

PATIENT SATISFACTION AND TREATMENT ADHERENCE OF STABLE HIV INFECTED PATIENTS

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Thesis presented in partial fulfilment of the requirements for the degree of
Master of Nursing Science in the faculty of Medicine and Health Sciences

Stellenbosch University

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March 2016

DECLARATION

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ABSTRACT

South Africa had a 75% increase in access to Antiretroviral Treatment (ART) in 2011. Effective strategies to improve access and manage care need to be implemented into ART programs. ART adherence clubs is a new strategy that is being implemented in various parts of South Africa. The aim of the study was to investigate whether stable Human Immunodeficiency Virus (HIV) infected patients on ART who receive care in ART adherence clubs are more satisfied and more adherent to treatment than those who receive care in Primary Health Care (PHC) clinics.

A quantitative cross-sectional study was done to compare patient satisfaction and treatment adherence in ART adherence clubs and PHC clinics in the Eden district within the Western Cape.

The study sample included 320 participants (98 club and 222 clinic) from 13 PHC clinics (six with clubs and seven without clubs). One clinic was used for the pilot study and excluded from the data analysis. Stable HIV infected patients were recruited when they attended appointments for the club or clinic. Established questionnaires were used to measure patient satisfaction and self-reported treatment adherence. The questionnaires were completed by the research team for participants from September 2014 to March 2015 in Afrikaans, English and Xhosa. Descriptive and inferential statistics was done with STATISTICA and regression analysis in SPSS. The guideline for determining significance was 5% ($p < 0.05$).

The analyses showed that higher levels of satisfaction are predicted with club participants than with clinic participants. There was no significant difference between clinic and club participants with regards to estimated adherence ($p > 0.05$). However, the odds of being adherent was more likely in participants that were satisfied ($p < 0.05$, 95%, CI 0.252 to 0.882).

ART adherence clubs therefore provide a service that patients may be more satisfied with, although they are not more adherent to treatment.

PHC clinics with large patient volumes could use ART adherence clubs to reduce patient loads and to improve satisfaction of their stable HIV infected patients. Further research of patient experiences in ART adherence clubs may provide insight to the link between patient satisfaction and treatment adherence.

OPSOMMING

Suid Afrika het 'n 75% styging gehad in die toegang tot Antiretrovirale Terapie (ART) in 2011. Effektiewe strategieë om die toeganklikheid en bestuur daarvan te verbeter in ART programme moet geïmplementeer word. ART nakomingsklubs is 'n nuwe strategie wat in verskeie dele van Suid-Afrika geïmplementeer word. Die doel van die studie was om te ondersoek of stabiele Menslike Immuniteitsgebreek Virus (MIV) geïnfekteerde pasiënte op ART wat hul sorg by ART nakomingsklubs ontvang, meer tevrede is en meer getrou is met die gebruik van hul terapieteenoor die pasiënte wat hul sorg by Primêre Gesondheidsorg (PGS) klinieke ontvang.

'n Kwantitatiewe deursnee studie was gedoen om pasiënt tevredenheid en behandeling nakoming te vergelyk in ART nakomings klubs en PGS klinieke in die Wes Kaapse Eden distrik.

Die studie het 320 (98 klub en 222 kliniek) pasiënte ingesluit van 13 PGS klinieke (ses met klubs en sewe sonder klubs). Een kliniek was as die loodsstudie gebruik en uitgesluit uit die data analise. Stabiele MIV pasiënte was genader en ingesluit soos per bywoning by kliniek of klub. Vasgestelde vraelyste was gebruik om pasiënt tevredenheid asook subjektiewe behandeling nakoming te meet. Die vraelyste is voltooi deur lede van die navorsingsspan vanaf September 2014 tot Maart 2015 in Afrikaans, Engels en Xhosa. Beskrywende en afleibare statistieke was gedoen deur STATISTICA en regressie analise in SPSS. Die maatstaf om beduidendheid te toon was 5% ($p < 0.05$).

Die analise het getoon dat hoër vlakke van tevredenheid verwag kan word onder die klub pasiënte in vergelyking met die kliniek pasiënte. Daar was geen beduidende verskil tussen die klub en kliniek pasiënte ten opsigte van behandeling nakoming nie ($p < 0.05$). Die kans om meer getrou te wees was wel hoër in pasiënte wat meer tevrede was ($p < 0.05$, 95%, CI 0.252 tot 0.882).

ART nakomingsklubs lewer dus 'n diens waarmee pasiënte meer tevrede is, alhoewel hulle nie meer getrou is tot behandeling is nie.

PGS klinieke met hoë pasiënt volumes kan gebruik maak van ART nakomings klubs om die pasiënt lading te verminder en stabiele MIV geïnfekteerde pasiënte se tevredenheid te verbeter. Verdere navorsing van pasiënte in ART nakomings klubs kan verdere insae lewer oor die verhouding tussen pasiënt tevredenheid en terapie nakoming.

ACKNOWLEDGEMENTS

The researcher would like to express her gratitude to:

- Talitha Crowley, her supervisor- for all her support, inspiration, guidance and encouragement through the last three years for without her this would not have become a reality.
- Her husband, Frik- for supporting and helping her climb this mountain.
- Her Family- their support and encouragement has helped her each step of the way.
- Phillip Holtz- her support, inspiration to live life to the full and assistance in the last few days has been immeasurable.
- Tonya Esterhuizen- for your assistance with statistical analysis and interpretation.
- Stellenbosch University- for the opportunity to expand her knowledge and experience with their support.
- The participants- for their participation and patience.
- The fieldworkers- for their hard work and diligence to complete the data collection.
- The facilities- to all the clinic sisters, nurses, counsellors and data capturers for their endless dedication and compassion for their patients.
- The translators- for their expertise and assistance.

DEDICATION

My children, Kay and Jan-Louis the world awaits you with many opportunities, dreams and challenges. May the commitment to this work inspire you to always work hard, dream big and persevere to the end, but most importantly remember that Jesus, Our King is with you and with Him all things are possible.

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ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral Treatment/ Antiretrovirale Terapie
CAG	Community Adherence Group
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
MIV	Menslike Immuniteitsgebrek Virus
PGS	Primêre Gesondheidsorg
PHC	Primary Health Care
UNAIDS	Joint United Nations programs on HIV/AIDS

CHAPTER 1: SCIENTIFIC FOUNDATION FOR THE STUDY

1.1 INTRODUCTION

An estimated 35.3 million people in the world live with the Human Immunodeficiency Virus (HIV) with almost a third of these on HIV treatment (UNAIDS, 2013:47). From 2011 to 2012, 2.3 million people in Sub-Saharan Africa were added to HIV/Acquired Immune Deficiency Syndrome (AIDS) programs (UNAIDS, 2012:17) and South Africa had a 75% increase in access to Antiretroviral Treatment (ART) (UNAIDS, 2012:17). Effective strategies need to be implemented into ART programs to help alleviate the pressure on health care services (Van Damme, Kober & Laga, 2006:653). One such strategy requiring more research is ART adherence clubs. This chapter outlines the rationale behind the study of ART adherence clubs, the research objectives and the research methodology of this study.

