optimal ART adherence is linked to (1) the extent to which an individual retains information, (2) the individual’s motivation to act on the information, and (3) the individual’s ability to adopt positive behavioural skills. These three components are discussed in the section that follows.

Firstly, ART adherence related information comprises giving out the exact information on specific schedules, ART dosing and optimal adherence, and side effects associated with the regimen (Fisher et al., 2006).

Secondly, an individual's motivation to adhere to treatment may be influenced by attitudes towards adherence, beliefs about health outcomes and evaluations of these outcomes (Amico et al., 2005). In essence, a highly motivated individual may be inclined to adhere to ART treatment and vice versa. Moreover, social motivation to adhere depends on one's perceptions about social support (Ajzen, 1991). Ajzen suggests that an individual's perceptions regarding ART adherence and social support are associated with greater ART adherence.

Lastly, behavioural skills are thought to be critical in ensuring ART adherence (Fisher et al., 2006). The authors suggest that behavioural skills associated with ART adherence include observing and strictly following prescribed regimens, ability to minimize and cope with adverse effects, integration of HAART into social structures and maintaining optimal adherence.

However, Fisher et al. (2006) acknowledge that information and motivation may have direct effects on adherence behaviour in situations where complicated or new behavioural skills do not affect adherence. Nevertheless, in complex and challenging ART schedules, the effect of information and motivation on adherence behaviour is mediated by adherence related behavioural skills (Fisher et al., 2006). Moreover, an individual's characteristics and social context may moderate the cause-effect relationship. The model also stresses that ART adherence is directly connected with health outcomes which are believed to influence one's future ART adherence through a feedback loop (Fisher et al., 2006).

Through the IBM model, Fisher et al. (2006) demonstrated that health behaviour programmes targeted at promoting ART adherence are not modelled by a simple causal link. In addition, literature on factors affecting the implementation of ART programmes revealed that the implementation of ART programmes is moderated by a number of factors discussed earlier. Therefore, although it is logical that the Sizophila programme leads to improved ART health outcomes, to accept that the programme is informed by a simple causal link might be contentious. For this reason, an alternate programme theory

is proposed (Figure 4). This programme theory recognises the Sizohpila programme function through moderators such as quality of training and quality of delivery (Carroll et al., 2007) and patient characteristics and psycho-social factors (Fisher et al., 2006) and mediators (adherence behavioural skills) (Fisher et al., 2006). These moderators and mediators can either strengthen or weaken the intervention-outcome effect.

In conclusion, despite the variations in programme interventions, most empirical studies show that community based ART adherence programmes can be successful in the attainment of ART health outcomes programmes. However, some evaluators or researchers have advocated for the need to understand the degree to which moderating and mediating factors affect the relationship between the intervention and the intended outcomes (Fisher et al., 2006; Carroll et al., 2007; Donaldson, 2007; Leeman et al., 2010; Bärnighausen et al., 2011). It is paramount that future evaluations assess how these factors affect the achievement of the intended outcomes. For the purpose of this evaluation, the Sizohpila programme theory is plausible for the attainment of ART outcomes as evidenced by efficacy studies examined.

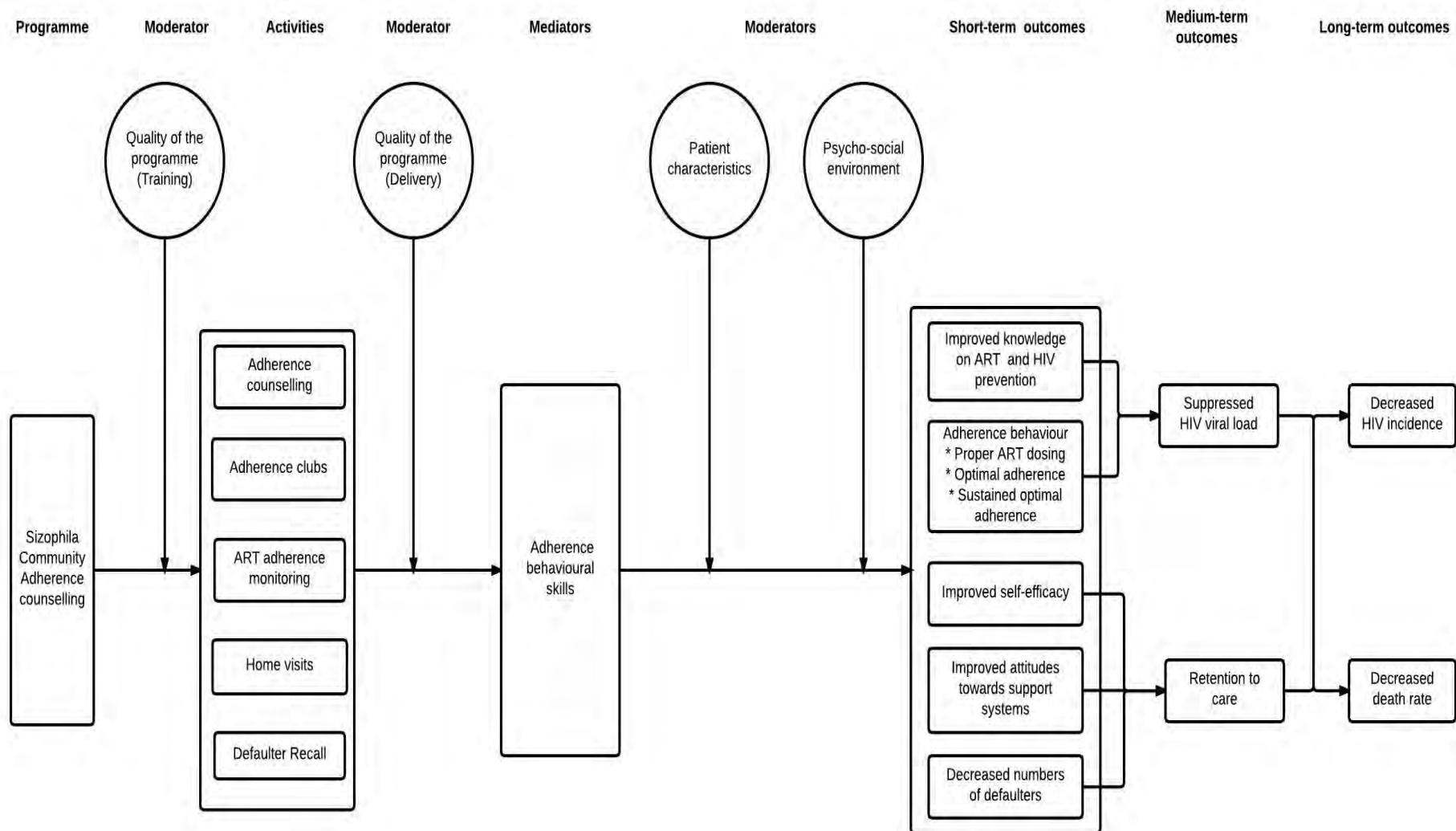


Figure 4. Revised Sizophila adherence counselling programme theory

Evaluation Scope and Questions

Implementation evaluation answers questions related to 3 main domains namely service utilisation, service delivery and organisational support. Service utilisation asserts whether the appropriate beneficiaries are being reached while service delivery focuses on the extent to which the programme is delivered to the intended beneficiaries (Rossi et al., 2004). The last domain, organisational support relates to the available resources required in accomplishing the programme functions (Rossi et al., 2004).

The task of tailoring the evaluation questions was achieved by collaborating with programme stakeholders. After careful deliberation about the nature of the programme, the evaluator and the stakeholders came to a conclusion that a process and an outcome evaluation were ideal. The following evaluation questions were therefore formulated:

Implementation evaluation questions

Service utilisation questions

1. Who has utilised the therapeutic counselling services (with specific focus on age, gender, level of education and employment status)?
2. What proportion of patients enrolled in the programme elected to receive:
 - a. Either 3 individual or 3 group treatment readiness sessions?
 - b. Follow-up home visits?
 - c. Of those patients who elected to participate in the follow-up home visit, how many home visits did they actually receive?
3. What proportion of patients who commenced on ART:
 - a. Were 'red flagged' during visits to the health facility?
 - b. For the patients who were red flagged what were their demographics?
 - c. For the patients who were red flagged, how many received further counselling sessions for treatment change?

Service delivery questions

4. What is the ratio of CCWs conducting home visits to patients?

5. On the whole,
 - a. How many home visits do the CCWs actually conduct?
 - b. When do the home visits take place?
 - c. How often do CCWs conduct the home visits?
6. What is the sequence of the counselling activities and did all clients get the same sequence?
7. In the view of the Programme Coordinator, what factors contribute to the effectiveness/ineffectiveness of the home visits?

Organizational support questions

8. What skills are imparted to TCs/CCWs?
9. What support is available to TCs/CCWs?

The evaluation will also answer questions related to programme outcomes. Essential to this type of evaluation is the ability to assess the degree to which the programme yields improvement in the programme participants or social conditions (Rossi et al., 2004). The Sizophila programme is a mature programme with over 10 years of existence; nevertheless, an impact evaluation is not feasible due to limited time and lack of funds. Thus a medium-term outcome evaluation was agreed upon mainly because:

- a. The stakeholders were interested in investigating the effect of the home visit intervention on the ART outcomes, and
- b. Given the availability of data and the limited period of time, it was agreed that a retrospective study was appropriate.

The outcomes of interest are; retention to care and HIV viral load suppression.

Outcome Evaluation Questions

10. At four months post ART initiation, did the patients who elected to receive the full spectrum of programme services (home visits) experience significantly higher retention rates?
11. At four months post ART initiation, did patients who elected to receive the full spectrum of programme services (home visits) experience HIV viral load suppression?

CHAPTER TWO

RESEARCH DESIGN AND METHODOLOGY

The aim of this chapter is to present the research design and methodology used for evaluating Sizophila programme. The chapter presents five sections namely the design, data, materials and procedures, measures and data analysis.

Design

A study's design determines how one samples a population, amasses measurements and analyses information (Joubert, & Ehrlich, 2007). The evaluation design included descriptive, exploratory and analytic approaches to answer evaluation questions.

Descriptive studies do not make an attempt to analyse the links between exposure and effect, they are limited to the description of an occurrence under investigation (Beaglehole, Bonita & Kjelleström, 2006). This design describes the phenomenon under study based on available data or data collected from research participants. Evaluation Question 1 (Who has utilised the therapeutic counselling services with specific focus to age, gender, level of education and employment status?) is an example of an evaluation question that was answered within a descriptive framework.

In contrast, Evaluation question 7 (In the view of the Programme Coordinator, what factors contribute to the effectiveness/ineffectiveness of the home visits?), which aims at gathering information about the factors that contribute to the effectiveness or ineffectiveness of the home visit intervention, could not be answered by means of precise measurement and thus an exploratory approach was used to elicit an understanding of the phenomena under study (Beaglehole et al., 2006).

Analytic studies go beyond describing data. Analytic statistics use techniques that enable generalisations to be made about populations from which a sample was obtained (Christensen, Johnson and Turner, 2011). The authors note that analytic designs typically follow the laws of probability and allow the investigator to infer findings about population

parameters based on statistics. Evaluation question 10 and 11 were answered by adopting analytic techniques.

Rossi et al., (2004) advocated for a RCT as the most appropriate method of establishing the cause-effect relationship. Nevertheless, this type of design was not feasible in this study mainly because of time constraints, as well as ethical and logistical issues inherent in randomising study participants to particular treatment scenarios. Thus, a quasi-experimental design was adopted which classified patients according to the intervention (Table 1). The evaluator utilised archived clinical data to obtain information about patient's intervention profiles, as well as HIV viral load measures and lost to follow-up status.

Table 1

Evaluation Design for the Sizophila Home Visit Intervention

Group	Intervention		Post-intervention measures
	Pre-treatment home visit		HIV viral load measurement four months post treatment initiation
Treatment group	NR	X	O ₁
Comparison group	NR		O ₁

Table 1 illustrates the design used in this study. The acronym NR represents non-random assignment, X stands for the intervention and O₁ represents the initial observation. Unfortunately, the design could not be strengthened by means of a pre-treatment (baseline) HIV viral load measurement because these were not routinely conducted by the clinic. Because this post-test only design was rather weak, adding a comparison group proved vital in substantiating counterfactual inferences (Shadish, Cook & Campbell, 2002). While this design allowed for the assessment of the effect of home visit intervention on medium term-outcomes, it was prone to threats to internal validity that had the potential of obscuring the effects of the home visit intervention. Hence the subsequent subsection discusses and gauges the degree of threats.

History

According to Shadish et al., (2002) history relates to events that occur during treatment rollout right through post-test measurements and are likely to affect the outcome. In this instance, historical events were ruled-out in that all participants came from the same geographic area and the measurement schedule was conducted within four months post-intervention. In addition, incorporating a comparison group controlled for any possible historical effects.

Maturation

This relates to any natural changes that would occur even in the absence of treatment (Shadish et al., 2002). Nevertheless, this is controlled for by including a comparison group and imposing a limited time period for the post-intervention analysis.

Testing

This was not a threat as the analysis utilised archived data to determine the effect of the home visit intervention on medium-term outcomes.

Instrumentation

Viral load testing is one aspect of managing ART that complements clinical observation. Meintjes et al. (2012) stipulates that all HIV results with a plasma viral load less than 50 copies/ml are categorized as 'viral suppression'. Thus, the standardized measures of HIV viral load quantification and lost to follow-up outcomes were used, therefore minimizing measurement irregularities.

Selection

Selection bias was a possible threat to internal validity in this study. Sampling bias was possible as the likelihood that patient records absent from the clinic register were positively correlated with the lost to follow up outcome. This will be further explained later in the chapter.

Attrition

Shadish et al. (2002) define attrition as the inability of an individual to complete the outcome measures. This was a plausible threat to internal validity as evidenced by reduced sub-sample size at data analysis stage.

Data

Programme documents access and review

The process of collecting data began in August 2014 after obtaining ethical clearance from the Faculty of Health Sciences Human Research Ethics Committee (Appendix C) and the Faculty of Commerce Ethics in Research Committee (Appendix D) both at the University of Cape Town. Stakeholder engagement revealed that as the study was primarily based on secondary programmatic data and did not involve manipulating human subjects, an ethical clearance from the Western Cape Department of Health was said not to be vital.

Relevant programme staff were contacted prior to data collection and briefed about the evaluation. The Programme Manager supplied the evaluator with an electronic patient database comprising patients' demographic data, baseline CD4 cell count results, HIV viral load results, lost to follow-up status, and information on date and cause of mortality. In addition, the evaluator was given access to clinic paper-based records and the Programme Coordinator supplied the evaluator with the CCW-home visit electronic register.

Data Providers

Data for the evaluation study were obtained mainly from sources as detailed in Table 2.

Table 2

A Summary of Data Providers

Data provider	Sample of data providers	Method of data collection
Programme staff	1 x Programme Manager	Questionnaire by email
	1 x Programme Coordinator	Interview
	10 x Community care workers	Questionnaires- face to face
Programme records	Home visit data (May, June & July records)	Electronic register
	1524 electronic records	Electronic data base(Contents of records: viral load results, lost to follow-up status)
	639 paper based clinical records	Record reviews (Contents of records: demographic data, home visit status)

Table 2 illustrates the roles adopted by each data provider in the Sizophila programme. The primary data providers included the Programme Manager, Programme Coordinator and CCWs. Purposive sampling was used to select the programme staff as it allowed the evaluator to gather relevant information from individuals that had an in-depth understanding of the programme and possessed valuable experiences and reflections of the programme (Christensen et al., 2011). The evaluator had initially planned to collect data from both TCs and CCWs, $n = 25$. However, it was made clear during data collection that only 15 CCWs conducted home visits. Moreover, of the 15 CCWs, the evaluator only managed to collect data from $n = 10$. Of the 5 CCWs that did not partake in the evaluation, 2 were on vacation, 2 kept procrastinating mainly because of a busy schedule while 1 was not present at the clinic at time of data collection.

Secondary data was used as well in the evaluation. Programmatic data such as paper-based clinical records, the electronic patient database and an electronic register for home visits

were used to inform the Sizophila evaluation questions. Essentially, the review of clinic paper-based data augmented the electronic database with missing information such as demographic characteristics of patients and home visit status.

Materials and Procedures

This section describes the materials and procedures used to obtain data for the evaluation.

Service utilisation questions

Evaluation questions 1-3

These questions were informed by both the electronic patient database and patient paper-based clinical records. A random number generator (www.randomizer.org) (Christensen et al., 2011) was used to randomly select paper-based clinical records for a more detailed folder review. In total, 639 paper-based clinical records were pulled and reviewed (out of an entire population of 1524). This was achieved by randomly retrieving paper-based clinical records until the minimum sample size quota and proportions indicated by the priori sample size calculations had been met for each group (treatment and comparison). The data provided by these 639 paper-based clinical records were subsequently used to answer the evaluation questions around service utilisation.

Programmatic data was routinely collected prior to ART treatment initiation. From this data, the evaluator was able to;

1. Determine the demographic characteristics of patients,
2. Classify patients as having received either 3 group or 3 individual treatment readiness sessions, and
3. Determine the proportion of patients who were red flagged during visits to the health facility.

Some limitations noted were related to incomplete data. Of the 639 clinical records reviewed, 136 were omitted from the analysis due to incomplete demographic data. Thus the sample consisted of 503 clinical records. Moreover, the follow-up home visit questions could not be answered as there was no data.

Service delivery questions

In this section, various sources were used to obtain data as outlined below.

Evaluation question 4

An electronic register was used to determine the total number of patients receiving home visits. The Programme Coordinator furnished the evaluator with recently captured data on the number of patients visited by each CCW for the month of May, June and July 2014. In addition, according to programme records only 15 CCWs conducted home visits. These figures were used to determine the ratio of CCW to patients.

Evaluation questions 5 and 6

A questionnaire was administered to CCWs to gather data about service delivery (Appendix E). The questions were specific to the delivery of home visits (Section I) and CCWs' counselling skills (Section II). This allowed the evaluator to determine how and when CCWs conducted home visits and whether the activities were delivered in the same manner. Section II of the questionnaire was adapted from the Dewing and Mathews (2011) Basic Counselling Skills Tool (BCoST) which is aimed at assessing performance in basic counselling skills as proposed by Egan (2002) *Skilled Helper* and *Options for Health*. In essence, this tool evaluates the CCWs' performance in basic counselling skills associated with problem-management approach to counselling which was found to be deficient among CCWs (Dewing and Mathews, 2011). The authors advocate for the use of this tool in assessing counselling sessions for research purposes.

Initially, the evaluator had opted for a self-administered questionnaire method. However, the evaluator was cautioned of the disadvantage of using this method by the Programme

Manager as it was likely to provide a low response rate. With this in regard, the evaluator altered the method and issued the questionnaires to CCWs and monitored completion. The presence of the evaluator during questionnaire completion allowed for clarification of any misunderstanding at the same time enhancing the response rates without manipulation. Prior to issuing out the questionnaires, CCWs were briefed about the evaluation and were asked to complete a consent form to indicate voluntary participation.

Evaluation question 7

This question was informed by a face to face interview with the Programme Coordinator. An appointment was made with the Programme Coordinator prior to the interview to explain the evaluation. Only 1 question was formulated and was answered by means of an open-ended interview. Through this technique, the evaluator was able to make follow-ups and seek further descriptions and clarifications. This facilitated the exploration of factors that contribute to the effectiveness or ineffectiveness of the home visit approach in enhancing ART treatment. Permission to audio record the interview was solicited. As a result, the evaluator was able to transcribe the data verbatim.

Evaluation question 8 and 9

A closed ended questionnaire (Appendix F) was emailed to the Programme Manager to obtain information about the organisational support offered to TCs and CCWs. The questionnaire was adapted from WHO Community Health Worker Assessment and Improvement Matrix: A Toolkit for Improving CHW Programs and Services (WHO, 2011).

Evaluation question 10 and 11

These two questions focused on medium-term outcomes of the programme. Patient retention/lost to follow-up and HIV viral load suppression were the outcomes of focus. Data from these questions were obtained from the electronic patient database.

Methods

Study population and sampling

The Sizophila home visit intervention is intended for newly diagnosed HIV positive patients seeking ART medication. Ideally, patients are supposed to receive a pre-treatment home visit and 4 post-treatment initiation home visits (1 visit per month for the first 4 months). However, approximately 5% of the patients do not receive these visits mainly because either they refuse home visits or they reside outside the geographic visiting range (L.G. Bekker, personal communication, March 31st, 2014). This permitted a two group design described earlier in the chapter. The treatment group comprised of patients receiving home visits between January 2012 and December 2013 while the comparison group comprised those who did not receive home visits in the same period.

Patient clinical records were eligible if;

1. Patients were 18 years of age
2. Not pregnant.

The exclusion criteria included

1. Patients transferred-in from other health facilities

Consequently, the study population comprised of 1524 patients as listed in the electronic patient database. However, during data collection, it emerged that 19.88% patients randomly selected from the electronic database had their paper-based clinical records missing from the clinic. This was a potential limitation for the lost to follow-up outcome as discussed later in the chapter.

Sample size calculation

Sample size calculations were done prior to obtaining an electronic patient database which comprised a list of all patient identification codes. Therefore, calculations were informed by parameters derived from the literature (for the viral load outcome) and the Sizophila

stakeholder consultations (for the lost to follow-up outcome) which suggested the probability of lost to follow up in the clinic population was around 20%.

For the lost to follow-up outcome, G*Power 3.1.9.2 Software (Faul, Erdfelder, Lang & Buchner, 2007) was used to determine the sample size. The sample size required given $\Pr(Y=1|X=0) H_0 = 0.2$, $\alpha = 0.05$ and power $(1-\beta \text{ err prob}) = 0.8$ was 218. For more detailed sample size calculations please refer to Appendix G.

However, the electronic patient database revealed that the proportion of patients lost to follow-up within 4 months of treatment initiation was in fact only 12%. Based on this, a post hoc power analysis was conducted to determine whether a logistic regression with the observed sample parameters (sample size $n = 218$, $\alpha = 0.05$ and $\Pr(Y=1|X=0) H_0 = 0.12$, odds ratio = 2.87) would have reasonable power of accepting an alternative hypothesis (Faul et al., 2007). The power was $(1-\beta \text{ err prob}) = 0.84$, indicating that a 12% probability of loss to follow up was adequate to perform the logistic regression for the lost to follow up outcome.

Unfortunately, the effective sample size for the viral load outcome was much less than 218. After excluding ineligible cases and accounting for missing viral load data, the final sample size available for analysis was 106 (Figure 5). AS A RESULT THE

A post hoc power analysis was conducted to determine whether or not a logistic regression on the odds of treatment failure (as indicated by viral load levels at 4 months) had reasonable power of accepting an alternative hypothesis (Faul et al., 2007). Consequently, G*Power 3.1.9.2 Software (Faul et al., 2007) was used to determine power given a sample size $n = 106$, $\alpha = 0.05$ and $\Pr(Y=1|X=0) H_0 = 0.31$, odds ratio = 2.22. Unfortunately, the power was $(1-\beta \text{ err prob}) = 0.38$, which indicates that the resulting analysis for this outcome was likely to be underpowered.

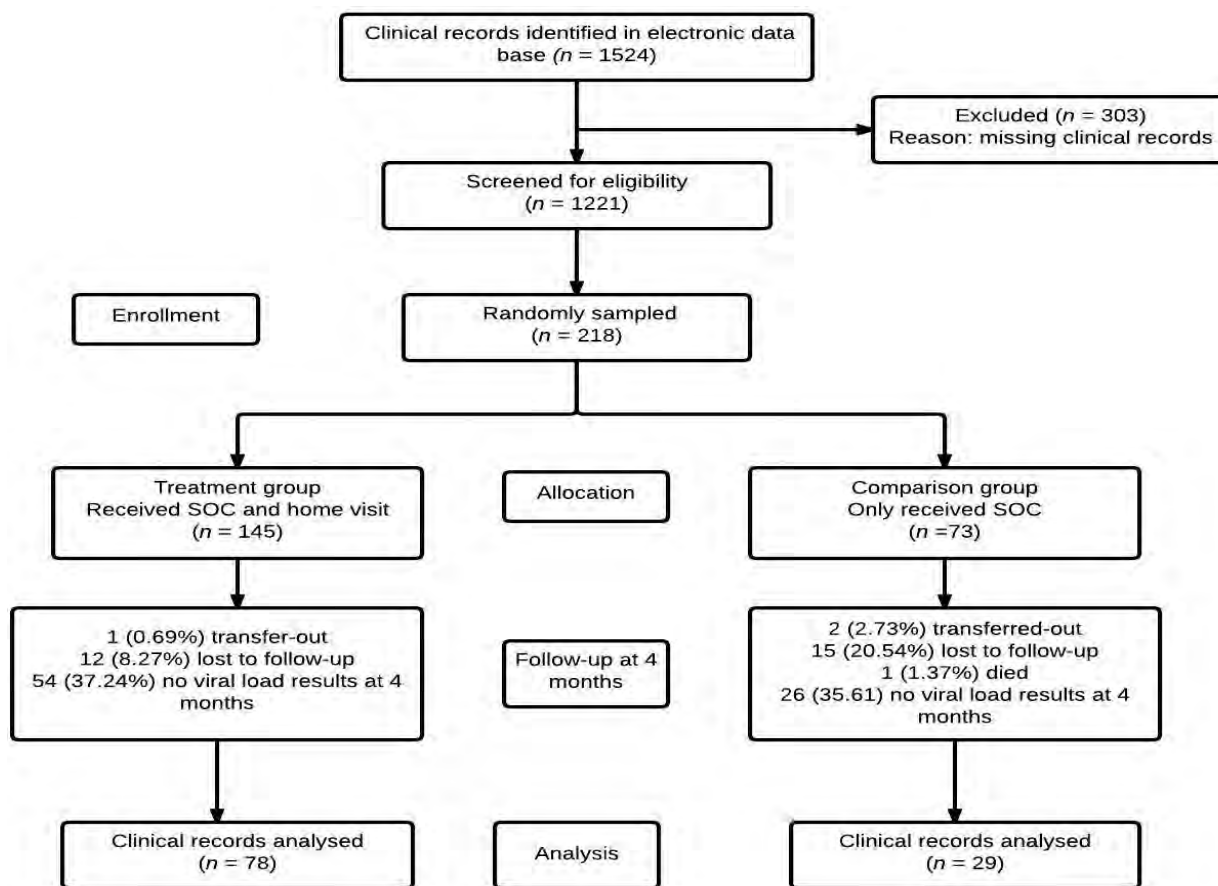


Figure 5. Flow diagram of the analysis of the HIV viral load suppression outcome

Allocation

The study was a retrospective 2 arm design with an imbalanced allocation [1:2]. There is a ratio of 1:2 in terms of number of clinical records in the comparison group to the number of clinical records in the treatment group. Therefore, for every non-home visit (comparison group) record randomly selected, the evaluator selected two records from the home visit group (treatment group).

The criteria for allocating clinical records to the treatment group was as follows: patients should have received standard of care (SOC) which included 3 treatment readiness adherence counselling sessions and an initial home visit and 4 post-treatment home visits.

However, a limitation to defining the treatment group criteria was that on reviewing paper-based clinical records, the evaluator observed that subsequent home visits were not documented. This was also confirmed by the Programme Manager. As such, the treatment group intervention was limited to the initial home visit and SOC. The comparison group did not receive home visits; however, they received SOC which consisted of 3 treatment readiness adherence counselling sessions. They did not receive any further adherence counselling support beyond the clinic's routine sessions. The treatment intervention period is therefore 4 months post ART treatment initiation.

Sampling Strategy

A list of patient identification codes commencing ART treatment between 2012 and 2013 was obtained from the electronic database. A simple random sampling strategy 'without replacement' was used to select the study sample this was achieved by using a computerised random number generator (www.randomizer.org) (Christensen et al., 2011). The patient files selected for sampling were then classified by means of a clinical folder review as either part of the treatment group or the comparison group. This method was utilised until the quota set by the sample size calculations for each group was met.

A potential source of bias that should be noted was related to the lost to follow-up outcome variable. As aforementioned, during paper-based clinical record reviews, the evaluator observed that 20% of the paper-based clinical records selected randomly from the electronic database were missing from the clinic records. It later emerged during the results review by programme staff that the missing records were likely related to the lost to follow-up outcome, as some of the records had been removed from the filing cabinet since they either belonged to deceased patients or patients who were lost to follow-up. While this is certainly a potential source of bias, it should also be noted that this feature of the data is only likely to be problematic if there were unobserved or unknown sources of systematic bias associated with whether or not the record for a patient that was lost to follow up was excluded from the clinic. In essence, if the decision made by clinic clerics to remove or retain the clinical records of patients who had been lost to follow up was arbitrary, and not correlated with patient characteristics, the amount, type or quality of

treatment received by the patient, then the results will not be biased. With this potential limitation in mind, and given that there was still adequate to power to perform a logistic regression for the lost to follow up outcome, the results of this analysis have with some reservations been tentatively generalised to the entire clinic population.

Measures

Independent variables

The main predictor variable was the initial home visit. Other covariates included baseline CD4 cell count and demographic characteristics such as age, gender and employment. The data was analysed using the Statistical Package for Social Sciences version 22 (SPSS) software. The predictor variables were coded in the following manner:

'Home visit, (Yes) = 1'; 'home visits, (No) = 0',

'Employment, (Yes) = 1'; 'employment, (No) = 0',

Gender was coded as follows 'female = 1' and 'male = 0', and

Age was recoded into a binary variable '18-39 years =1' and '40 and above = 2'

Dependent variables

Lost to follow-up outcome

According to Dr Richard Kaplan (personal communication, March 31st, 2014), lost to follow-up is a period of absence in which a patient fails to report at the clinic for ART refill within a 12 week period after the last visit and cannot be confirmed dead or transferred to another facility. So patients who were absent from the clinic for 12 or more consecutive weeks were classified as lost to follow-up. This outcome variable is binary and thus coded as follows:

'Lost to follow-up, (Yes) = 1' or 'lost to follow-up, (No) = 0'.

HIV viral load suppression outcome

To adhere to the national HIV/AIDS guidelines, all results with a plasma viral load less than 50 copies/ml were categorized as 'viral suppression' (Meintjes et al., 2012). This variable was coded as follows:

'Viral suppression, (Yes) = 1' and 'viral suppression, (No) = 0'.

Data Analysis

Data analysis commenced by methodically organising raw material encountered during data collection into an error free data (Patton, 1990). Thus, data was prepared in three sequential tasks of: coding, entering and cleaning. Tables, graphs and figures were used to visually communicate data.