1.2 BACKGROUND AND SIGNIFICANCE OF THE PROBLEM

South Africa has the largest population of HIV infected people, with estimated numbers standing at 6.4 million (Shisana, Rehle, Simbayi, Zuma, Jooste et al., 2014:29; UNAIDS, 2012:7). There are currently an estimated 2.3 million people in South Africa on ART (Simelela & Venter, 2014:251). Recent ART guidelines now state that patients with a CD4 cell count of 500 or less are eligible for ART (South Africa, 2014:65). Prior to these changes, treatment guidelines stipulated that a patient was only eligible for ART once the CD4 cell count dropped to 200 and below, later revised guidelines stipulated a CD4 cell count of 350 and below was sufficient (South Africa, 2010:1; South Africa, 2013:5). These changes in treatment guidelines have led to marked increase in new patients receiving ART, with numbers in excess of 300 000 annually (Meyer-Rath, Pillay, Blecher, Brennan, Long et al., 2010:2). It is projected that by 2016 there will be 3.5 million people on treatment in South Africa (Meyer-Rath et al., 2010:7).

Health care systems with Health Care Worker (HCW) or clinical staff shortages face significant challenges to continue the provision of ART to large growing numbers (Van Damme et al., 2006:653; Bemelmans, Baert, Goemaere, Wilkinson, Vandendyck et al., 2014:968). A systematic review done in 2007 indicated that only 60% of patients remained on ART two years after starting treatment in Sub-Saharan Africa, with loss to follow-up and death as the leading causes of patient attrition (Rosen, Fox & Gill, 2007:1691). It is with these two challenges in mind, that new strategies of ART delivery and care are being explored by

researchers. Various strategies are being investigated in order to alleviate the strain on the national health care system and improve retention in care of ART patients.

These include task-shifting of HIV treatment and the decentralisation of ART to Primary Health Care (PHC) clinics and community ART adherence groups. Task-shifting allows for specific care tasks to be moved from highly qualified HCW, for example doctors to HCW, such as nurses with shorter training and fewer qualifications (World Health Organization, 2008:2). Decentralization describes moving ART delivery from hospitals to more peripheral health facilities, such as clinics and even into communities (Kredo, McCaul & Volmink, 2015:1). These two strategies have provided essential relief and assistance in increasing access to ART for patients. There are, however, still high rates of patient attrition and it is argued that service delivery should be expanded to the community (Ford & Mills, 2011:1; Fatti, Grimwood & Bock, 2010:8). Ford and Mills (2011:2) recommend care be made available as close as possible to a patient's home and that it be as minimally intrusive to patient's lives as possible, as with ART adherence clubs.

The World Health Organisation promotes patient support groups as an intervention to address poor adherence and improve retention in care (Bateganya, Amanyeiwe, Roxo & Dong, 2015:368). Patient support groups are an essential mechanism of service delivery in providing patients with health education and peer support within the community (Luque-Fernandez, Van Cutsem, Goemaere, Hildebrand, Schomaker et al., 2013:2). Luque-Fernandez and colleagues (2013:7) found that patient support groups, such as ART adherence clubs are an effective model for improving retention in care and documented viral suppression rates.

ART adherence clubs consist of 15 to 30 stable ART patients who meet as a group every two months either at the PHC clinic outside of busy times or in the community. A stable ART patient is defined as someone who has been on ART for at least 12 months and has two recent consecutive viral loads undetectable (<400 copies/ml) (Medicins Sans Frontieres, 2014:15). The ART adherence club is facilitated by a non-clinical staff member (counsellors) and medicines are pre-packed for each person and brought to the club by the counsellor.

A study on ART adherence clubs in an urban setting showed that ART adherence clubs improve retention in care and that fewer patients in the ART adherence club were not viral load suppressed compared to PHC clinic patients (Luque-Fernandez et al., 2013:7). The Western Cape Department of Health has adopted the guidelines for ART adherence clubs suggested by Luque-Fernandez and colleagues as a means to improve retention in care and adherence (Wilkinson, 2013:49).

Treatment adherence is the extent to which a patient's behaviour (taking medication, following a diet and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider (World Health Organisation, 2003:3). With ART, adherence to treatment is critical to ensure that the life-extending benefits of ART are maximised and viral suppression is gained (Chaiyachati, Hirschhorn, Tanser, Newell & Barnighausen, 2011:942). Treatment adherence according to Dang, Westbrook, Black, Rodriguez-Barradas and Giordano (2013:4) is positively influenced by overall patient satisfaction. Patient satisfaction is defined as a patient's general orientation towards a total experience of health care (Wouters, Heunis, Van Rensburg & Meulemans, 2008:2). Satisfied patients are likely to be an indication of a successful HIV program with more adherent patients (Dang et al., 2013:4; Wouters et al., 2008:1). Little is known about patient satisfaction and treatment adherence of ART adherence club patients.

1.3 RATIONALE

ART adherence clubs is a new model of care for stable ART patients and it is being implemented in various parts of South Africa, in particular the Western Cape. A South African study explored the effect of ART adherence clubs on retention in care and viral load suppression of stable adult patients in long term ART care in Khayelitha, Cape Town (Luque-Fernandez et al., 2013:1). The study found this model of care to be effective in this urban setting. Along with this, a recent study found a positive link between patient satisfaction and treatment adherence to ART (Dang et al., 2013:1). The study revealed that overall patient satisfaction positively effects treatment adherence which suggests that if patients are more satisfied they are likely to be more adherent to treatment (Dang et al., 2013:1). Patient satisfaction was not investigated in the Cape Town, Khayelitsha study nor was any other study found. Knowledge of patient satisfaction and treatment adherence in a rural setting with regards to ART adherence clubs could support decisions for further roll-out of ART adherence clubs in South Africa.

1.4 RESEARCH PROBLEM

ART adherence clubs are an effective model of care for stable adult ART patients in an urban setting (Luque-Fernandez et al., 2013:7). In the Western Cape this strategy has been fully implemented. Patient satisfaction and effectiveness of ART adherence clubs has not been scientifically evaluated in other settings. The Eden district, a rural district of the Western Cape has 14 757 patients on ART (Smit, 2015:1; Massyn, Day, Dombo, Barron, Padarath, et al., 2013:208). Of these, 1747 patients are receiving care in ART adherence clubs (Smit, 2015:1). No study has been undertaken in the Eden district to evaluate patient satisfaction and ART adherence in PHC clinics or ART adherence clubs. The literature asserts that since ART

adherence clubs may be more convenient for patients (outside busy clinic times and in the community), it may improve their satisfaction, leading to improved adherence. There is however no scientific evidence in the South African context to support this assumption.

1.5 RESEARCH QUESTION

The researcher explored the following question in the study: Are stable HIV infected patients on ART who receive care in ART adherence clubs more adherent and more satisfied to treatment than those who receive care in PHC clinics?

1.6 RESEARCH HYPOTHESES

The research hypotheses were:

- Stable HIV infected patients who receive care in ART adherence clubs are more adherent to treatment than patients in PHC clinics.
- Stable HIV infected patients who receive care in ART adherence clubs have higher levels of patient satisfaction than patients in PHC clinics.

1.7 STUDY AIM

The aim of the study was to investigate whether stable HIV infected patients on ART who receive care in ART adherence clubs are more adherent to treatment and more satisfied than those whom receive care in PHC clinics.

1.8 STUDY OBJECTIVES

The objectives of the study were to:

- Determine the level of treatment adherence of stable ART patients in PHC clinics and ART adherence clubs
- Determine the level of patient satisfaction of stable ART patients in PHC clinics and ART adherence clubs
- Compare and link levels of treatment adherence and satisfaction of patients in PHC clinics and ART adherence clubs

1.9 RESEARCH METHODOLOGY

In this chapter an overview of the methods will be provided with a detailed description in chapter 3.