Exploratory Analysis

Evaluation question 7 was qualitative in nature and required an analysis that was different from quantitative data. Data familiarisation was achieved by listening to the audio-tape recorded material which was later transcribed verbatim. Thereafter, a thematic content analysis was used to analyse data in which themes running through the data were identified. This was supported by direct quotes and paraphrased responses.

Descriptive statistics

Discrete variables were analysed via frequency distributions and proportions, whereas continuous variables were analysed through measures of central tendency and dispersion.

Analytic statistics

Inferential statistics comprised of odds ratio, Chi-square and Fisher's exact which measured the strength of association between dependent and independent variables.

Odds of being lost to follow-up outcome

Evaluation question 10 was analysed using a binomial logistic regression to determine if the probability (P) of being lost to follow-up (Y =1) was significantly higher or lower than one would expect from the group that received home visits (X =1) versus the group that did not receive home visits (X =0), while adjusting for predictors such as home visits, baseline CD4 cell count, age, gender and employment. The logistic regression model tested the following alternative hypothesis (H₁):

$$H_1 \quad P(Y = 1 | X = 1) \neq P(Y = 1 | X = 0)$$

The final logistic regression model from which the probability of lost to follow-up was predicted is as shown below.

$$\text{Probability of Lost to follow-up} = \frac{1}{1 + e^{-(\beta_0 + \beta_1 \text{Home visit} + \varepsilon)}}$$

Where e is the base of natural logarithms,

β_0 Intercept = the average effect on lost to follow-up when the home visits predictor is held at zero that is excluded from the model,

β_1 = the regression coefficient quantifies the influence home visits on lost to follow-up, and
 ε = Error term, denoting all factors not observed that affects the prediction of the probability of lost to follow-up.

HIV viral load suppression outcome

Initially, the evaluator had planned to perform a generalised linear mixed model with repeated measures of HIV viral load at baseline and 4 months. This design would have been appropriate since it allowed for analysis between groups and within subjects while factoring repeated measures over time (Field, 2013). However, it was later revealed that baseline viral load measures were not routinely collected. For this reason, a logistic regression was adopted to determine if the odds of viral suppression (Y =1) at four months were significantly higher or lower than one would expect from the treatment group (X =1) versus the comparison group (X =0), while adjusting for covariates mentioned earlier. The logistic regression model tested the following alternative hypothesis (H₁):

$$H_1 \quad P(Y=1|X=1) \neq P(Y=1|X=0)$$

The final logistic regression model from which the probability of viral suppression was predicted is shown below.

$$\text{Probability of HIV viral suppression} = \frac{1}{1 + e^{-(\beta_0 + \beta_1 \text{Home visit} + \beta_2 \text{CD4 count} + \beta_3 \text{Age} + \beta_4 \text{Gender} + \beta_5 \text{Employment} + \varepsilon)}}$$

Where e is the base of natural logarithms,

β_0 Intercept = the average effect on viral load suppression when all predictors (home visits, baseline CD4 cell count, age, gender and employment) are held at zero,

$\beta_1, \beta_2, \beta_3, \beta_4,$ and β_5 = are regression coefficients which quantifies the influence home visits, baseline CD4 cell count, age, gender and employment on HIV viral suppression, and

ε = Error term, notes all extraneous factors affecting the prediction of the probability of HIV viral suppression.

Conclusion

This chapter gave an outline of the research design, data collection methods and data analysis techniques adopted in this evaluation. It is paramount to note that though the evaluator tried to construct a high-quality research design suited for this purpose, lack of data and incomplete programme records resulted in analyses with a number of limitations as noted in this chapter.

CHAPTER THREE

RESULTS

Introduction

This chapter presents the results based on the previously identified evaluation questions. Therefore, both descriptive and inferential statistics will be presented.

Implementation Evaluation Questions

Service utilisation

Evaluation Question 1: Who has utilised the therapeutic counselling services with specific focus to age, gender, level of education and employment status?

A total of 639 patient records were reviewed. However, as previously noted 136 (21.3%) clinical records were omitted from the analysis due to incomplete patient demographic data. Thus the sample consisted of 503 patient records.

Of the 503 patient files reviewed, the majority of the patients were female. There were 303 (60.2%) female patients and 200 (39.8%) male patients. The mean age was 38.6 years ($SD = 9.87$). The majority of the patients, 78.5% were aged between 25-49 years. Almost all patients had formal education 98.8% ($n = 497$). The most common category comprised of patients with secondary education 183 (36.4%). However, from those with a formal education only 1.4% ($n = 7$) had tertiary education. More than three quarters of the patients, 75.5% were unemployed.

Table 3

Socio-demographic Characteristics of Patients as a Percentage of Sample

Characteristic	Category	Frequency (<i>n</i> = 503)
Gender	Male	39.8
	Female	60.2
Age (Years)	18-24	5.4
	25-49	78.5
	50+	16.1
Education Level	No education	1.2
	Primary	33.0
	Secondary	36.4
	High School	28.0
	Tertiary	1.4
Employment status	Employed	24.5
	Unemployed	75.5

Evaluation Question 2: What proportion of patients enrolled in the programme elected to receive:

2(a) Either 3 individual or 3 group treatment readiness sessions?

Of the 503 patients commencing ART treatment, the majority of the patients attended 3 group treatment readiness sessions as shown in Table 4. Eighty seven percent (*n* = 440) of the patients received 3 group treatment readiness sessions while a little over 10% opted for 3 individual sessions.

Table 4

Three Treatment Readiness Sessions Attendance

Attended	Frequency (<i>n</i> = 503)	Percentage (%)
Yes	440	87.5
No	63	12.5

2(b) Follow-up home visits

The follow-up home visit question could not be answered as there was no data mainly because CCWs did not record the follow-up home visits though this was a core activity.

2(c) Of those patients who elected to participate in the follow-up home visit, how many home visits did they actually receive?

Again for the same reason mentioned in 2 (b), this question could not be answered as there was no data.

Evaluation Question 3: What proportion of patients who commenced on ART;**3(a) Were red flagged during visits to the health facility?**

Table 5 shows the proportion of patients who were red flagged. Of the 639 patient files reviewed, only 25 (3.9%) patients were red flagged.

Table 5

Proportion of Patients Red Flagged

Red Flagged	Frequency (<i>n</i> = 639)	Percentage (%)
Yes	25	3.9
No	614	96.1

3(b) For the patients who were red flagged what were their demographics?

A total of 25 files comprising of red flagged patients were reviewed. Results revealed that, the majority of the red flagged patients were female, 68.0% ($n = 17$). The mean age was 33.7 years ($SD = 7.4$). With regard to education, the secondary education category comprised of most patients who were red flagged, 48% ($n = 12$). More than 70% of the red flagged patients were unemployed. Table 6 shows the socio-demographic characteristics of patients who were red flagged.

Table 6

Socio-demographic Characteristics of Patients Red Flagged as a Percentage of Sample

Characteristic	Category	Frequency ($n = 25$)
Gender	Male	32.0
	Female	68.0
Age (Years)	18-24	8.0
	25- 29	28.0
	30-34	32.0
	35-39	4.0
	40-44	20.0
	45-49	8.0
Education Level	Primary	16.0
	Secondary	48.0
	High School	36.0
Employment status	Employed	24.0
	Unemployed	76.0

A Chi-square test was conducted to assess if being red flagged was associated with demographic characteristics namely gender and employment. The results revealed that:

- There was a statistically insignificant association between gender and being red flagged, $\chi^2(1, N = 503) = .66, p = .42$.
- There was no statistical significance between employment and being red flagged, $\chi^2(1, N = 503) = .003, p = .96$

The Pearson Chi-square test assumes that the expected value for each cell is five or higher (Field, 2013). This assumption was violated when the relationship between red flagged and the following variables; age, and level of education were tested. Thus, a Fisher's exact test was adopted to assess for significance. Results revealed that:

- There a statistical insignificant association between being red flagged and age, $p = .13$
- There was no statistically significant relationship between first line treatment failure and educational level, $p = .34$.

3(c) For the patients who were red flagged, how many received further counselling sessions for treatment change?

Table 7 illustrates that 28.0% ($n = 7$) of the patients who were red flagged received counselling sessions for ART treatment switch from '1st line.' to '2nd line' regimen.

Table 7

Treatment Readiness sessions for 2nd Line Treatment as a Percentage of Sample

Received treatment readiness sessions	Frequency ($n = 25$)
Yes	28.0
No	72.0

Service Delivery

Evaluation Question 4: What is the ratio of CCWs conducting home visits to patients?

The electronic register was used to determine the total numbers of patients receiving home visits. According to the register, 15 CCWs conduct home visits. The figures used to determine the ratio of CCW to patients were obtained for the month of May, June and July 2014. A total of 508, 545 and 451 patients were reported receiving home visits in the month of May, June and July 2014 respectively. Figure 6 shows the numbers of patients receiving home visits from each CCW. On average the ratio of CCW to patient was 1: 33.4.

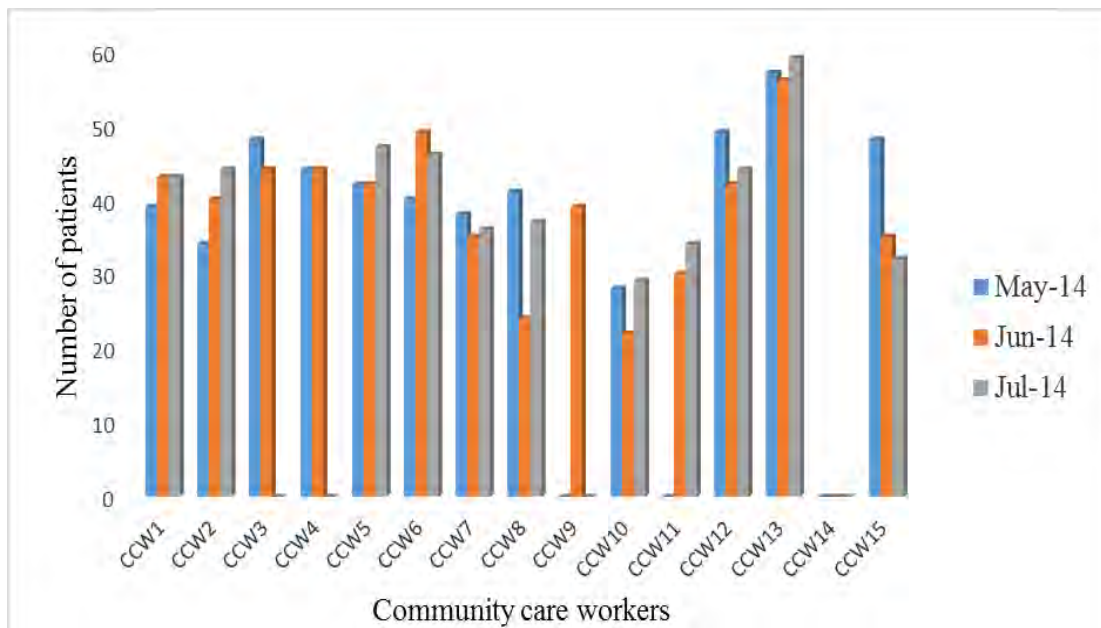


Figure 6. Total number of patients receiving home visits per month

Evaluation Question 5: Home visits

The implementation of the home visit activity was assessed through questionnaires handed-out to CCWs. Table 8 shows the CCWs responses in relation to the statements posed. Fewer than half, 4 (40.0%) CCWs strongly agreed with the statement that “I don’t have enough time to conduct home visits.” The majority of the participants 6 (60.0%)

strongly agreed with the statement “I am well prepared in providing home visits.” Half of the participants strongly disagreed with the statement “I am not confident in delivering the home visit intervention.” Five (50.0%) participants strongly disagreed with the statement “I feel that home visits are not important in enhancing ART adherence.” Half of the participants 50.0% (5) indicated that they sometimes “do not inform the participants beforehand about the home visit.” Five of the CCWs reported that they sometimes “can easily access participants for home visits.” With regard to home visits guidelines, 90.0% of the participants revealed that home visits are informed by guidelines while 1 participant revealed that the guidelines do not specify when home visits should take place.

Table 8

Community Care Workers’ Perspectives about Home Visits (*n* =15)

Statement	Response	Frequency (%)
I don’t have enough time to conduct home visits	Strongly disagree	4 (40.0%)
	Disagree	2(20.0%)
	Agree	2(20.0%)
	Strongly agree	2(20.0%)
I am well prepared in providing home visits	Agree	4 (40.0%)
	Strongly agree	6 (60.0%)
I am not confident in delivering the home visit intervention	Strongly disagree	5 (50.0%)
	Disagree	2(20.0%)
	Agree	2(20.0%)
	Strongly agree	1 (10.0%)
I feel that home visits are not important in enhancing ART adherence	Strongly disagree	5 (50.0%)
	Disagree	4 (40.0%)
	Strongly agree	1 (10.0%)
I do not inform the participants beforehand about the home visit	All the time	1 (10.0%)
	Sometimes	5 (50.0%)
	Never	4 (40.0%)
I can easily access participants for home visits	All the time	3 (30.0%)
	Sometimes	5 (50.0%)
	Never	2(20.0%)
Are there guidelines that inform you on how to deliver home visits?	Yes	9 (90.0%)
	No	1 (10.0%)
Do guidelines specify when home visits should take place?	Yes	9 (90.0%)
	No	1 (10.0%)

5(a) How many home visits do the CCWs actually conduct?

A questionnaire was used in order to determine the number of home visits provided by the CCWs per day. Six of the 10 CCWs surveyed reported conducting 1-4 home visits per day. Two (20.0%) CCWs reported conducting more than 13 home visits per day (Figure 7).

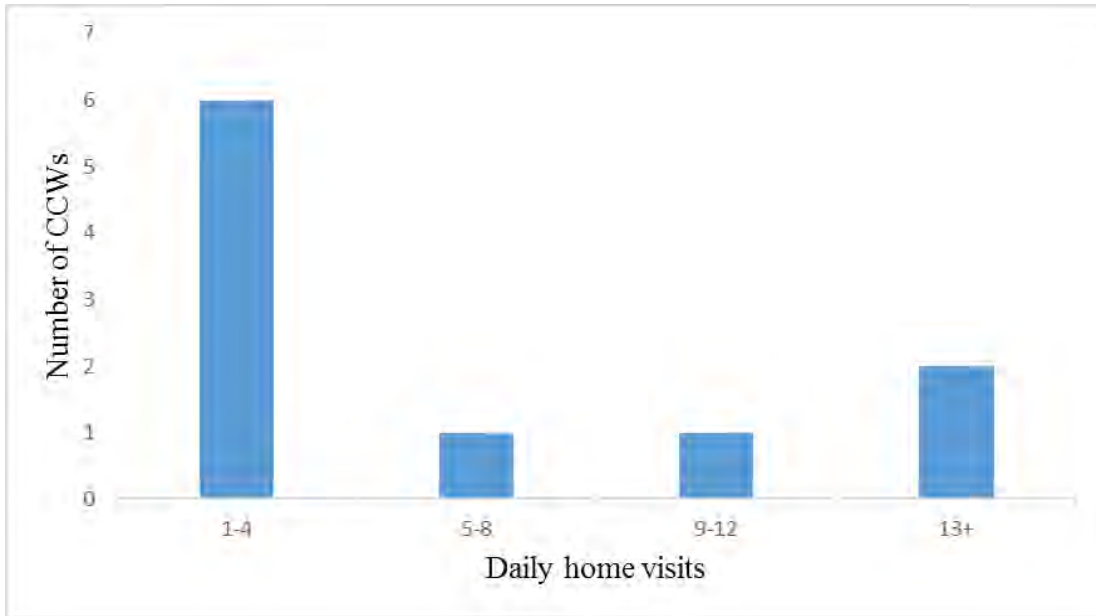


Figure 7. Approximate numbers of daily home visits

5(b) When do the home visits take place?

To determine when the home visits took place, CCWs were asked to indicate their responses via a questionnaire. The majority of the CCWs 70.0% (7) indicated that they conducted home visits any time of the day. Only 3 (30.0%) CCWs indicated conducting home visits in the morning. Figure 8 depicts the time when home visits take place.

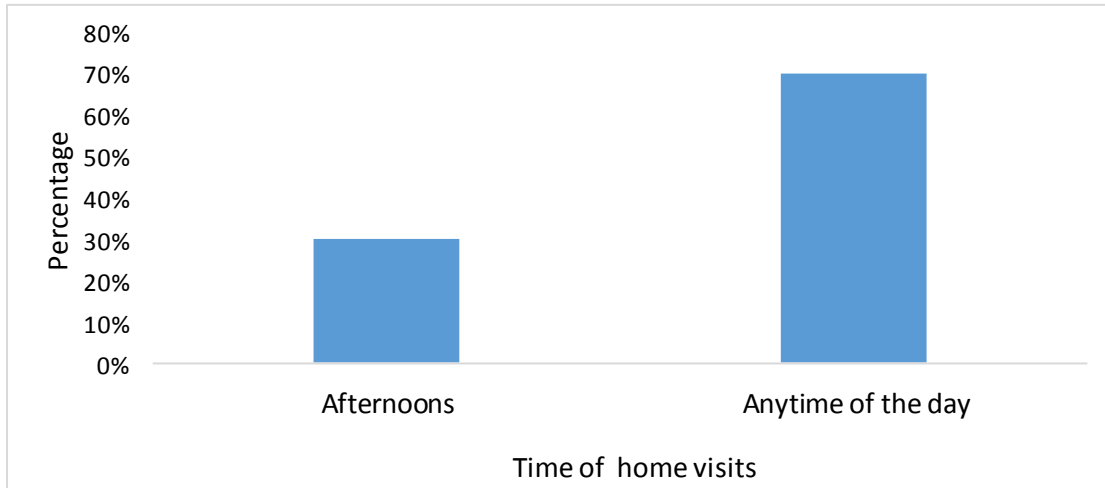


Figure 8. Time of home visit activity

5(c) How often do CCWs conduct home visits?

In order to establish how often CCWs conducted the home visit intervention, a questionnaire was used to obtain the results. Results revealed that four (40.0%) CCWs conducted home visits three times a week. Three (30.0%) CCWs indicated that they conducted home visits daily (Figure 9).

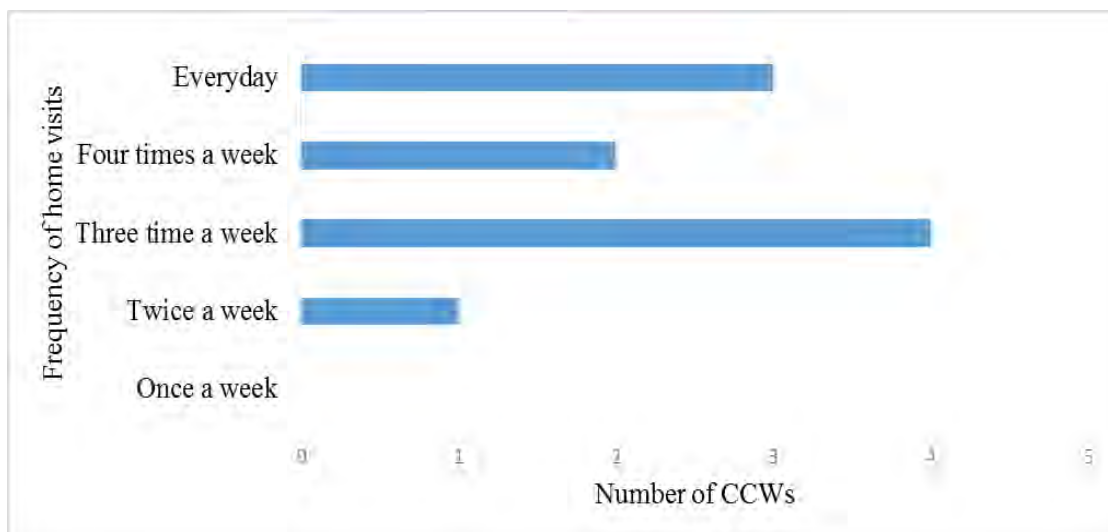


Figure 9. Frequency of home visits

Evaluation Question 6: What is the sequence of the counselling activities and did all clients get the same sequence?

Table 9 presents the required counselling etiquette and the responses from the CCWs. On the whole, the four major aspects of counselling were implemented with fidelity. All the CCWs reported that they conducted all 15 steps of the 4 major categories assessed. All the CCWs introduced the initial counselling session. However, only 7 (70.0%) gave a strong indication that they engaged patients in greetings. Sixty percent of the CCWs gave a strong indication regarding role explanation. The majority of the CCWs 80.0% and 70.0% were in strong agreement with statements relating to explaining counselling sessions, and confidentiality and including its limits respectively.

All CCWs engaged the patients in problem identification and understanding. However, there were mixed responses with regard to identification of patients' problems and attempts to understand reasons for ART adherence and non-adherence. Just 50.0% of the CCWs gave a strong indication that they engaged clients in discussions pertaining problem identification, adherence and non-adherence issues.

With regard to problem solving more than 70% of the CCWs strongly indicated that they discuss solutions to solve perceived problems with patients. Moreover, 80.0% of the CCWs gave a strong indication that they encouraged patients to identify and share solutions before they recommend solutions. However, only 40.0% of the CCWs strongly indicated offering relevant information tailored to the patients' situation. In addition, only 40% of the CCWs strongly indicated helping patients to agree to realistic solutions. Forty percent of the CCWs revealed that they strongly engaged patients in discussions of their ability to adopt the proposed solutions.

More than 80% of the CCWs strongly indicated that they summarised issues discussed, offered patients the opportunity to ask questions and provide answers, and also made appointment dates for a follow-up session.

Table 9

Basic ART Adherence Counselling Protocol for Initial and Subsequent Sessions

Statement	Proficiency: Level of Agreement				
	Weak	Low	Average	Good	Strong
Initial Counselling Session					
I engage the client in greetings	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	7 (70.0%)
I explain my role in counselling	0 (0.0%)	1 (10.0%)	0 (0.0%)	3 (30.0%)	6 (60.0%)
I explain the reason for the counselling session	0 (0.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	8 (80.0%)
I explain confidentiality including its limits	0 (0.0%)	2 (20.0%)	0 (0.0%)	1 (10.0%)	7 (70.0%)
Initial and Ongoing Sessions: Problem identification & Understanding					
I use open ended questions and allow clients to express themselves	0 (0.0%)	0 (0.0%)	1 (10.0%)	3 (30.0%)	6 (60.0%)
I identify and clarify the clients' problems	0 (0.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	6 (60.0%)
I attempt to understand the clients' reason for both adherence and non-adherence	0 (0.0%)	1 (10.0%)	0 (0.0%)	4 (40.0%)	5 (50.0%)
Problem Solving					
I discuss with the clients the solutions to solve problems	0 (0.0%)	0 (0.0%)	2 (20.0%)	1 (10.0%)	7 (70.0%)
I ask the client to share their solutions before I share mine	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	8 (80.0%)
I offer relevant information to the clients' situation	0 (0.0%)	0 (0.0%)	2 (20.0%)	4 (40.0%)	4 (40.0%)
I help the client to agree to solutions that are realistic	1 (10.0%)	0 (0.0%)	2 (20.0%)	3 (30.0%)	4 (40.0%)
The client and I discuss if the client is able to use the solutions	0 (0.0%)	1 (10.0%)	2 (20.0%)	3 (30.0%)	4 (40.0%)
Closing Sessions					
At the end of each session, I summarise the issues that were raised in the session	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (20.0%)	8 (80.0%)
At the end of each session, I offer the client time to ask questions and answer them	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	9 (90.0%)
At the end of each session, if needs be, I set up a follow-up date	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	9 (90.0%)

Evaluation Question 7: In the view of Programme Coordinator, what factors contribute to the effectiveness/ineffectiveness of the home visits?

The Programme Coordinator highlighted the importance of home visits in enhancing ART adherence. A thematic content analysis of the interview identified four themes related to: patient, socio-cultural and organisational, and CCWs' profile.

Patient factors

Substance abuse

Excessive substance abuse was identified as an obstacle to the successful implementation of the home visit intervention. The Programme Coordinator reported that alcohol and drug abuse affected the delivery of home visits since patients with a history of substance abuse tended to decline home visits, or if they did grant permission for a home visit, patients could not be located.

Age

The Programme Coordinator revealed that age was a hindrance to visiting patients. Minor patients could not be visited without consent from the parents.

“We have children who have mothers who are working and caregivers who do not honour dates and these children have poor adherence. These are the people who refuse home visits.”

In addition, the Programme Coordinator noted that adolescents are in the stage of social experimentation. They often present teenage problems and refuse any form of participation in club activities and home visits.

Socio-cultural factors

Stigma and discrimination

The Programme Coordinator revealed that stigma, though slowly diminishing; remains a major problem for patients with HIV/AIDS. Stigma and discrimination was thought to deter CCWs from conducting home visits. Patients lived in fear of being identified as HIV positive hence they declined home visits.

“... Pregnant women attending Midwife Obstetric Unit (MOU) clinic refuse home visits. This is especially associated with how they interact with their families and friends in the community. They are afraid of being identified with CCWs, as a visit from the CCW will immediately classify one as HIV positive.”

Disclosure

Non-disclosure was cited as a major barrier to implementing home visits effectively. The Programme Coordinator revealed CCWs often raised concerns with regards to disclosure of HIV status. It was indicated that patients still find it difficult to share their HIV status with relatives and friends. As such they decline home visits.

"..It is difficult to conduct a home visit if the client has not disclosed to family members. Sometimes you cannot discuss anything if there are other people in the house. You just turn-up and the patient say they don't have time and arrange for an appointment at the clinic ..."

Alternative therapy

Alternative therapy was noted as a barrier to the delivery of home visits. Some patients still believed that HIV was a result of witchcraft and therefore relied on traditional therapy to combat the disease. This was thought to influence non-adherence behaviours.

Organisational factors

Community care workers' profile

Community care workers were identified from the community and were familiar with the culture and social dimensions of their communities. This was thought to be vital as CCWs could identify with contextual issues affecting the community.

"... CCWs are allocated patients according to their area, where they reside. In the early stages of the programme implementation, it was a problem but now people know they can go to a counsellor's house, which might be just next door to discuss medication issues. In addition, patients not attending our clinic are using the services of our counsellors because they know the counsellors deal with ART issues..."

Information publicity

The availability of information regarding HIV and AIDS has led to more acceptable attitudes and behaviours concerning community based interventions. Moreover, a multisectoral

approach to HIV knowledge dissemination has led to communities being more accepting of HIV prevention activities.

Liaison with other sectors

Liaison with other community organisations and referral services has enhanced the home visit approach. If CCWs encountered issues outside their defined scope of practise, they referred patients to relevant departments (for instance, social services).

Training

The training afforded to CCWs enabled them to confidently disseminate the knowledge acquired. As such, CCWs are able to integrate their services within the community.

“...Through the education and training they receive, they have helped the patients. They have helped dispel myths presented by the patients...”

In addition, they are able to use the knowledge acquired to detect ART non-adherence.

Organizational Support

Evaluation Question 8: What skills are imparted to TCs and CCWs?

A questionnaire was used to obtain information about the nature of skills imparted to TCs and CCWs. Questions regarding the training programme for TCs and CCWs were posed. According to the Programme Manager, training is an essential part of skills development. All TCs and CCWs were reported to have received prior formal training to implement the Sizophila programme activities.

“...training sessions are held throughout the year and newly recruited CHWs attend the first available training. We have just employed 4 new CHWs and they will attend the 10 day training within the 1st week of starting their jobs as it happens to be available.”

In order to establish the frequency of continuous training and if guidelines exist to inform when the training is provided, a question was posed to the Programme Manager. The Programme Manager revealed that guidelines were not available however;

“The programme only specifies the initial 10 day training for CCWs and 30 day training for adherence counsellors but does not provide specific guidelines for continuing training.”

The Programme Manager highlighted the following with regard to CCW’s ongoing training and career development prospects:

“An attempt is made to provide some training on an annual basis for all CHWs while opportunities for more advanced training are offered to CHWs on an ad hoc basis if available, for example 4 CHWs were offered enrolment in a 2 year advanced counselling course. The selection was made on merit as judged by the programmes project and line managers.”

Evaluation Question 9: What support is available to TCs and CCWs?

In order to assess whether TCs and CCWs received support for the services that they rendered both at the clinic and in the community, questions were posed to the Programme Manager. From the responses given, it appears that both TCs and CCWs receive constant supervision from the Programme Coordinator. However, the Programme Manager highlighted the following;

“The Sizophila manager is on duty daily. Supervision visits to households with CCWs should also occur and there are guidelines for this.”

The Programme Manager revealed that the Programme Coordinator conducts supervisory home visits and checklists are available to help guide the supervisor. In terms of career advancement opportunities for CCWs, the Programme Manager revealed that there are;

“No formal opportunities but some CHWs do move into other programmes in the Desmond Tutu HIV/AIDS Foundation and DOH and CHWs have to go through appropriate channels of vacancy application if an opportunity arose.”

Outcome Evaluation Questions

Evaluation Question 10. At four months post ART initiation, did the patients who elected to receive the full spectrum of programme services (home visits) experience significantly higher retention rates?

This section sought to test the alternative hypothesis that there is a difference in the probability (P) of being lost to follow-up ($Y = 1$) between the group that received home visits ($X = 1$) and the group that did not receive home visits ($X = 0$).

$$H_1 \quad P(Y = 1 | X = 1) \neq P(Y = 1 | X = 0)$$

To test this hypothesis, a binomial logistic regression was used to assess if the odds of being lost to follow-up were significantly higher or lower than one would expect from the group that received home visits versus the group that did not receive home visits, while adjusting for covariates such as baseline CD4 count, gender, age and employment.

This section begins by presenting the descriptive statistics for the patients' demographic characteristics. Table 10 shows the socio demographic characteristics. A total of 218 patient files were reviewed. Generally, the majority of the patients were female 131 (60.1%) with 66.7% and 53.5% females in the treatment and comparison group respectively. The mean age of the group was 36.04 years ($SD = 9.92$) and the majority of the patients 40.0% were aged between 30-39 years. The proportion of participants aged between 30-39 years was 41.0 and 33.8 years in the treatment and comparison group respectively. Almost 40% of the patients had secondary education. Moreover, the majority of the patients were unemployed 164 (76.3%). Both the treatment and comparison group recorded unemployment levels of more than 70.0%.