1.9.1 Research design

A quantitative research design was used to compare treatment adherence and patient satisfaction in ART adherence clubs and PHC clinics. Since ART adherence clubs is a new model of care in the implementation phase, an analytical, cross-sectional study was used to determine whether ART adherence club attendance is associated with higher levels of treatment adherence and patient satisfaction.

1.9.2 Study setting

The study was conducted at seven PHC clinics (one used for pilot study) with ART adherence clubs and seven PHC clinics without ART adherence clubs. ART adherence clubs were introduced in the Eden district in 2013, but have not been implemented in all PHC clinics. Most PHC clinics in this rural district provide ART care. The pilot study was done at one of these clinics with an ART adherence club. The clinics selected for the study are all in the Eden district of the Western Cape. The Western Cape is made up of six districts of which one is urban and five are rural, namely Cape Winelands, West Coast, Overberg, Eden and Karoo.

1.9.3 Study population and sampling

The study population (N=14757) included stable HIV infected patients on ART receiving care either in ART adherence clubs or in PHC clinics in the Eden district of the Western Cape (Smit, 2015:1). According to the Eden District Health Department, there are 38 PHC clinics that provide ART care in the district. After communicating with the clinic managers the researcher confirmed that there are only seven clinics that provide ART care in both ART adherence clubs and in the PHC setting. The researcher purposefully selected these seven clinics that had established ART adherence clubs at least six months prior to the start of the study. An additional seven clinics without ART adherence clubs were randomly selected with the use of a computer program from the remaining clinics in the district.

The sample included clinic patients (n=222) and ART adherence club patients (n=98). The initial estimated required sample was 105 clinic patients and 105 club patients (with a 95% confidence level and 80% power). This was calculated using the Luque-Fernandez et al. (2013:1) study as an example that compared clinic patients to ART adherence club patients and found a 12% difference in retention in care. With assistance from the statistician it was decided to sample clinic patients from clinics with clubs and clinics without clubs as control for the possible effect a club may have on the services of clinics that have clubs. The statistician

confirmed that the final study sample size had sufficient power to detect significant differences between groups.

1.9.3.1 Inclusion criteria

For inclusion in the study patients had to be 18 years old and HIV infected. Patients had to be on ART for at least 12 months and had to have been attending the clinic or club for at least six months.

1.9.3.2 Exclusion criteria

All pregnant patients were excluded as they would need to attend the clinic more frequently during pregnancy. Patients who refused participation were excluded.

1.9.4 Instrumentation

A paper-based questionnaire (Appendix 5) containing three sections was completed by the researcher or trained fieldworkers for the study participants. The questionnaire was formed from established questionnaires and available in English, Afrikaans and Xhosa after being translated by an experienced translators.

1.9.5 Pilot study

A pilot study was conducted at one of the seven clinics that had ART adherence clubs with 34 participants (17 clinic and 17 club). From this group of participants the interim statistical analysis was done. This data was excluded from the study analysis. The pilot study helped to determine feasibility of the study and to clear out any practical problems associated with the data collection tool.

1.9.6 Reliability and validity

The content validity of the data collection instrument was ensured by using two questionnaires from the literature namely the Chaiyachati Patient Adherence questionnaire (Chaiyachati et al., 2011) and the Wouters Patient Satisfaction with ART Services questionnaire (Wouters et al., 2008) from previous studies. Permission to use the Wouters Patient Satisfaction with ART Services questionnaire was granted by the authors (Appendix 10). The researcher wrote to Chaiyachati and colleagues, the authors of Chaiyachati Patient Adherence questionnaire and had no response. The questions of this questionnaire were published in the Chaiyachati and colleagues paper and these were used citing the authors. Both these questionnaires were used in South Africa with HIV infected patients on ART. Experts in the field, Dr Jannie Mouton and Dr Phillip Botha were consulted to ensure the content validity of the instruments. Dr Jannie Mouton was the Clinical manager of the HIV/AIDS Program for the Western Cape Province at the time of the study. He was responsible for the management of the ART adherence clubs

in the Western Cape. Dr Philip Botha is an infectious disease specialist at Tygerberg Hospital, Cape Town.

The face validity and readability of the questionnaire was assessed during the pilot study. The reliability of the data collection instrument was ensured by using established questionnaires from the literature in which stability and equivalent reliability have been established. The internal consistency of the instrument was calculated using the Cronbach's alpha coefficient which was done during the data analysis.

1.9.7 Data collection

The researcher trained three fieldworkers to assist with the data collection. The fieldworkers were fluent in all three languages and conducted interviews with all of the Xhosa speaking participants and with either English or Afrikaans speaking participants as was needed. The researcher conducted interviews with participants in either English or Afrikaans. Patients attending either the PHC clinic or the ART adherence club on the same day were invited to participate after having received their treatment. An interview of approximately 10 minutes was conducted in a private consultation room at the respective clinics.

1.9.8 Data analysis and interpretation

The data collected was first prepared for analysis by being entered into Microsoft Excel program. The data was then cross-checked by the researcher for any errors and missing data. Once the data was checked it was analyzed with a statistical software program SPSS version 22 and STATISTICA version 12 with assistance from statisticians, i.e. Professor Martin Kidd (Centre for Statistical Consultation, Stellenbosch University), Professor Daan Nel (Centre for Statistical Consultation, Stellenbosch University) and Tonya Esterhuizen (Department of Biostatistics and Statistics, Stellenbosch University).

Descriptive statistics (measures of center and variance) were used to initially describe the data. The average patient scores for satisfaction and adherence were calculated for the two groups (club group vs clinic group). The following statistical analyses were done: Chi-squared analysis, independent t-test, Fisher's exact test, Mann-Whitney U test, bivariate correlations and regression analysis. The level of significance was set at $p = 0.05$. Data interpretation was done with assistance from the statisticians.

1.10 CONCEPTUAL FRAMEWORK

A recent study showed that high levels of patient satisfaction do influence ART adherence and retention in care (Dang et al., 2013:4). The study suggests that by improving contextual components of care (who, where and how care is provided), HIV outcomes such as retention

in care and adherence may improve (Dang et al., 2013:5). The patient satisfaction questionnaire developed by Wouters et al. (2008:210) identified 12 items according to which the level of patient satisfaction was measured. These are: medical care, complaint procedure, cleanliness of facility, privacy during examination, confidentiality of medical records, respect shown by nurses, health information about HIV/AIDS, information provided about ART medication, opportunity to ask questions, language used during consultations, facility opening times, and waiting time before consultation. These items can be linked to the contextual components of who, where and how suggested by Dang and colleagues.

The “who” describes factors relating to the person providing the care. This would link to: respect shown by nurses or health care workers (HCWs), opportunity to ask questions, health information about HIV/AIDS given, information given about ART medication and the language used during consultations. The “where” describes factors related to the physical aspects of the facility in which care is provided. Namely: cleanliness of the facility, facility opening times, waiting time before consultation and complaint procedures. The “how” describes the manner in which care is provided. These are: medical care, privacy during examination and confidentiality of medical records. If each of these three contextual components of care are improved then patient satisfaction levels are likely to improve and this could improve HIV outcomes such as treatment adherence and retention in care (Dang et al., 2013:5). Figure 1.1 illustrates how a HIV outcome namely treatment adherence can be improved by improving patient satisfaction.



Figure 1.1: Conceptual framework for patient satisfaction and treatment adherence

1.11 ETHICAL CONSIDERATIONS

Before the research was commenced the researcher sought to ensure that all ethical principles based on the Declaration of Helsinki (Human, 1974) and the Singapore Statement on Research Integrity (Resnik & Shamoo, 2011) were adhered to. Firstly based on the Stellenbosch University Ethics policy, the Health Research Ethics Committee (HREC) at Stellenbosch University approved the study (S14/03/055) (Appendix 1 & 2). Further approval was obtained from the Western Cape Department of Health Ethics committee (RP 101/2014) (Appendix 3). The researcher obtained permission from the Eden district municipal management and each clinic manager personally granted permission for the research to be conducted in the respective clinics. The further assurance of ethical standards was done by adhering to specific human rights and these will be discussed categorically.

1.11.1 Right to self-determination

The right of self-determination is based on the ethical principle of respect for persons (Burns & Grove, 2011:110). This was safeguarded in three ways: information about the study was provided, participation was by choice and withdrawal from the study at any time was permitted without any discrimination. All participants were given an information leaflet that described briefly what ART adherence clubs are, the purpose of the study and details about participation in the study (Appendix 4). Thereafter participants were given opportunity to ask any questions. The researcher requested all participants to sign written informed consent and this was done by all participants. Participants were entitled to withdraw from the study at any time with no consequence to them, even after agreeing to participate. Participants were approached after having collected treatment to ensure that no participant felt obligated to participate.

1.11.2 Right to privacy

Due to the sensitive nature of the study it was imperative that the right to privacy was protected. The professional nurse in charge of ART care or club counsellor identified patients according to the inclusion criteria and directed each one to the researcher discreetly. The researcher asked each person if they would be willing to answer a few questions, if agreed he/she was escorted to a private consultation room. Once in the consultation room, the nature and essential information concerning the study was given and an interview conducted with those that consented. The researcher gathered further relative patient information from patient folders and/or a computer program with assistance from the professional nurse and the data-capturer. The computer-program used by the clinics to store patient information was Tier.net which is password protected. Consent was given for the information obtained from patient folders and Tier.net by the participants.

1.11.3 Right to anonymity and confidentiality

Anonymity exist if the participant's identity cannot be linked, even by the researcher, with his/her individual responses (Grove, Gray & Burns, 2015:172). Each participant's signed consent form, separate from the questionnaire, was placed inside the completed questionnaire which had no patient indicators (name, file number or date of birth) on it. The completed questionnaires and consent forms were kept by the researcher during data collection. After the researcher had gathered relative information from either the patient folder or Tier.net, each consent form and questionnaire was separated and placed in separate opaque envelopes. The researcher and fieldworkers assured participants that any private information shared would remain confidential. Anonymity and confidentiality were further ensured with the researcher keeping all research documents in a locked filing cabinet for at least five years.

1.11.4 Right to fair treatment

The selection and treatment of participants was fair as only patients that met the study criteria were asked to participate. The research questionnaires were available in three languages to ensure that no participants were excluded due to language. Persons that refused to participate were excluded from the study. The researcher advised participants that no remuneration for participation would be given.

1.11.5 Right to protection from harm and discomfort

The ethical principle of beneficence, which states that one should do good and above all, do no harm is the basis for the right to protection from harm and discomfort (Burns & Grove, 2011:118). As no intervention was applied during the study no harm was expected. Some discomfort or inconvenience may have been experienced by participants whilst completing the questionnaire. The knowledge gained from the study would benefit future patients which made the benefit-risk ratio acceptable. One participant did become emotional whilst completing the questionnaire and was referred to the clinic counsellor.

1.12 OPERATIONAL DEFINITIONS

Adherence: the extent to which a patient's behaviour (taking of pills, following a diet and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider (WHO, 2003:3). For this study, adherence was measured by using the Chaiyachati Adherence questionnaire (Chaiyachati et al., 2011:165).

Adherence club: a group of 15 to 30 patients that meet every two months and is facilitated by a non-clinical staff member who provides a basic health assessment, referral where

necessary, peer support and distribution of pre-packed ART (Medicins Sans Frontieres, 2014:6).

Clinic: a health care facility that is primarily devoted to the care of primary care outpatients (Oxford Dictionary, 2009, s.v. 'clinic')

Patient satisfaction: a person's general orientation towards a total experience of health care (WHO, 2003:10). For this study, patient satisfaction was measured by using the Patient Satisfaction with ART services questionnaire by Wouters and colleagues (2008:210).

Stable HIV infected patient: adult patient who is infected with HIV, on ART for at least 12 months and with the two most recent consecutive viral loads undetectable (<400 copies/ml) (Medicins Sans Frontieres, 2014:15).

1.13 DURATION OF THE STUDY

The research proposal was submitted for ethical approval to the Health Research Ethics Committee at Stellenbosch University and approval was obtained on 24 June 2014 (Appendix 1). Further approval was obtained from the Western Cape Health department and Eden District Municipality on 15 and 16 September 2014 respectively. Data was collected from September 2014 to March 2015 and data analysis was done from April 2015 till June 2015. The thesis was submitted in November 2015 for examination.

1.14 CHAPTER OUTLINE

Chapter 1: Scientific foundation for the study

This chapter outlines the significance of the research problem, the research question, objectives and aims and it includes a brief description of the research methodology used.

Chapter 2: Literature Review

This chapter provides an in-depth review of the literature that relates to the study providing insight and understanding of the research area.

Chapter 3: Research Methodology

This chapter entails the details of the research methodology as outlined in chapter one and how it was applied in the study.

Chapter 4: Results

This chapter describes all the study findings of the data analysis and how these findings can be interpreted.

Chapter 5: Discussion, Conclusions and Recommendations

Based on the analysis and interpretation done in chapter four, the researcher provides a discussion, conclusions and recommendations from the study.

1.15 SIGNIFICANCE OF THE STUDY

Very little is currently known about the effectiveness of ART adherence clubs as a model of care to deliver ART to stable HIV infected patients. This study yielded scientific evidence on the treatment adherence and satisfaction of patients who currently receive care in ART adherence clubs compared to patients receiving care in PHC clinics. It is the first study of its kind conducted in the Eden district of the Western Cape.

1.16 SUMMARY

In this chapter the relevance of the study along with the research aims, hypotheses and objectives were discussed. A conceptual framework was briefly discussed in order to link the study to theory and illustrate how the theory would influence the study. The research methodology for the study was outlined. An in-depth review of the literature to clarify essential topics related to ART adherence clubs, patient satisfaction and treatment adherence will follow in chapter two.

1.17 CONCLUSION

There are millions of HIV infected patients needing access to and care in HIV/AIDS programs. Effective strategies need to be implemented into HIV/AIDS programs in order to assist the health care service to improve access and provide quality care to patients. ART adherence clubs appear to be a promising strategy in reducing clinic patient load without compromising patient outcomes. Due to the paucity of evidence to support this theory, the researcher sought to investigate the effectiveness of this strategy with particular focus on treatment adherence and patient satisfaction.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

In 2011 there was 1.6 million increase globally in people receiving Antiretroviral Treatment (ART) (UNAIDS, 2013:46). The rapid growth in access to ART for eligible Human Immunodeficiency Virus (HIV) infected patients along with retaining existing patients remains a challenge for health care programs (Van Damme et al., 2006:653; Fox & Rosen, 2010:1; Bemelmans et al., 2014:968). Based on this, a review of literature was done to gather the latest information regarding HIV/Acquired Immune Deficiency Syndrome (AIDS) treatment programs and their outcomes. The key words used to search for information were: HIV, ART, treatment adherence/compliance, patient satisfaction, support/community groups, retention in care, sub-Saharan Africa and South Africa. PubMed and Google Scholar were the databases used for the searches as well as the reference lists from relevant published articles. The findings of the literature review will be discussed in this chapter.