Table 10

Socio-demographic Characteristics of Patients as a Percentage of Sample

Characteristic	Category	Treatment group (n = 145)	Comparison Group (n = 73)
Gender			
	Male	33.3	46.5
	Female	66.7	53.5
Age (Years)			
	18 – 29	18.8	25.4
	30 – 39	41.0	33.8
	40 – 49	22.9	31.0
	50 -59	15.3	8.5
	60+	2.1	1.4
Educational level			
	No education	2.1	1.4
	Primary	19.4	5.6
	Secondary	27.5	25.4
	High School	33.5	29.6
	Tertiary	0.7	4.2
	Unknown	15.3	33.4
Employment status			
	Employed	21.5	28.2
	Unemployed	78.5	71.8

Proportion lost to follow-up

Table 11 overleaf illustrates the proportion of patients lost to follow-up. From the 218 records reviewed, 12.4% of the patients were lost to follow-up. From those who were lost to follow-up, 55.6% received home visits.

Table 11

Proportion of Participants Lost to Follow-up

		Lost to Follow-up	
		Frequency	
		Yes (n =27)	No (n= 191)
Intervention	Yes	15 (10.1%)	133 (89.9%)
	No	12 (17.1%)	58 (82.9%)

A Chi-square test was conducted to assess if being lost to follow-up was associated with home visits. Results revealed that there was a highly statistically significant relationship between lost to follow-up and home visits, $\chi^2(1, N = 218) = 6.74, p = .009$.

Assessing the Model of best fit

A hierarchical analysis was conducted to determine the predictive relationship between the dependent variable (lost to follow up) and the predictor variables (home visit, CD4 baseline age, gender and employment). Thus, a total of two models were fitted to the data to determine the model of best fit. The first model, Model 1 only included the intervention-home visit as a predictor variable. Model 2 encompassed five predictor variables (home visit, CD4 baseline, age, gender and employment). Results revealed that adding employment, gender, age and baseline CD4 count to Model 1 gives a model that is statistically insignificant, $\chi^2(4) = 4.29, p = .37$. Thus, Model 1 with a statistically significant result, $\chi^2(1) = 6.35, p = .012$ was utilised to determine the predictive value of the home visit intervention on lost to follow-up outcome (Table 12).

The Model Summary that provides insight into how much variation in the dependent variable can be explained by the model revealed that the Nagelkerke R Square was equal to .055. This indicates that home visits accounts for 5.5% of the variation in the lost to follow-up variable.

Table 12

Predictors of Lost to Follow-up, with 95% Confidence Intervals

	<i>b</i> (SE)	<i>p</i>	95% CI for Odds Ratio		
			Lower	Odds Ratio	Upper
Model					
Intervention (1)	1.05 (0.42)	.012	1.26	2.87	6.5
Constant	-2.41(0.3)	.000		0.90	

Note. $R^2 = .029$ (Cox & Snell), $.055$ (Nagelkerke). Model $\chi^2(1) = 6.35$, $p = .012$

The Wald test was statistically significant $b = 1.05$, Wald $\chi^2(1) = 6.35$, $p = .012$ reflecting that the home visit intervention added significantly to the model. Therefore, the odds of being lost to follow-up were 2.87 times higher for patients not receiving home visits than those receiving home visits with a 95% CI [1.26, 6.5].

Evaluation Question 11. At four months post ART initiation, did the patients who elected to receive the full spectrum of programme services (home visits) experience significant HIV viral load suppression?

The following section sought to test the alternative hypothesis that the home visit intervention significantly contribute to HIV viral load suppression.

$$H_1 \quad P(Y = 1 | X = 1) \neq P(Y = 1 | X = 0)$$

To begin with, a Chi-square test was conducted to assess if HIV viral load suppression was associated with home visits. Results revealed that there was a non-significant association between HIV viral load suppression and home visits, $\chi^2(1, N = 107) = .082$, $p = .774$.

Although a Chi-square test revealed non-significant relationship between home visits and HIV viral load suppression, a logistic regression was conducted to determine the predictive relationship between the predictor variables (home visit, CD4 baseline age, gender and

employment) and the dependent variable (HIV viral load suppression). Results revealed that adding the predictor variables gave a model that is statistically insignificant, $\chi^2 (4) = 9.79, p = .13$. Table 13 illustrates the predictor variables in the model. The Wald statistic was used to determine the statistical significance of the predictor variables.

Table 13

Predictors of HIV Viral Load Suppression, with 95% Confidence Intervals

	<i>b</i> (SE)	<i>p</i>	95% CI for Odds Ratio		
			Lower	Odds Ratio	Upper
Model					
Intervention (1= comparison group)	-0.21(0.51)	.68	0.30	0.81	2.18
Gender (1 = male)	0.70 (0.52)	.18	0.73	2.01	5.56
Age (1 = 18-39yrs)	0.94 (0.47)	.05	1.01	2.54	6.41
Employment (1= unemployed)	0.85 (0.56)	.13	0.79	2.33	6.01
Baseline CD4	0.002 (0.002)	.28	0.1	1.00	1.01
Constant	0.83 (0.74)	.26		0.44	

Note. $R^2 = .09$ (Cox & Snell), $.13$ (Nagelkerke). Model $\chi^2 (4) = 9.79, p = .13$

The Model Summary that provides insight into how much variation in the dependent variable can be explained by the model, results revealed that the Nagelkerke R Square was equal to .127. This indicates that home visit, CD4 baseline age, gender and employment accounts for 12.7% of the variation in the HIV viral load suppression variable.

The Wald test was statistically insignificant $b = 1.56$, Wald $\chi^2 (4) = 9.79, p = .13$ reflecting that the predictor variables did not add significantly to the model. Therefore, there was no significant relationship between the three predictor variables (baseline CD4, employment and gender) and HIV viral suppression. On the other hand, age was statistically significant p

= .05. It is likely that age confounds the relationship between the home visit intervention and HIV viral load suppression given that in the absence of the intervention, age as a factor has a positive effect on viral load suppression.

However, as the study was underpowered as noted in methods chapter, it may be that failure to detect a significant association was due to a type II error.

Conclusion

Data relating to service utilisation indicated that the Sizophila programme beneficiaries were mostly female. A small proportion of patients (4%) were red flagged. However, not all red flagged patients received the full spectrum of programme activities post 1st line treatment failure. The service delivery results revealed that the majority of the CCWs implemented programme activities with fidelity. It appears that the Sizophila CCWs are adequately supported in implementing the planned programme activities.

An outcome evaluation failed to detect a significant association between the home visit intervention and HIV viral load suppression. However, home visits did contribute significantly to retaining patients to care.

CHAPTER FOUR

DISCUSSION

Introduction

The purpose of this study was to assess the implementation of the Sizophila programme. The three main domains of implementation evaluation namely service utilisation, service delivery and organisational support components were investigated. The results revealed that the programme was implemented as intended.

In addition, the study sought to determine if an initial home visit could improve ART health outcomes. Logistic regression models were used to determine if the home visit intervention significantly predicted retention to care and HIV viral suppression. Numerous previous empirical studies used RCTs to assess the impact of behavioural and cognitive interventions on ART related outcomes (Marino et al., 2007; Cooperman et al., 2012). The current study is however inimitable in that it lacked the element of random assignment and rather applied a quasi-experimental design. The main findings of the outcome evaluation are that the Sizophila home visit intervention significantly contributed to retention of patients to care but did not result in HIV viral suppression. Despite the positive finding on the lost to follow-up outcome, it is paramount that this result be interpreted with caution for reasons highlighted in the methods chapter.

The subsequent sections discuss the evaluation findings in relation to the evaluation questions formulated earlier. Furthermore, the chapter will also present sections on the implication of the evaluation- suggestions for improving the programme, recommendations for future evaluations and programme improvement, contribution to knowledge and the conclusion.

Implementation Evaluation

Service Utilisation

Evaluation Question 1: Who has utilised the therapeutic counselling services with specific focus to age, gender, level of education and employment status?

The evaluation revealed that almost two thirds of the sample was female. There is evidence to suggest that females are the major beneficiaries of ART programmes. WHO (as cited in Peacock et al., 2008) noted that in South Africa, 68% of the patients accessing ART were women. An attempt to account for this large gender discrepancy has been made. One probable reason could be due to social constructs in which males exercise resilience and as such health seeking behaviours are viewed as a sign of weakness (Peacock et al., 2008). An additional potential reason could be that many health reproductive interventions do not adequately address sexual and reproductive health needs of men (Kunene, 2003). This is evidenced by the failure of voluntary counselling and testing services to attract and accommodate men (Kunene, 2003).

In addition, the higher infection rates among women have been noted as a contributing factor to this discrepancy. Epidemiological studies have accounted for gender vulnerability differences in HIV transmission (Higgins, Hoffman & Dworkin, 2010). Higgins et al. noted that women in heterosexual relationship were at greater risk of HIV infection compared to man. The plausibility of this paradigm was confirmed through an analogy with other sexual transmitted infections which have shown differing transmission likelihoods from males to females than from females to males (Higgins et al., 2010).

An implication of having a female-dominated populace is that Sizophila may possibly be able to modify their services to include addressing challenges that are more likely to be experienced by HIV infected females.

The majority of patients utilising the Sizophila programme services were aged between 25-49years. The current study finding reflects that a much larger proportion of adults aged between 25-49 years are within the phase of ART treatment eligibility as compared to

much older adults. In addition, the age profile of the population within the community might explain this variation. A larger population concentrate (50%) is among the 25-49 years age group (Western Cape Population Unit, 2011).

Education provides people with the knowledge and skills that can lead to a better quality of life. The majority of the patients had secondary education (Grade 10). This is in line with findings by Pienaar et al. (2006) who noted that the majority of the patients accessing ART medication in Western Cape Province had attained Grade 10. The fact that the level of formal education was high among patients suggests that the Sizophila CCWs should utilise this vantage stance to promote ART uptake.

Despite the high levels of formal education, the majority of the patients utilising the Sizophila programme services were unemployed. This finding can be attributed to the fact that the Sizophila programme is administered from a state clinic that supports the provision of HAART in the public sector. Consequently, many unemployed individuals who cannot afford medical schemes are able to access full-scale ART treatment interventions from state funded health facilities.

Evaluation Question 2: What proportion of participants enrolled in the programme elected to receive either 3 individual or 3 group treatment readiness sessions?

The majority of the patients (87.5%) opted for group counselling sessions. This is a positive indication of the community's achievements in dismantling the barriers of social inhibition. The fact that individuals can unite towards a common goal without fear of ostracism is unequivocally important in tackling controversy surrounding stigma and self-doubt (Macalino et al., 2007). Community based programmes facilitating support and knowledge based interventions reported that ART adherence improved significantly among patients attending group sessions (Rueda et al., 2006).

Evaluation Question 3: What proportion of patients who commenced on ART:

3(a) Were red flagged during visits to the health facility?

The proportion of clients experiencing first line treatment failure (red flagged) was less than 4%. This finding is encouraging as the result is in line with findings of a study conducted by Ford, Mills and Calmy (2006) which revealed that developing countries had a 3% first line treatment failure rate. Interventions aimed at improving ART outcomes among PLWHA such as improved counselling approaches and procedures that stimulate regular clinic visits ensures that beneficiaries are aware of the risks related to ART non-adherence (Ford et al., 2006).

Literature on models of cognitive and behaviour change postulates that ART adherence can be enhanced through information dissemination, patient motivation and by adopting positive behaviour change skills (Fisher et al., 2006). Extrapolating the IBM model into Sizophila context, one would assume that patients accessing Sizophila programme activities are knowledgeable, well-motivated to act and have thus adopted positive behaviour traits that empower them to act efficiently. As a result, they have higher prospects of adhering to the recommended treatment plan and in so doing; they reduce the probability of treatment failure (Fisher et al., 2006).

The logical cause-effect relationship of the Sizophila programme theory posits that adherence counselling will lead to suppressed viral load. This assertion is well grounded in the literature. Researchers concede that adherence counselling is important in maintaining optimal levels of adherence (Tuldra et al., 2000; Amico et al., 2005). The Sizophila programme activities such as adherence counselling and adherence monitoring systems enhance treatment reinforcement and early detection of anomalies. The fact that the interventions were implemented with fidelity suggests that the programme activities might lead to the intended outcomes.

3(b) For those participants who were red flagged what were their demographics?

The majority of the red flagged patients were females. Most of the participants were unemployed. However, statistically there was no significant association between socio-demographic characteristics and being red flagged.

3(c) For the patients who were red flagged, how many received further counselling sessions for treatment change?

It is concerning that only very few patients (28%) who were virological unsuppressed (red flagged) received adherence counselling sessions for switching treatment from first-line to second-line therapy. This figure does not compare favourably with findings from Swaziland where 73% of the patients experiencing first-line treatment failure received enhanced adherence counselling (Jobanputra et al., 2014). Since treatment switching is a proxy indicator for poor adherence, one would expect that a large number of patients would have received adherence counselling. This finding deviates from the programme theory's assumption that adherence counselling is an essential operational activity that facilitates the achievement of the desired outcome of HIV viral load suppression. Failure to operationalise this activity might have implications for programme success as failure to engage these patients in adherence counselling will result in unintended effects.

However, the findings of the evaluation should also be interpreted with caution. Anecdotal accounts from CCWs revealed that all patients red flagged (experiencing treatment failure) received extra adherence counselling, carefully monitored adherence levels and regular home visits. This information however contradicts the findings from paper-based clinical record reviews. It is likely that CCWs are not diligent in documenting counselling related information as evidenced by inconsistencies in data capturing. This assertion is congruent with reports from Dewing et al. (2013) who found irregularities in data capturing methods among lay counsellors in 20 ART facilities in Cape Town. With the current evaluation finding in mind, it is likely that coverage is underreported.

A diligent approach to data capturing especially for patients experiencing poor adherence would be invaluable in determining the prevalence of treatment failure. A suggestion for this finding would be to institute a simple and better facility based monitoring system on data capturing. This would potentially identify irregularities in data capturing methods and allow for institutionalisation of corrective measures.

Service Delivery

Evaluation Question 4: What is the ratio of CCWs to patients?

The ratio of CCWs to patients can influence the quality of services rendered. Small population ratios imply less workload and this in turn allows for better service delivery. The current study found a ratio of 1 CCW per 33 households (1:33). Rural Health Advocacy Project (RHAP) (2012) projected ratios that ranged as low as 1 CCW per 50 households in resource constrained areas to as high as 1 in 80 in more affluent urban areas of KwaZulu Natal. Therefore extrapolating findings in KwaZulu Natal to the Sizophila context, one would say the CCW to patient ratios for the Sizophila programme are reasonably adequate.

This finding is encouraging as it places the Sizophila programme at an advantaged stance. One of the suppositions of the programme theory is that activities will be implemented as planned. The fact that CCW-patient ratios were adequate suggests that home visit interventions are presented in an efficient and effective manner that might lead to intended outcomes.

Evaluation Question 5: Home visits

The assessment of the patient's home environment is conducted prior to treatment initiation in order to identify possible motivators and obstacles to adherence (Dr R. Kaplan, personal communication, February 21st, 2014). The implementation of the home visit activity was satisfactory. With only a few exceptions, most CCWs indicated that they have sufficient time to conduct home visits. This is crucial in the implementation of the core activity that ensures continued care post ART treatment initiation. However, there is a need

to look into why 4 CCWs strongly agreed with the statement “I don’t have enough time to conduct home visits.”