Firstly a background to HIV care and HIV treatment programs will be given. Following this, the latest strategies implemented to assist HIV/AIDS programs will be discussed after which a review of treatment adherence and patient satisfaction within HIV/AIDS programs will be made. Lastly, the link between patient satisfaction and treatment adherence will be addressed.

2.2 BACKGROUND TO HIV CARE AND HIV TREATMENT PROGRAMS

In 2012 it was reported that 35.3 million people globally are infected with HIV (WHO, 2014:15). Seventy five percent of patients on ART live in sub-Saharan Africa (UNAIDS 2014:2). More than six million people in South Africa are HIV infected, the largest HIV population globally (Shisana et al., 2014:28). Along with this large HIV infected population there are currently an estimated 2.3 million patients in South Africa on ART (Simelela & Venter, 2014:3).

Recent ART guidelines state that patients with a CD4 cell count that is less or equal to 500 are now eligible for ART (South Africa, 2014:65; South Africa, 2015:15;23). Prior to these changes, a patient was only eligible for ART once the CD4 cell count dropped to 200 and below (South Africa, 2010:1). Then a few years later guidelines were adjusted to include CD4 cell counts from 350 and below (South Africa, 2013:6). These changes in guidelines have led to a marked increase in the number of patients being eligible for ART. The estimated number of new ART patients exceeds 300 000 annually and it is projected that by 2016 there will be 3.5 million patients on treatment in South Africa (Meyer-Rath et al., 2010:7). The South African Department of Health has set specific targets for 2030: to ensure 90% of the population is

tested for HIV; to ensure that 90% of eligible ART patients receive treatment; and ensure that 90% of those on treatment have suppressed viral loads (South Africa, 2015:14).

Traditionally patients receiving ART are seen by specialised doctors at hospitals in major cities and towns and are monitored carefully and frequently (Long, Brennan, Fox, Ndibongo, Jaffray et al., 2011:4). The limited number of specialised health care staff leads to a bottleneck of patients waiting to be seen (Van Damme et al., 2006:654; Daviaud & Chopra, 2008:46). Along with large patient loads in HIV/AIDS programs, retaining patients in care remains problematic (Fox & Rosen, 2010:12). A systematic review conducted in 2007 indicated that only 60% of patients remained on ART two years after starting treatment in sub-Saharan Africa (Rosen, Fox & Gill, 2007:1691). Along with high attrition rates human resource shortages in many sub-Saharan African countries places more pressure on HIV/AIDS programs to increase access (Daviaud & Chopra, 2008:46; Zachariah, Ford, Philips, Lynch, Massaquoi et al., 2009:550). It is with this in mind that new strategies of ART delivery and care are being explored by numerous researchers worldwide (Van Damme et al., 2006:654). Some of these strategies include task-shifting of HIV treatment, the decentralisation of ART and ART community groups. These strategies seek to improve the retention of ART patients in care and relieve the burden on health care staff.

2.3 HIV TREATMENT STRATEGIES

2.3.1 Task-shifting of HIV treatment

Task-shifting is described as the redistribution of tasks to different members of the health care team. Specific tasks are moved from highly qualified health care workers, for example doctors to health care workers with shorter training and fewer qualifications, such as nurses and lay health care workers (WHO, 2008:2). Task-shifting has been established as an effective strategy to address critical human resource shortages and provide high-quality, cost-effective care in HIV/AIDS programs (Crowley & Mayers, 2015:1; Callaghan, Ford & Schneider, 2010:1).

A systematic review of task-shifting for HIV treatment and care high-lighted benefits of task-shifting for HIV/AIDS programs (Callaghan et al., 2010:1). Firstly, task-shifting increases efficiency through saving time of senior clinical staff for complicated patients and by reducing costs of HIV/AIDS programs with less dependence on doctors to initiate and manage ART care (Callaghan et al., 2010:2). Secondly, this review concluded that numerous studies reported increased access to ART through task-shifting without compromising the quality of care (Callaghan et al., 2010:5). Thirdly, a comparison of nurse-managed and doctor-managed ART in South Africa found the outcomes of nurse-managed ART on par with doctor-managed

ART and concluded that quality care in HIV/AIDS programs continues (Callaghan et al., 2010:5). Fourthly, task-shifting has shown to reduce loss-to-follow-up and mortality, outcomes for HIV/AIDS programs, increases retention in care and improves adherence (Callaghan et al., 2010:5). Lastly, the systematic review noted that some team dynamics were improved through task-shifting such as improved job satisfaction, reduced workload and improved patient involvement in care (Callaghan et al., 2010:6).

The literature revealed that there were still numerous challenges faced by health systems implementing task-shifting despite the notable success of the strategy. In both South Africa and Ethiopia task-shifting has not significantly reduced health costs (Crowley & Mayers, 2015:4; Kredo, Adeniyi, Bateganya & Pienaar, 2014:28). For task-shifting to be effective, sufficient clinical and managerial support is needed, along with ongoing training of staff and the re-organisation of care which is complex and costly (Crowley & Mayers, 2015:5; Kredo et al., 2014:29). Reports show that in some areas tasks are delegated without prior training and that a 'trial-and-error' approach was followed (Crowley & Mayers, 2015:5). Further challenges noted were the need for competency assessment and quality assurance mechanisms to be developed and implemented (Crowley & Mayers, 2015:6). The accreditation and regulation of these newly trained health care workers (HCWs), as recommended by the WHO, still needs to be implemented, but remains problematic (Crowley & Mayers, 2015:5).

2.3.2 The decentralisation of ART

Decentralisation of ART allows stable patients to be referred to their closest Primary Health Care (PHC) clinic for further treatment and follow-up (Mukora, Charalambous, Dahab, Hamilton & Karstaedet, 2011:1). This strategy has been implemented in sub-Saharan Africa with measured success in: (i) improved retention in care, (ii) less patient attrition, (iii) effective management and (iv) patient benefits.

In Malawi, a study reported that patients who were decentralized were 60% less likely to default treatment thus assisting the vital issue of retention in care in HIV/AIDS programs while increasing access (Chan, Mateyu, Jahn, Schouten, Arora et al., 2010:92). However, a cause for concern, were that in certain PHC facilities essential drugs and laboratory services were not available (Chan et al., 2010:96). The authors stressed the need for policies and planning to ensure adequate human resources, access to essential drugs and laboratory services to accompany this model of care (Chan et al., 2010:96).

A systematic review of the decentralization of HIV treatment found that in general with both full decentralization (ART initiation and management at a PHC clinic) and partial decentralization (ART initiation at hospital and management at a PHC clinic), there was less

patient attrition and fewer patients lost to follow-up (Kredo, Ford, Adeniyi & Garner, 2013:2). This systematic review did acknowledge that the quality of evidence for facility based models of care, for example clinics was low and that adequate training, supervision and support were essential when providing HIV care through more basic tiers of the health system (Kredo et al., 2013:28).

Furthermore, Fatti and colleagues reported that ART management at PHC clinics in South Africa is more effective than at a hospital-based setting (Fatti, Grimwood & Bock, 2010:9). PHC clinics had better retention in care rates, fewer patients' lost-to-follow-up and lower mortality rates than both district level and hospital-based ART care (Fatti, Grimwood & Bock, 2010:1).

In addition to improved HIV outcomes there were benefits for patients. The benefits for patients were that ART enrolment was closer to the patient's home, it saved the patient time and travel costs were reduced (Mukora et al., 2011:1,7). However patients, in one study, favoured centralized care as there was less stigma, patients had established relationships with HCWs and additional services were easily available (Mukora et al., 2011:1).

2.3.3 Patient support groups

Task-shifting and decentralization of care has provided essential relief and assistance in increasing access of ART to patients. Further decentralization of ART care into the community is needed to further improve access to care and spread the workload for HCWs (Grimsrud, Sharp, Kalombo, Bekker & Myer, 2015:4; Bemelmans et al., 2014:968). Patient support groups based in the community are an essential mechanism of service delivery with potential benefits on outcomes for the health system and the patient (Luque-Fernandez et al., 2013:2; Bateganya et al., 2015:372). There are various forms of patient support groups implemented in sub-Saharan Africa and two will be discussed, community ART groups and ART adherence clubs.

In Mozambique, Community ART Group (CAG) is one form of patient support group being used to increase access to treatment and improve patient retention (Decroo, Telfer, Biot, Mai & Dezebembro, 2011:39). A CAG is a group of six patients who work as a team to collect treatment (Decroo et al., 2011:40). A rotation system is put in place with a different group member attending the clinic each month to collect treatment for the group (Decroo et al., 2011:40). This system ensures that a member of the group attends the clinic at least once every six months, instead of each individual attending monthly. These CAGs were found to improve retention in care and benefitted patients through reduced travel costs (Decroo et al., 2011:40-42). Other patient benefits reported were improved peer support, increased

community participation to support adherence and less time spent at the clinic (Decroo et al., 2011:42; Bemelmans et al., 2014:970). Marked reduction in patient consultations of CAG patients by health care staff was noted, which in turn reduced the workload for health care staff. CAG programs have clear potential in supporting long-term ART management, and the retention of patients in the HIV program (Bateganya et al., 2015:373). For health systems potential benefits include a reduced workload for clinical staff, improved health outcomes and cost saving (Bemelmans et al., 2014:970). Patient support groups are suggested by WHO to address retention in care and adherence among HIV infected patients (Bateganya et al., 2015:368). Another type patient support group, ART adherence clubs will now be discussed.

2.4 ART ADHERENCE CLUBS

2.4.1 Definition

ART adherence clubs are patient support groups being used in South Africa (Luque-Fernandez et al. 2013: 2). ART adherence clubs, according to Luque-Fernandez (2013:2) are formed by 15 to 30 stable ART patients meeting every second month as a group at the PHC clinic outside of busy times or in their community. A non-clinical staff member (lay HCW or counsellor) facilitates the club with a short health discussion. Then the weight and symptom-based health assessment are done for each patient after which pre-packed medicines are distributed as the club is concluded. Any patient reporting any symptoms or any weight loss is referred back to the clinic to be assessed by a professional nurse. An annual visit to the club by a professional nurse is done to draw blood for viral load and CD4 count testing (Luque-Fernandez et al., 2013:2; Wilkinson et al. 2013:48; Grimsrud et al., 2015:2).

2.4.2 Criteria for ART adherence clubs

With these patient support groups (ART adherence clubs or CAGs) patients are not seen by a clinician, for example doctor or nurse at each visit. There may be concern as to whether it is safe and feasible for the responsibility of screening ART patients to lie with lay HCWs and how stable patients should be identified (Macleod, Maskew, Man, Jaffray, Macphail et al., 2013:82). A South African study done by MacLoed and colleagues (2013:82-83) defined possible criteria for stable ART patients and evaluated the feasibility of screening using this set of criteria. The criteria for stable ART patients identified were: patients on ART for more than 6 months; viral load below 400 copies/ml (viral load suppressed); stable weight; on current ART regimen for more than 3 months and no other medical condition requiring more frequent follow-up (Macleod et al., 2013:83). The study assessed the medical visits for over 14 000 patients in a four year and nine month period. Applying the criteria for a stable patient visit, they found that of the total visits, 33% could be classified as stable patient visits. With the use of clinical signs

and laboratory results to identify a nonstable visit needing a clinical examination, they found that the identified criteria had high sensitivity (72.6% to 88.9%) to detect a non-stable visit with a low specificity (43.9% to 46.1%). The study concluded that these criteria could reduce clinical examinations by more than 40% (MacLeod et al., 2013:85). This suggests that stable ART patients do not need a clinical examination at each clinic visit and could be seen less frequently (MacLeod et al., 2013:82-83). This study has assisted in defining stable ART patients eligible for patient support groups. In South Africa, ART adherence club patients are selected based on the following criteria: on ART for at least 12 months and two consecutive undetectable viral loads (less than 400 copies/ml) (Wilkinson et al., 2013:48).

2.4.3 Effectiveness of ART adherence clubs

A South African study evaluated the effectiveness of patient adherence groups, ART adherence clubs compared with traditional clinic-based care in maintaining or improving long-term retention in care and HIV viral suppression (Luque-Fernandez et al., 2013:2). The study was conducted in Cape Town, Khayelitsha which hosts a large population of ART patients as part of a cohort study in this region. This retrospective observational study concluded that patient adherence groups are an effective model for improving retention in care and promises to assist in the next wave of increased access to HIV treatment (Grimsrud et al., 2015:4; Luque-Fernandez et al., 2013:7).

2.5 HIV TREATMENT OUTCOMES

Treatment success is evident if a patient has a suppressed viral load and this is dependent on the adherence of the patient. In addition to the biological measurements of treatment success, researchers are increasingly acknowledging the importance of quality care measures such as patient satisfaction as key to determining treatment success.

2.5.1 Treatment adherence

Adherence is defined as the extent to which a patient's behaviour (taking medication, following a diet and/or executing lifestyle changes) corresponds with agreed recommendations from a health care provider (WHO, 2003:3). Even with increased access to treatment, the success of ART is dependent on high rates of adherence being sustained (Peltzer, Friend-du Preez, Ramlagan & Anderson, 2010:1; Hardon, Akurut, Comoro, Ekezie, Irunde et al., 2007:658). For ART to work effectively it requires a minimum adherence of 95%, which means that more than nine out of ten doses need to be taken at the right time and correctly (Peltzer, et al., 2010:1). For HIV/AIDS programs to be successful, interventions to improve and maintain adherences are needed (Mills, Nachega, Bangsberg, Singh, Rachlis et al., 2006:2040).

Poor ART adherence could result in treatment failure, immune suppression and drug resistance (Kunutsor, Walley, Muchuro, Katabira, Balidawa et al., 2012:1308; Bezabhe, Chalmers, Berezinicki, Peterson, Bimirew et al., 2014:1). Drug resistance to first line ART is troublesome to both the patient and the HIV/AIDS program as alternative regimens are limited and costly (Hardon et al., 2007:658; Peltzer et al., 2010:1).

Adherence is a complex concept. It is influenced by determinants such as the individual, the treatment, the patient and HCW relationship, HCW efficiency, and the health care system (Ammassari, Trotta, Murri, Casteli, Narciso et al., 2002:S123). Several studies have investigated the factors affecting adherence (Mills et al., 2006:2054-2055; Hardon et al., 2007:658; Peltzer et al., 2010: 2).