All CCWs indicated that they are well prepared in conducting home visits. This may be due to the fact that they attend trainings on aspects of HIV/AIDS management and other related courses thus enhancing their knowledge. It may also be due to the fact that weekly multi-disciplinary meetings provide channels for addressing challenges and passing of plausible solutions. In addition, CCWs expressed confidence in delivering the home visit intervention. The importance of the home visit approach in enhancing ART has been advocated as a vital intervention in HIV management (Williams et al. 2006). Almost all CCWs (90.0%) expressed confidence in their role of enhancing treatment adherence. Rueda et al. (2006) provided evidence from systemic reviews that linked the benefits of managing HIV/AIDS through community based approaches to improved adherence to ART therapy.

The majority of the participants indicated that they conduct home visits on an ad hoc basis. They sometimes do not inform the patients beforehand about the home visit. As such, about 50% of the CCWs reported that they can only sometimes access patients during home visits. The potential impact of not informing patients beforehand is that it could lead to high proportions of unsuccessful visits. The majority of the CCWs indicated that the initial home visit approach is informed by guidelines. This ensures that the home visit intervention is delivered in a standardised manner.

All in all, the home visit approach appears to be delivered with fidelity. This probably means that the intervention is delivered in a standardized and effective manner. In fact, the assumption of implementing home visits with fidelity is aligned to the programme theory’s supposition that if patients receive home visits, they will likely achieve the intended outcomes. A limitation to this finding is that the evaluator relied on CCWs’ self-reports. Data from the patients could have provided insights on factors that affect the implementation of home visits.

5(a) How many home visits do the CCWs actually conduct?

The majority of the CCWs reported conducting 1 to 4 home visits a day. Pienaar et al. (2006) revealed that the home visit approach varied among five state funded ART facilities (GF Jooste Hospital, Gugulethu Community Health Centre, Hout Bay Clinic, Michael Mapongwana Day Hospital and TC Newman Hospital). Facilities conducting home visits reported that patient advocates were conducting home visit at an average of 4.8 home visits per day (Pienaar et al., 2006).

The implication of this finding is that Sizophila CCWs conduct fewer home visits per day than is typical for Cape Town based programmes. This might suggest that the Sizophila programme is probably well resourced to satisfactorily implement the home visit related tasks. This low figure might also explain why the intervention was generally implemented well. Essentially, the low number of CCW-household daily visits ensures that CCWs overcome challenges that come with unmanageable workloads (Jobanputra et al., 2014).

5(b) When do the home visits take place?

Generally, Sizophila CCWs conducted home visits anytime of the day. In comparison, a study conducted in Hout Bay Clinic found that, home visits commenced in the morning after clocking-in at 8h30 for a duration of 4 hours (Pienaar et al., 2006). It is evident that the two models, the Sizophila and the Hout Bay differ in their approaches to implementing home visits. It appears that the Sizophila CCWs have more leeway regarding when they should conduct home visits. This approach is likely to work for both the patients and CCWs. Restricting CCWs to a set time period might exclude certain classes of people from benefiting from home visits (Leeman et al., 2010), for example, the working class. However, an effective tool for monitoring home visits should be instituted in order to explore the hypothesis that standardized times might lead to an inefficient approach.

5(c) How often do CCWs conduct home visits?

Most CCWs reported conducting home visit three times a week. The frequency of home visits often determines the number of patients visited by each CCW. Jaskiewicz & Tulenko

(2012) noted that most CHWs' visits to individual household depend on the household catchment area and the number of households to be visited. Jaskiewicz & Tulenko point out that there is no specified formula to determine the frequency of household visits. However, they stipulate that programmes should exercise caution to ascertain that CHWs satisfactorily reach the assigned households.

Evaluation Question 6: What is the sequence of the programme activities and did all clients get the same sequence?

The counselling component was assessed through an adapted BCoST (Dewing and Mathews, 2011). In fact, the tool assessed the CCWs' ability to deliver the 4 components of counselling namely, initial counselling session, problem identification and understanding, problem solving and the closing session. All patients received the same sequence of activities. However, there were some slight variations in the manner in which CCWs conducted counselling sessions. These variations were more pronounced in problem identification and understanding, and problem solving components. Just above 50% of the CCWs gave a strong indication of addressing these components. This indicates the CCWs' skill variations. These findings are consistent with results from Leeman et al. (2010) who noted that some programme implementers did not use reflective questions when addressing these issues. The inability to address the above components effectively will likely compromise the successful implementation of the programme.

The findings of the study suggest the need for CCWs to attend refresher courses. Moreover, quality assurance strategies in the form of impromptu assessments from either internal or external assessors could benefit CCWs. In the same way, facilitation strategies such as constructive feedback and explicit acknowledgement of the significance of quality of delivery might enhance CCWs' counselling skills (Carroll et al., 2007).

Another implication for future evaluation would be to assess the CCWs' adherence to counselling skills. For instance, lay counsellors were found not to be proficient in motivational interviewing techniques and this was thought to influence the integration of

behaviour change counselling strategies (Mash as cited in Dewing et al., 2013). The results of this current evaluation could potentially provide a platform for addressing adherence counselling related issues.

Evaluation Question 7: In the view of Programme Coordinator, what factors contribute to the effectiveness/ineffectiveness of the home visits?

The Programme Coordinator revealed that patient, socio-cultural and organisational factors influenced the utilisation and delivery of the home visit intervention. Patient factors were identified as potential barriers to accepting the intervention as well as the inability of CCWs to implement home visits. Two major factors identified as barriers to acceptance and delivery of home visits were related to substance abuse and patient's age. The Programme Coordinator also cited socio-cultural factors as some of the barriers to implementing home visits; and these factors included beliefs and values towards HIV infection. Moreover, disclosure issues, stigma and discrimination were thought to impede the delivery of home visits. These factors if not addressed have the potential to moderate programme intervention effects (Roura et al., 2009).

The organisational factors cited (training, liaison with other structures, information publicity and CCWs' profile) were thought to facilitate the effective delivery of home visits. The fact that CCWs were chosen from the community meant that patients could easily identify with them and this created an enabling environment. Herman et al. (2009) advocates for organisations to use local human resources in integrating HIV activities as their participation is crucial in enhancing long-term retention to care.

Organisational support

Evaluation Question 8: What skills are imparted to TCs and CCWs?

The study findings show that all TCs and CCWs received the mandatory initial HIV/AIDS training as per Western Cape Province Training manuals. However, there was no concrete stance on whether TCs and CCWs received refresher courses. The Programme Manager

highlighted that there are no specific guidelines that inform ongoing training. This is a cause of concern as Evans (2013) revealed that the absence of regular refresher training would likely erode the acquired skills and knowledge while on the other hand, continued training may be more beneficial. Wringe et al. (2010) revealed that lack of ongoing training resulted in false information being relayed to patients.

These results have an implication on the delivery of counselling services. The inability to keep abreast with changes in HIV/AIDS management and counselling techniques often leads to dissemination of inaccurate information and feelings of frustration among CHWs (Jaskiewicz & Tulenko, 2012). It is suggested that Sizophila should consider improving opportunities of ongoing training as training was found to be associated with unrelenting motivation and effective handling of client concerns (Jaskiewicz & Tulenko, 2012).

Evaluation Question 9: What support is available to TCs/CCWs?

It is generally acknowledged that the success of ART adherence programmes hinges on consistent and reliable supervision and support (WHO, 2007). As well, it is recognised that supervision is often amongst one of the most tenuous links in ART programmes (Jaskiewicz & Tulenko, 2012). The current study revealed that CCWs received constant supervision from the Programme Coordinator. Supervisory procedures were said to be clearly defined as guidelines specified who should supervise CCWs and what should constitute supervision. This finding implies that well supervised CCWs if provided with constructive feedback will likely enhance skills, remain competent and cultivate esprit de corps (Jaskiewicz & Tulenko, 2012).

In addition, the Programme Manager revealed that individual performance evaluations were conducted to assess CCWs' occupational functions. This provides an opportunity to identify gaps, rectify misunderstandings and recognise achievements. In essence, performance monitoring provides feedback on CCWs' performance while at the same time indirectly recognising the effectiveness of programme functions. Lastly, the organisation provides professional development opportunities for CCWs. Community care workers

showing exceptional talents are offered an opportunity to study a 2 year advanced counselling course with the University of Cape Town. This provides CCWs the prospects of moving up the rungs of chosen career paths.

In summary, Sizophila is implementing the programme as planned. However, it appears that ongoing training is not offered on a regular basis. In essence the aspect of training needs consideration as it is likely to prevent the successful implementation of the programme interventions.

Outcome Evaluation

Evaluation Question 10. At four months post ART initiation, did patients who elected to receive the full spectrum of programme services (home visits) experience significantly higher retention rates?

The current study revealed that the impact of home visits on lost to follow-up was statistically significant as evidenced by a p-value of $p = .012$. Patients declining home visits were 2.87 times more likely to be lost to follow-up than those accepting home visits. This finding might be related to undisclosed HIV status. Disclosure is often linked to one's acceptance and commitment to HIV care. Mills et al. (2006) noted that patients who did not disclose their HIV status were more likely to suffer frequent treatment interruptions mainly because for them the process of taking medicine is a secret. Therefore, one would assume that declining the home visit intervention might have been associated with undisclosed HIV status. As a result, these patients were more likely to be lost to follow-up.

In addition, patients who are committed to lifelong treatment of ART often have excellent social support systems (Mills et al., 2006). Studies have shown that social support was significantly higher amongst patients who were retained to care compared to those who were lost to follow-up (Mills et al., 2006; Visnegarwala et al., 2006). Because the Sizophila CCWs provide support through home visits, the fact that patients who declined home visits did not receive any form of support from CCWs beyond the health facility would probably suggest that these patients were ill equipped to maintain ART adherence.

On the other hand, the wider confidence interval (lower limit is 1.26 and upper limit is 6.5) signifies that a small sample size may not be well representative to the clinic population. This is evidenced by small sample size among the patients that were lost to follow-up ($n = 15$, $n = 12$; intervention and comparison group respectively). Consequently, if another study was conducted with a larger sample size, the confidence interval would probably be narrower thus yielding a better estimate to the true value of the population (Attia, 2005).

A possible limitation to this finding is the potential of having the cause-effect relationship being mediated by a third variable. It is highly likely that patients who did not receive home visits resided out-off the geographic range prescribed by CCWs activities. This geographic range element was likely to be associated with whether or not a patient received home visits and has a potential effect on the lost to follow-up outcome. In essence, patients who are located far from the clinic are both less likely to receive a home visit, and more likely to be lost to follow up because the clinic is located far from their place of residence. This might have the potential of explaining the observed effect. It is unfortunate that the evaluator could not establish the patients' residential distance from the clinic. Future studies could consider including the distance element as a covariate, so as to assess for any significance in predicting the lost to follow-up outcome.

Evaluation Question 11. At four months post ART initiation, did patients who elected to receive the full spectrum of programme services (home visits) experience significant lower HIV-1 RNA viral load levels?

The home visit intervention is implemented mainly to enhance ART adherence among patients. Therefore the question above sought to establish if the home visit intervention led to significant HIV viral suppression. The study findings revealed that there was no significant relationship between the predictor variables and HIV viral suppression ($p = .13$). This finding is a congruent with findings by Williams et al. (2006). The authors revealed that the community-based-patient-nominated treatment supporter intervention had no significant effect on HIV viral load.

Some studies have however shown contradicting results. Kipp et al. (2012) and Kenya et al. (2013) revealed that ART were associated with suppressed viral load. The current evaluation findings might be potentially explained by three domains: firstly, it is important to note that the methodologies employed differed from the current study which employed a retrospective review of records while the above studies utilised RCTs (Kenya et al., 2013) and prospective cohort study (Kipp et al., 2012). Secondly, the intervention periods greatly varied as patients were followed up for 12 months (Kenya et al., 2013) and 24 months (Kipp et al., 2012). The current study only utilised a baseline home visit assessment. Lastly, patient characteristics and eligibility criteria differed for instance Kenya et al. (2013) included patients with a history of HAART non-adherence while Kipp et al. (2012) included newly diagnosed patients in a rural based environment who had no access to treatment. Therefore, patients in these studies were likely to be highly motivated as they had underlying concerns and as well that they received extra attention.

In addition to these domains, the current study resulted in trimming of the sample; 51% of the participants were excluded from the analysis as they did not have HIV viral load results at 4 month follow-up. Post hoc power calculations revealed that the HIV viral load outcome was underpowered ($1-\beta$ err prob) = 0.38, hence a logistic regression statistical test could not detect a significant effect of the association of between the home visit intervention and HIV viral load suppression outcome. Consequently, the combined effect of the above mentioned factors might have influenced the non-significant finding of the home visit intervention on HIV viral load.

Limitations

The evaluation identified a number of limitations as highlighted below:

A key limitation to the study was its inability to utilise a RCT that had the potential to determine the impact of the home visit intervention on ART health outcomes. The use of a RCT could have controlled for internal validity threats such as selection bias and attrition discussed previously in the methods chapter.

Secondly, the study was a quasi-experimental retrospective study and relied on data obtained from archives. This presented problems of selection bias and contributed to the weakness of the evaluation method. In addition, the evaluator had no control on ensuring data credibility. In such circumstances, a comparative prospective study would have been more appropriate. The prospective study would have enhanced credibility of the results as it would have allowed the evaluator to track the cohort.

Thirdly, as previously stated, trimming of the sample size resulted in an underpowered study ($1 - \beta = 0.38$). In fact, just above 50% of the records related to the HIV viral load suppression outcome were omitted from the analysis due to attrition (reasons indicated in Figure 5). This had an impact on assessing for the viral load suppression. Therefore, the HIV viral load outcome results cannot be generalised to a wider population.

Fourthly, the study was limited to obtaining data from the programme staff and programme records. More understanding could have been gained by augmenting the data with a survey from the programme beneficiaries regarding the home visit intervention.

In addition, the evaluation relied on the prescribed home visit intervention protocol of a pre-treatment home visit while a number of studies have extended the period of intervention to 12 months with intense CCW-patient interactions which were then tapered as patients progressed on ART treatment (Mitty et al., 2005; Macalino et al., 2007; Sarna et al., 2008; Kipp et al., 2012). Additionally, some of the studies have augmented adherence counselling with medication monitoring systems such as monitored single dose administration, pill counts and electronic reminder systems (Visnegarwala et al., 2006; Pearson et al., 2007; Taiwo et al., 2010; Chung et al., 2011).

Finally, the evaluator was not conversant in Xhosa. Therefore, being unable to explain unfamiliar concepts in vernacular might have disadvantaged the CCWs as they could not comprehend very subtle differences in the responses provided on the questionnaire.

Suggestions for Improving the Programme

Implementation evaluation

A formative evaluation is a process evaluation that gathers information aimed at improving the programme's performance (Rossi et al., 2004). Based on the evaluations results, the following are suggestions for improving the programme:

Service Utilisation

Based on findings on data capturing irregularities, it is recommended that a simple facility based monitoring system on data capturing be instituted. Implementing a clinic based monitoring system would identify irregularities in data capturing methods and therefore allow for the institution of corrective measures.

Service Delivery

To ensure counselling standardisation, CCWs can use checklists during counselling sessions to ensure coverage of all counselling components. Moreover, a rotational method of information dissemination can be adopted as opposed to one CCW continuously presenting information on a well versed topic. This might serve as informal assessments as CCWs might have an opportunity to provide feedback to colleagues. In the same way, it is also recommended that CCWs receive regular counselling skills assessments which can be vital in providing constructive feedback. Baseline training is vital; however, to ensure up-to-date information and skills enhancement, CCWs would need ongoing training.