A systematic review examined the patient-reported barriers and facilitators of adherence for ART (Mills et al., 2006:2040). Patient-related barriers included substance abuse, forgetfulness, financial constraints, fear of disclosure and difficulty understanding treatment instructions (Mills et al., 2006: 2054). Beliefs about medication such as side-effects, complicated regimens and doubts about treatment efficacy do impact patient adherence (Mills et al., 2006:2055). Patients reported difficulty incorporating work and family with ART, traveling long distances to receive treatment and transport difficulties (Mills et al., 2006:2055). Other barriers reported were running out of medication and being away from home (Mills et al., 2006:2055). Another study identified transport costs, long waiting times, hunger, stigma, side-effects and HCW workloads as challenges to optimal adherence (Hardon et al., 2007:660).

The list of factors affecting adherence are numerous and many are linked to the patient himself and the patient's perception. There are a few factors that health care facilities could improve to assist patients. For example waiting times, hunger and traveling long distances could be resolved through mechanisms supported by the health care facility. Patient satisfaction has been established as a determinant of adherence and can be measured by facilities with patient satisfaction surveys (Anderson, Camacho & Balkrishnan, 2007:3; Barbosa, Balp, Kulich, Germain & Rofail, 2012:47; Preau, Protopopescu, Raffi, Rey, Chene et al., 2012:438; Dang, Westbrook, Black, Rodriguez-Barradas & Giordano, 2013:4).

2.5.2 Patient satisfaction

Patient satisfaction can be defined as a patient's general orientation towards a total experience of health care (Wouters et al., 2008:2). It is the extent to which the health care experience matches the patient's expectations of health care (Preau et al., 2012:434). The measurement of patient satisfaction provides an indication as to what degree the service is meeting the patient's needs and expectations (Preau et al., 2012:434). The measurement of a patient's

level of satisfaction is valuable as it has clinical relevance and is a measure of performance for quality health care (Chimbindi, Barnighausen & Newell, 2014:12; Preau et al., 2012:434; Wouters et al., 2008:2). Wouters and colleagues (2008:2) suggest that with a strained health system, patient satisfaction is crucial for a HIV/AIDS program to be successful and to maximise the benefits of scarce resources.

Patient satisfaction has a positive impact on retention in care, which is vital for HIV/AIDS programs (Dang et al., 2013:5). For patient satisfaction to be improved it is important to know what factors influence patient satisfaction. Peltzer and colleagues (2012:11) found numerous factors influencing patient satisfaction. These include confidentiality, communication, respect, access, autonomy, discriminatory experiences, HCW relationship, social support, availability and facility elements such as waiting time, clinic hours, noise and cleanliness (Peltzer & Phaswana-Mafuya, 2012:11; Preau et al., 2012:438; Dang, Westbrook, Rodriguez-Barradas & Giordano, 2012:6). These factors could be grouped into contextual components (who, where and how) as mentioned in the contextual framework (1.10) and these can be used to improve patient satisfaction as depicted in Table 2.1.

Table 2.1: Contextual components and factors influencing patient satisfaction

Contextual component	Factors influencing patient satisfaction
Who – by whom care is delivered.	Communication and respect shown by HCW Relationship of HCW with patient Social support provided
Where – the place where care is delivered.	Access Availability Facility elements
How – the manner in which care is delivered.	Confidentiality of patient information Autonomy Discriminatory experiences Communication

Source: adapted from Dang et al. (2013: 6)

One South African study evaluated patient satisfaction in a rural area and found that 95% of patients were satisfied with the service they received (Chimbindi et al., 2014:7). However, in this study more than half of the HIV infected participants reported that some of the staff did not treat the patients with respect (Chimbindi et al., 2014:10). Contrary to this, almost all the patients agreed that patient information is kept private (Chimbindi et al., 2014:10). Yet, it may appear that respect and privacy and confidentiality do not impact largely on patient satisfaction. This study, along with Wouters and colleagues study showed that a large number of patients agreed that queues were too long (Chimbindi et al., 2014:10; Wouters et al., 2008:11). The waiting time was the most significant factor determining patient satisfaction and

this hinders the adherence of patients (Wouters et al., 2008:13; Anderson et al., 2007:1). High overall satisfaction appears to mask substantial dissatisfaction with other aspects of service as mentioned (Chimbindi et al. 2014: 12). Chimbindi and colleagues (2014: 15) suggest dissatisfaction with specific components of care point toward possible interventions to improve patient satisfaction. A recent review explored the link between patient satisfaction and treatment adherence and found an association between the two (Barbosa et al., 2012: 47). Greater patient satisfaction is associated with better adherence and specifically for ART and HIV care (Barbosa et al. 2012:47; Preau et al., 2012:437-438).

2.6 THE LINK BETWEEN PATIENT SATISFACTION, TREATMENT ADHERENCE AND PATIENT SUPPORT GROUPS

As mentioned in 2.5.2, research supports the positive link between patient satisfaction and treatment adherence (Barbosa et al. 2012; Preau et al., 2012). Numerous factors exist that influence patient satisfaction and treatment adherence. There are factors that influence both these and the themes are: access to treatment, amount and quality of social support, waiting times, facility elements and the quality of the care provider (Dang et al., 2012:5-6; Peltzer & Phaswana-Mafuya, 2012:1-2).

Patient support groups have shown to have positive effects for patients (Luque-Fernandez et al., 2013:2; Bateganya et al., 2015:372). The benefits noted from patient support groups for HIV infected patients, as highlighted in 2.3.3 are: reduced travel costs, improved peer support, increased community participation to support adherence, retention in care and less time spent at the clinic (Bateganya et al., 2015:372; Bemelmans et al., 2014:975; Decroo et al., 2011:e42). Patient support groups could be used alongside other interventions to increase patient satisfaction resulting in improved adherence outcomes and retention in care of HIV/AIDS programs (Luque-Fernandez et al., 2013:7; Dang et al.,2013:5).

2.7 CONCLUSION

In South Africa particularly there has been a rapid increase in access to ART and the need for ART will continue to grow. Effective strategies need to be implemented into HIV/AIDS programs to assist these programs to improve retention in care and treatment adherence. Patient support groups have shown to positively impact certain HIV outcomes and these are being implemented in South Africa. Treatment adherence remains a concern for HIV/AIDS programs with numerous factors affecting adherence. Patient satisfaction positively impacts treatment adherence and as such, needs to be considered an important tool in improving HIV/AIDS outcomes.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter describes the different aspects of the research methodology in detail as outlined in chapter one. The following will be discussed: the study setting, the research design used and the study population and sampling. Some aspects from chapter 2 are discussed, such as the literature used to formulate the data collection tool. The details regarding the data collection and analysis are highlighted.

3.2 AIMS AND OBJECTIVES

The study aim was to compare the treatment adherence and patient satisfaction of stable Human Immunodeficiency Virus (HIV) infected patients on Antiretroviral Treatment (ART) in either Primary Health Care (PHC) clinics or ART adherence clubs. The study objectives were three-fold: determine the level of treatment adherence in PHC clinics and ART adherence clubs, determine the level of patient satisfaction in PHC clinics and ART adherence clubs and compare and link patient satisfaction and treatment adherence of ART adherence club patients with PHC clinic patients. The research hypotheses were that stable HIV infected patients that receive care in ART adherence clubs will have both higher levels of treatment adherence and patient satisfaction than patients that receive care in PHC clinics.