Organisational Support

As mentioned before CCWs could benefit from regular refresher courses. Lack of training will moderate CCWs' counselling skills thus affecting programme implementation.

Outcome Evaluation

Rossi et al. (2004) defines an outcome evaluation as an evaluation conducted to determine if the programme's performance is achieving the programme objectives. An underpowered study resulted in the failure to attain the outcome of suppressed HIV viral load. The

majority of the participants had no viral load results at 4 months (see Figure 5). Therefore, it is highly recommended that the stipulated laboratory tests be conducted within the recommended time frame.

Recommendations for Future Evaluation

Though some studies in South Africa have tried to account for the impact of ART adherence programmes on ART health outcomes, this study is unique in that it is both formative and outcomes oriented in nature. Formative evaluation combines baseline and follow-up data with the objective of linking information on inputs/outputs to programme successes (Rossi et al., 2004). It is therefore recommended that a rigorous outcome evaluation with a RCT design be conducted to determine the association between home visits and ART health outcomes.

Secondly, the study was retrospective and in itself did not permit the modification of the intervention strategy-home visits. Future evaluations could also consider evaluating programme fidelity by tailoring the intervention and meticulously monitoring it.

Contribution to Knowledge

Given that this is the first evaluation of its kind on the Sizophila programme, this could potentially be a baseline comparison for other future studies conducted within the programme. In addition, the fact that the evaluation includes both implementation and outcome evaluation, it has the potential to make significant contribution to the literature in South African HIV/AIDS community based programmes since most of the studies were impact evaluations.

The evaluation highlighted the methodological challenges of dealing with archived data especially in the health sector. The limitations highlighted can provide insight on challenges that might be encountered. As such future researchers should be wary of such challenges.

Conclusion

As health advocates are drawn from local communities they have the potential to provide preeminent and utmost comprehensive care to underprivileged patients. Studies have shown the importance of CCWs in enhancing access and coverage of HIV/AIDS health care service to communities at large (Igumbor et al., 2011; Kenya et al., 2013; van Loggerenberg et al., 2014). Focusing on the current study, although CCWs implemented the home visit interventions with fidelity, lack of applying meticulous steps in documenting programmatic data may very likely override the successes of programme delivery. It is recommended that the programme institute simple and better data capturing and documentation procedures so as to enhance data quality that can support future evaluations of the programme and also augment management/decision making processes. Moreover, variations in the manner in which CCWs conducted counselling sessions indicate the need for CCWs to attend refresher courses so as to enhance uniformity in disseminating counselling sessions.

The outcome evaluation showed that the home visit intervention had no significant effect on HIV viral load suppression. This might be explained by an underpowered study. However, there is greater need for ensuring that any recommended HIV related standardised laboratory quantification tests be executed per recommended follow-up period as the absence of data may obscure the effects of the programme. On the contrary, the home visits intervention had an impact on retention of patients to care. It may well be acceptable that there is significance in exposing patients to the home visit intervention.

To rationalise the merit of such programmes, future evaluation studies should adopt rigorous prospective designs that have the potential of producing unquestionable and credible interpretations. Together with this, time and resources permitting, a RCT is recommended.

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APPENDIX A: SUMMARY OF STUDIES EMPIRICAL INCLUDED IN THE REVIEW

Authors & Year of Publication	Study Title & Design	Study Setting	Aim of the Study	Description of participants & sample size	Intervention and duration	Outcomes
Altice et al., (2007)	Superiority of Directly Administered Antiretroviral Therapy over Self-Administered Therapy among HIV-Infected Drug Users: A Prospective, Randomized, Controlled Trial	New Haven Connecticut	The objective was to determine the potential efficacy of a 6-month DAART program on HIV infection, using surrogate markers of HIV-1 RNA level and CD4 cell count.	HIV infected drug users; 141 patients (88 in DAART and 53 self-administered therapy)	6 months Directly administered antiretroviral therapy (DAART)	HIV RNA viral load suppression was significantly higher in the DAART arm than in the SAT arm (70.5% vs. 54.7%; adjusted OR, 2.6; 95% CI, 1.2–5.5; $p = .02$).
Bogart et al., (2012)	Community HIV treatment Advocacy Programs may support treatment adherence Community based participatory research	Los Angeles County	Aim to engage clients into care and support antiretroviral treatment (ART) adherence through client-centred counselling; advocate for patients with providers	121 patients (36 in TA and 85 not in TA)	Treatment advocacy 6 months duration	TA participants (vs. non-TA participants) showed higher electronically monitored [85.3% vs. 70.7% of doses taken; $b(SE) = 13.16(5.55)$, $p < .05$] and self-reported [91.1% vs. 75.0%; $b(SE) = 11.60(5.65)$, $p < .05$]
Chung et al., 2011	A randomized controlled trial comparing the effects of counselling and alarm device on HAART adherence and virologic outcomes. Randomised control Trial	Nairobi Kenya	This study compared the impact of counselling and use of an alarm device on adherence and biological outcomes in a resource-limited setting.	400 individuals were enrolled, 362 initiated HAART, and 310 completed follow-up	Four arms- Counselling (three sessions around ART initiation), alarm (pocket electronic pill reminder carried for 6 months), counselling plus alarm, and neither counselling nor alarm. Participants were followed for 18 months after HAART initiation.	Participants who received counselling were 29% less likely to have monthly adherence <80% (hazard ratio [HR]=0.71; 95% [CI] 0.49-1.01; $p=0.055$) and 59% less likely to experience viral failure (HR 0.41; 95% CI 0.21-0.81; $p=0.01$) compared to those who received no counselling. Neither counselling nor alarm was significantly associated with mortality or rate of immune reconstitution.
Coetzee et al., (2004)	Promoting adherence to antiretroviral therapy: the experience from a primary care setting in Khayelitsha,	Cape Town South Africa	To describe the approach used to promote adherence to antiretroviral therapy	287 patients	Standard of care- including counselling, peer support, material	The probability of survival was 86.3% at 24 months. The median CD4 cell count gain was 288 cells/ml at 24 months. Viral load was less than 400

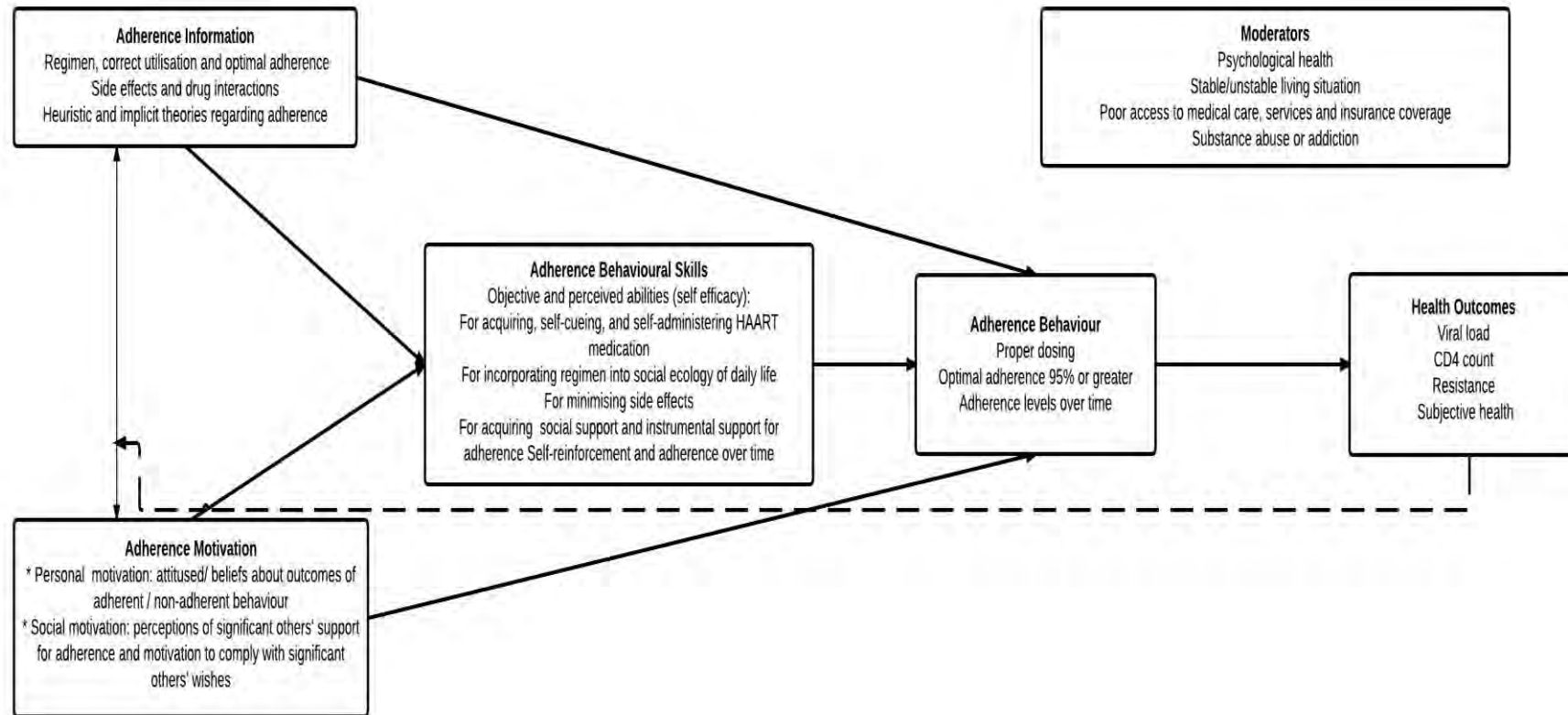
	South Africa Prospective open cohort		(ART) and to present the outcomes in the first primary care public sector ART project in South Africa		support	copies/ml in 89.2, 84.2 and 69.7% of patients at 6, 12 and 24 months, respectively.
Cooperman et al., (2012)	Impact of adherence counselling dose on antiretroviral adherence and HIV viral load among HIV-infected methadone maintained drug users Randomized, Controlled Trial	New York USA	To investigate ART adherence and HIV viral load relative to the number of hours of adherence counselling received by 60 HIV-infected drug users	HIV infected drug users; 60 participants	The intervention combined motivational interviewing and cognitive-behavioural counselling to improve antiretroviral adherence during a 24-week intervention period	Among those who participated in adherence counselling, dose of counselling had a significant positive relationship with antiretroviral adherence measured after the conclusion of counselling. However participants receiving STAR-DOT lower adherence (61% vs. 78%, $p = 0.05$) and higher viral load (2.96 vs. 2.24 log ₁₀ copies/ml, $p = 0.05$) than those who did not receive counselling
Igumbor et al., (2011)	An evaluation of the impact of a community-based adherence support programme on ART outcomes in selected government HIV treatment sites in South Africa Retrospective study	South Africa	To assess the impact of a community-based adherence support service on the outcomes of patients on antiretroviral therapy (ART)	540 records	Comparison of patient records from ART site with and without patient advocates 2 years	This study noted that a significantly higher proportion of patients with a community-based adherence supporter (also known as a patient advocate, PA) had viral load (VL) of less than 400 copies/ml at six months of treatment (70%, $p = 0.001$); a significantly higher proportion of patients with PAs (89%) attained a treatment pickup rate of over 95% (67%; $p = 0.021$).
Kabore et al., (2010)	The Effect of Community-Based Support Services on Clinical Efficacy and Health-Related Quality of Life in HIV/AIDS Patients in Resource-Limited Settings in Sub-Saharan Africa Enhanced Patients Evaluation (EPE) Prospective, observational study	Multi-site (Lesotho, South Africa, Namibia and Botswana.)	To document changes in patients' clinical outcomes as measured by CD4 cell count, health-related quality of life and adherence to ART	377 HIV positive patients	Clinical and health-related quality of life (HRQOL) combined with community support service 18 months	Patients exposed to community-based supportive services experienced a more rapid and greater overall increase in CD4 cell counts than unexposed patients. They also had higher levels of adherence, attributed primarily to exposure to home-based care services
Kenya et al., (2013)	Using Community Health Workers to Improve Clinical	Miami, Florida USA	To determine if community health	91 HIV positive patients (43 in PACT	Participants were randomised either to	At 12 months, the mean VL in the intervention group was log 0.9

	Outcomes Among People Living with HIV Randomized Controlled Trial		workers could improve clinical outcomes among vulnerable African-Americans	programme and 48 in control group)	counselling on adherence and community health (COACH) programme or SOC 12 Months	copies/L lower than the control group. The CD4 counts were not significantly different among the groups.
Kipp et al., (2012)	Antiretroviral Treatment for HIV in Rural Uganda: Two-Year Treatment Outcomes of a Prospective Health Centre/Community-Based and Hospital-Based Cohort Comparative cohort study	Uganda	To assess the effectiveness of a rural HC/ community-based ART program in Rwimi sub county, Kabarole district; To compare the treatment outcome (VL) in both settings	385 patients (200 in hospital based and 185 in community based)	During the weekly visits, the volunteers performed a pill count and assessed the presence of clinical problems and adverse reactions. 2 years	Successful ART treatment outcomes in the HC/community-based cohort were equivalent to those in the hospital- based cohort after two years of treatment in on-treatment analysis (VL<400 copies/ml, 93.0% vs. 87.3%, $p = 0.12$),
Macalino et al., (2007)	A randomised clinical trial of community based directly observed therapy as an adherence intervention Randomised clinical trial	Rhodes Island and Massachusetts	To determine if directly observed HAART can increase CD4 cell counts and decrease viral load in HIV-positive injecting drug users	88 patients (44 in control group and 44 in MDOT group)	Participants were randomised either to standard of care (SOC) or modified directly observed therapy (MDOT) 12 months	Findings revealed that participants on MDOT intervention were likely to achieve plasma viral load suppression (odd ratio 2.16; 95% confidence interval
Mitty et al., (2005)	The Use of Community-Based Modified Directly Observed Therapy for the Treatment of HIV-Infected Persons Community Based Participatory	Massachusetts USA	To determine the long-term impact of modified directly observed HAART on HAART adherence, CD4 cell count and viral load Case Studies	69 patients who were on MDOT program	A near-peer outreach worker administered directly observed therapy everyday 6-12 months	The median baseline plasma viral load (PVL) was 4.8 log, and the median individual change in PVL from baseline to 6 months among participants receiving MDOT was a decrease of 2.7 log.
Mutchler et al. (2011)	Improving HIV/AIDS care through treatment advocacy: going beyond client education to empowerment by facilitating client-provider relationships Qualitative	Los Angeles County USA	The aim of the study was to explore how treatment advocacy helped in HIV care, ART initiation and adherence to ART.	25 treatment advocacy clients, 2 treatment advocates and 4 HIV medical providers	Treatment advocacy	TA services within an ASO also provide a safe place to discuss initial HIV diagnoses and other health issues in a more comprehensive manner
Nachega et al., (2010)	Randomised control trial of trained patient nominated treatment supporters providing partial directly observed ART	Cape Town South Africa	To compare the impact of partial ART DOT administered by community based patient nominated	274 patients (137 patients randomised to treatment supporter DOT-ART & 137 to self-	Directly observed Therapy 12 months	DOT-ART showed no effect on virologic outcomes ($p = 0.42$), but was associated with greater CD4 increases at 6-month follow-up 148 (IQR 84-222) vs. 111 (IQR 44-196) $p = 0.02$.

	Randomised control trial		treatment supporters with self-administered ART	administered ART)		Survival was significant DOT-ART (9 deaths) compared to Self-ART (20 deaths) ($p = 0.02$)
Pearson et al., (2007)	Randomized control trial of peer-delivered, modified directly observed therapy for HAART Randomised control trial	Mozambique	To assess the efficacy of a peer-delivered intervention to promote short-term (6-month) and long-term (12-month) adherence to HAART in a Mozambican clinic.	350 men and women (> or = 18 years) initiating HAART	Participants were randomly assigned to receive 6 weeks (Monday through Friday; 30 daily visits) of peer-delivered, MDOT or standard care	Intervention participants, compared to those in standard care, showed significant higher mean medication adherence at 6 months (92.7% vs. 84.9%, difference 7.8, 95% CI: (0.02, 13.0) and 12 months (94.4% vs. 87.7%), difference 6.8, 95% CI: (0.9, 12.9). There were no between-arm differences in CD4 counts.
Purcell et al., (2007)	Results From a Randomized Controlled Trial of a Peer-Mentoring Intervention to Reduce HIV Transmission and Increase Access to Care and Adherence to HIV Medications Among HIV-Seropositive Injection Drug Users Randomized Controlled Trial	Baltimore, Miami, New York and San Francisco USA	To evaluate the efficacy of an intervention to reduce sexual and injection transmission risk behaviours and to increase utilization of medical care and adherence to HIV medications among this population.	966 HIV positive IDUs randomly assigned to 10 sessions peer mentoring (intervention) or 8 session video discussion (control)	Peer mentoring intervention based on social learning theory, IMB model & social identity model 5 weeks	Overall retention rates for randomized participants were 87%, 83%, and 85% at 3, 6, and 12 months, respectively. Participants in both conditions reported significant reductions from baseline in injection and sexual transmission risk behaviours, but there were no significant differences between conditions.
Sarna et al., (2008)	Short- and long-term efficacy of modified directly observed antiretroviral treatment Randomized Control trial.	Mombasa, Kenya	To determine short- and long-term efficacy of modified directly observed therapy (m-DOT) on antiretroviral adherence.	234 HIV-infected adults were assigned MDOT or SOC (standard care).	24 weeks of twice weekly health center visits for observed pill ingestion, adherence support, and medication collection 72 weeks	Viral suppression at 48 weeks was 2.0 times (95% CI = 0.8 to 5.2; $p = 0.13$) as likely in MDOT participants as controls. Adherence with MDOT was 4.8 times greater ($p < 0.001$) with adjustment for depression and HIV-related hospitalization. In weeks 25-48, adherence with MDOT was similar to controls.
Taiwo et al., (2010)	Assessing the Virologic and Adherence Benefits of Patient-Selected HIV Treatment Partners in a Resource-limited Setting	Jos, Nigeria	To determine the efficacy of patient-selected treatment partners on virologic and adherence	499 HIV-infected adults were randomized to standard of care (SOC) or patient-	Each patient was followed for 48 weeks	At week 24, undetectable viral load was achieved by 61.7% of patients in the TPA arm versus 50.2% of those receiving SOC [OR = 1.58, 95% CI: 1.11 to 2.26, $p < 0.05$]. There was no

	Randomized Control trial.		outcomes during first-line antiretroviral therapy.	selected treatment partner-assisted therapy (TPA).		significant difference at week 48: 65.3% versus 59.4% for TPA and SOC, respectively (OR = 1.28, 95% CI: 0.89 to 1.84, P > 0.05).
van Loggerenberg et al., (2014)	Individualised Motivational Counselling to Enhance Adherence to Antiretroviral Therapy is not Superior to Didactic Counselling in South African Patients: Findings of the CAPRISA 058 Randomised Controlled Trial.	Durban South Africa	To evaluate more intensive individualised motivational adherence counselling.	297 HIV-positive patients randomised to receive either didactic counselling, prior to ART or an intensive motivational adherence intervention after initiating ART	Intensive motivational adherence for 6 months	Virologic suppression at 9 months was achieved in 89.8 % of didactic and 87.9 % of motivational counselling participants 82.9 % of didactic and 79.5 % of motivational counselling participants achieved >95 % adherence by pill count at 6 months. Participants receiving intensive motivational counselling did not achieve higher treatment adherence or virological suppression than those receiving routinely provided didactic adherence counselling
Visnegarwal et al., (2006)	Community outreach with weekly delivery of anti-retroviral drugs compared to cognitive-behavioural health care team-based approach to improve adherence among indigent women newly starting HAART Prospective Cohort Pilot Study	Texas, USA	To evaluate a novel strategy of weekly delivery of medications	50 women were enrolled into Adherence Coordination Services and 26 into Directly Delivered Therapy	6 months ASC-4-5 hours of HIV education, refill reminders and home visits DDT- delivery of ART, positive reinforcements	The proportion of women achieving virologic suppression in 4-8 month period for DDT; ACS and SoC groups were 86% (18/21); 54% (6/11); and 36% (8/22) ($p < 0.004$); and in the 10-14 month period were 80% (12/15); 54% (6/11) and 45%(10/22) ($p < 0.036$ for DDT vs. SoC). Retention rate in the DDT was 87%.
Williams et al., (2006)	Home Visits to Improve Adherence to Highly Active Antiretroviral Therapy Randomized Controlled Trial	USA	To determine the efficacy of interventions to improve medication adherence among patients prescribed highly active antiretroviral therapy	Participants were 171 HIV-infected adults prescribed a minimum of 3 antiretroviral agents	Subjects were randomly assigned to receive home visits for 1 year	The majority of participants in the intervention group demonstrated adherence greater than 90% compared to the control group at each time point after baseline. Extended Mantel-Haenszel test: 5.80, $p = 0.02$). A statistically significant intervention effect on HIV RNA level or CD4 cell count was not seen,

APPENDIX B: INFORMATION–MOTIVATION–BEHAVIOURAL SKILLS MODEL



APPENDIX C: FACULTY OF HEALTH SCIENCES ETHICAL APPROVAL



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492 • Facsimile [021] 406 6411
Email: Sunayah.ariefeldien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

30 June 2014

HREC/REF: 415/2014

Ms S Chapman
Management Studies
Faculty of Commerce
Upper Campus
UCT

Dear Ms Chapman

Project Title: A FORMATIVE EVALUATION OF A COMMUNITY BASED ANTIRETROVIRAL THERAPY ADHERENCE PROGRAMME: THE CASE OF SIZOPHILA, CAPE TOWN, SOUTH AFRICA (Masters-candidate-Constance Mubekapi) -linked 359/2002)

Thank you submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year until the 30 June 2015.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please add the UCT HREC contact details to the Informed consent document.

We acknowledge that the following student:- Constance Mubekapi is also involved in this project.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Hrec/ref:415/2014

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Hrec/ref:415/2014

APPENDIX D: FACULTY OF COMMERCE ETHICAL APPROVAL

UNIVERSITY OF CAPE TOWN



Faculty of Commerce Ethics in Research Committee

Courier: Room 2.21 Leslie Commerce Building Upper Campus University of Cape Town
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Email: Irwin.brown@uct.ac.za
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July 24, 2014

Constance Mubekapi
Management Studies

Project title:

A Formative Evaluation of a Community Based Antiretroviral Therapy Adherence Programme: The Case of Sizophila, Cape Town, South Africa

Dear Researcher,

This letter serves to confirm that this project as described in your submitted protocol has been approved.

Please note that if you make any substantial change in your research procedure that could affect the experiences of the participants, you must submit a revised protocol to the Committee for approval.

Regards,

Harold Kincaid

Professor Harold Kincaid
Commerce Faculty Ethics in Research Committee

APPENDIX E: HOME VISIT SERVICE DELIVERY QUESTIONNAIRE



Section I

Please indicate your response with a tick (✓) in the blocks provided below

Example statement: **I enjoyed the counselling training**

1 ✓ Strongly disagree	2 Disagree	3 Agree	4 Strongly agree
--------------------------	---------------	------------	---------------------

Gender Female Male

1. I don't have enough time to conduct home visits

1 Strongly disagree	2 Disagree	3 Agree	4 Strongly agree
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2. I am well prepared in providing home visits

1 Strongly disagree	2 Disagree	3 Agree	4 Strongly agree
------------------------	---------------	------------	---------------------

3. I am not confident in delivering the home visit intervention

1 Strongly disagree	2 Disagree	3 Agree	4 Strongly agree
------------------------	---------------	------------	---------------------

4. I feel that home visits are not important in enhancing ART adherence

1 Strongly disagree	2 Disagree	3 Agree	4 Strongly agree
------------------------	---------------	------------	---------------------

5. I do not inform the participants beforehand about the home visit

1 All the time	2 Sometimes	3 Never
-------------------	----------------	------------

6. I can easily access participants for home visits

1 All the time	2 Sometimes	3 Never
-------------------	----------------	------------

7. Are there any programme guidelines that inform you on how to deliver home visits?

Yes No

If yes, please list them:

8. Do guidelines specify when home visits should take place?

Yes No

If yes, when should the home visit take place_____

9. On average (Monday -Friday between 8 am and 5pm) how many home visits do you conduct per day? (Tick (✓) one response)

Less than 1 1-4 5-8 9-12 More than 12

10. How often do you conduct home visits? (Tick (✓) one response)

Once a week Twice a week Three times a week Four times a week Everyday

11. When do home visits take place? (Tick (✓) the appropriate response or responses)

Mornings Afternoons Evenings Anytime of the day

12. What has helped you to conduct home visit?_____

13. What challenges do you have face when conducting home visits?_____

Section II: BASIC COUNSELLING SKILLS TOOL

The statements provided below relate to counselling sessions. Please indicate the extent to which you address these issues during counselling sessions by circling only one number from 1 to 10. The numbers indicate the level of agreement with the statements. (The level of agreement is low at number 1 and strong at number 10). Therefore, on a scale of 1 to 10 please rate the extent to which you agree with the following statements

Question	Statement	Response (please circle)
1. INITIAL COUNSELLING SESSION		
1.1.	During the first counselling session, I engage the client in greetings	1 2 3 4 5 6 7 8 9 10
1.2.	During the first session, I explain my role in counselling	1 2 3 4 5 6 7 8 9 10
1.3.	During the first session, I explain the reason for the counselling session	1 2 3 4 5 6 7 8 9 10
1.4.	During the first counselling session, I explain confidentiality including its limits	1 2 3 4 5 6 7 8 9 10
2. INITIAL AND ONGOING COUNSELLING SESSIONS: PROBLEM IDENTIFICATION AND UNDERSTANDING		
2.1	In all counselling sessions, I use open ended questions and allow clients to express themselves	1 2 3 4 5 6 7 8 9 10
2.2.	In all counselling sessions, I identify and clarify the clients' problems	1 2 3 4 5 6 7 8 9 10
2.3.	In all counselling sessions, I attempt to understand the clients' reason for both adherence and non-adherence	1 2 3 4 5 6 7 8 9 10
3. PROBLEM IDENTIFICATION		
3.1.	In all counselling sessions, I discuss with the clients the solutions to solve problems	1 2 3 4 5 6 7 8 9 10
3. 2.	In all counselling sessions, I ask the client to share their solutions before I share mine	1 2 3 4 5 6 7 8 9 10
3.3.	In all counselling sessions, I offer relevant information to the clients' situation	1 2 3 4 5 6 7 8 9 10
3.4.	In all counselling sessions, I help the client to agree to solutions that are realistic	1 2 3 4 5 6 7 8 9 10
3.5.	In all counselling sessions, the client and I discuss if the client is able to use the solutions	1 2 3 4 5 6 7 8 9 10
4. CLOSING SESSIONS		
4.1.	At the end of each session, I summarise the issues that were raised in the session	1 2 3 4 5 6 7 8 9 10
4.2.	At the end of each session, I offer the client time to ask questions and answer them	1 2 3 4 5 6 7 8 9 10
4.3.	At the end of each session, if needs be, I set up a follow-up date	1 2 3 4 5 6 7 8 9 10

APPENDIX F: ORGANISATIONAL SUPPORT



Please indicate your response with a tick (✓) in the boxes provided and comment were appropriate

1. Recruitment of CHWs		
Does the program have written guidelines for recruiting CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
2. Role of CHWs		
Does the program have written guidelines describing the role of CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Do written job descriptions exist for CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is their role and task(s) clearly understood within the community?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
3. Initial Training		
Are there program records that track how many CHWs have received initial training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are there written guidelines that specify what topics should be covered during training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
According to the program, is there a specific time period during which a CHW should receive initial training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
4. Continuous Training		
Are there program records that track how many CHWs have received training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are there written guidelines on how to select CHWs for continuous training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
According to the program, is there a specific time period during which a CHW should receive continuing training?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
5. Equipment and Supplies		
Does a system exist for CHWs to regularly order equipment and supplies?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are there written guidelines to determine what equipment and supplies CHWs need to deliver services?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
6. Supervision		
Are there program guidelines that specify	Yes <input type="checkbox"/>	Comment:

how often supervision visits take place?	No <input type="checkbox"/>	
Are there guidelines that specify who should supervise CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are there written guidelines to determine what should take place during a supervision visit?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Do supervision checklists or any other supervision tools exist to help guide supervisors?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
7. Individual Performance Evaluation		
Is there a process for conducting individual performance evaluations for CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Does the process include community feedback	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
8. Incentives		
According to program documents, are any financial or non-financial incentives provided to CHWs by the program?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
According to program documents, are any financial or non-financial incentives provided to CHWs by the MOH?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are incentives provided based on good performance?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
9. Community Involvement		
Does the community play a role in supporting CHWs, (i.e. defining roles, providing feedback, providing incentives)?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
10. Referral System		
Is there a process that CHWs follow to determine when a referral is needed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Are formal referral slips used by CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there an established logistics plan for emergencies in the community?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there a system for the health center to provide CHWs with information about the patient once the referral has been made?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
11. Opportunity for Advancement		
Are advancement opportunities for CHWs offered by the program?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
If opportunities do exist, is there a process to inform CHWs of them?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:

Are there clear guidelines for criteria for advancement?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
12. Documentation and Information Management		
Do CHWs have a notebook or other method for documenting their home visits consistently and for recording other data?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Do supervisors monitor the quality of documents and provide assistance when needed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there a process for the supervisor or referral facility to work with CHWs to use data for solving problems?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
13. Linkages to Health System		
Does the health system support any of the following: training, supervision, referral, logistics, incentives, advancement and/or use of data?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
14. Program Performance Evaluation		
Are CHW activities (can be a sample) evaluated based on program targets, objectives, and indicators?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there a systematic process for conducting program performance evaluations?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there a process to provide feedback to CHWs based on the evaluation?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
15. Country Ownership		
Do national policies exist regarding the role of CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Does the health system play a role in supervising, training and/or supporting CHWs?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:
Is there an authorized budgetary line item in the health sector's budget to financially support the CHW program?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comment:

APPENDIX G: SAMPLE SIZE CALCULATION

z tests - Logistic regression

Options: Large sample z-Test, Demidenko (2007) with var corr

Analysis: A priori: Compute required sample size

Input:	Tail(s)	=	Two
	Odds ratio	=	0.2105263
	Pr(Y=1 X=1) H0	=	0.2
	α err prob	=	0.05
	Power (1- β err prob)	=	0.8
	R ² other X	=	0.16
	X distribution	=	Binomial
	X parm π	=	0.75
Output:	Critical z	=	-1.9599640
	Total sample size	=	218
	Actual power	=	0.8012288