3.3 STUDY SETTING

The study setting was clinics in the Eden district of the Western Cape that had ART adherence clubs established for at least six months. After having contacted each clinic telephonically, the researcher found seven clinics matched the said criteria. These were thus selected. In addition, one of the seven clinics was randomly selected for the pilot study. This random selection was done from a computer generated list of the clinics. On the conclusion of the pilot study and statistical analysis, an additional seven clinics that did not yet have ART adherence clubs were included. This was done to determine the possible effect the presence of an ART adherence club could have on the patient load of the clinics. The clinics with ART adherence clubs would have reduced numbers of stable ART patients attending the clinic monthly. The resulting reduction in patient loads at the clinic could affect aspects of patient satisfaction for clinic patients. The fourteen clinics used in the study were all in the Eden district and within two hours' drive from George. These clinics were all either in rural or semi-rural areas of the Western Cape.

3.4 RESEARCH DESIGN

A quantitative research design was used to determine if there was an association between the type of attendance (PHC clinic or ART adherence club) and treatment adherence and patient satisfaction. The study was an analytical, observational study as no intervention was applied by the researcher. The participants were interviewed at one point in time, creating a cross-sectional study of a portion of the stable HIV infected population in the Eden district of the Western Cape (Aldous, Rheeder & Esterhuizen, 2011:26).

3.5 POPULATION AND SAMPLING

Stable HIV infected patients receiving treatment either in ART adherence clubs or in PHC clinics in the Eden district of the Western Cape were the focus of the study. The total number of patients receiving ART in the Eden district is N=14757, with 38 clinics providing this service (Smit, 2015:1). Of the 38 clinics, 14 were used in the study. The study population included all stable HIV infected patients 18 years. Participants could not be pregnant and had to have been on ART for at least one year. Patients that met these criteria had to have been receiving treatment at the specific clinic or club for at least six months.

A simple random sampling method would have been the most suitable method to select patients attending the clinics and clubs in order to render a representative sample. However, the researcher could not obtain accurate up to date patient lists from either the ART adherence clubs or the clinics, making the suggested sampling method impossible. Patients attending the clinic or club were therefore asked to participate in the study when they attended the clinic. In order to control for bias, the researcher recruited participants on different days and different times throughout the clinic's operating hours to ensure that the population was well represented. Convenience sampling may result in multiple biases, some of which may be subtle and unrecognizable (Grove, Gray & Burns, 2015:264). However, serious biases are not always present in convenience sampling (Grove et al., 2015:264). Kerlinger and Lee in Grove et al. (2015:264) state that a convenience sample is acceptable when it is used with reasonable knowledge and care in implementing a study. As far as possible an equal number of club and clinic participants were included in the case where the clinic had a club. However, in most cases, a higher proportion of club patients were sampled due to the smaller number of club patients (Table 3.1).

Table 3.1: Clinic and club participant totals and percentage included

Clinic	Club Sample	Club Total	Club % seen	Clinic Sample	Clinic Total	Clinic % seen
Khayaletu	22	188	12	14	467	3
Parkdene	12	17	71	19	132	14
Thembaletu	14	368	4	27	2025	1
Alma	16	246	7	14	1048	1
Witlokasi	25	175	14	16	499	3
Rosemoor	9	24	37	16	168	10
Eyethu				18	350	5
Knysna				17	287	6
Mossel Bay ART				17	656	3
Crags				14	149	9
Lawaaikamp				19	430	4
Conville				15	309	4
Oudtshoorn				16	199	8
Total:	98			222		

The sample included participants receiving care in clinics with clubs (n=106), clinics without clubs (n=116) and ART adherence clubs (n=98). The required sample size needed to detect significant differences (95% confidence; 80% power) was calculated in OpenEpi using the Luque-Ferenandez and colleagues (2013) study as an example that compared retention in care of clinic patients with ART adherence club patients and found a 12% difference.

The patients from the clinics were recruited with assistance from the professional nurse in charge of ART care. The professional nurse identified all the patients that were coming to collect ART treatment and after patients were given their treatment, the professional nurse directed them to the researcher. The ART adherence club patients were approached by the researcher once a club meeting had concluded. All possible patients were questioned to determine whether the inclusion criteria were met (as discussed in 3.5.1).

3.5.1 Inclusion criteria

The inclusion criteria were as follows:

- HIV infected patients
- 18 years
- On ART /current regimen for at least 12 months
- Attending the clinic or ART adherence club for a minimum of 6 months

These criteria were mostly based on ART adherence club guidelines (Wilkinson, 2013:48). Attendance to either the clinic or club for a minimum of six months was to exclude participants evaluating their experience of the service received based on only one attendance.

3.5.2 Exclusion criteria

The exclusion criteria were as follows:

- Pregnant women
- Participants who refuse participation

During pregnancy, a woman would need to attend the clinic more frequently and therefore was excluded.

3.6 INSTRUMENTATION

Established questionnaires were used to formulate the questionnaire: Chaiyachati Patient adherence questionnaire by Chaiyachati and colleagues (2011:165) and the Patient satisfaction with ART services Questionnaire by Wouters and colleagues (2008:210). A rural South African PHC setting was the context for both these questionnaires similar to that of the Eden District of the Western Cape. The researcher or trained fieldworkers completed the three section paper-based questionnaire for the study participants (Appendix 5). Basic biographical information was obtained in Section A. The first question determined the type of visit, followed by nine biographical questions and three questions regarding HIV and ART. The next section Section B consisted of five questions regarding patient treatment adherence. The five questions were made up of four closed-ended questions and one visual analogue scale question. Section C consisted of 11 questions regarding patient satisfaction. A five-point Likert scale was used for ten of these questions and followed by one open-ended question for patient complaints or compliments. The questionnaire was available in English, Afrikaans and Xhosa after being translated by experienced translators.

3.7 PILOT STUDY

The clinic used for the pilot study was randomly selected from a list of clinics with the use of a computer program. The list comprised of seven clinics with established ART adherence clubs for a minimum of six months. The researcher and the fieldworker attended the clinic on four separate days to collect data.

Thirty-four participants that all met the inclusion criteria were asked to participate. Seventeen were from the ART adherence club and seventeen were from the clinic. The data from the pilot study was used for an interim statistical analysis. The analysis showed that there was minimal difference in treatment adherence and patient satisfaction between club and clinic participants. Therefore the researcher sought to include clinics without ART adherence clubs to further investigate this difference between ART adherence clubs and clinics with regards to treatment adherence and patient satisfaction. The presence of ART adherence clubs would

reduce the number of stable ART patients attending the clinic to collect treatment. This reduction in patient numbers would possibly affect aspects of patient satisfaction. Approval from the Health Research Ethics Committee and the Eden district municipality was obtained to add clinics in the district that did not yet have ART adherence clubs running for at least six months (Appendix 2).

The pilot study assisted to determine the feasibility of the study and to clear out any practical problems associated with the data collection tool. The translated items of the questionnaire were checked for meaning during the pilot study. The researcher trained the fieldworker(s) prior to commencing with the study and assessed the fieldworkers during the pilot study. The fieldworkers were trained in aspects of good clinical practice, how to obtain informed consent and how to ask questions without probing. There were no changes made to the questionnaire after the pilot study. The data from the pilot study was excluded from the data analysis.

3.8 VALIDITY AND RELIABILITY

3.8.1 Validity

Validity of an instrument, according to Burns and Grove (2011:334) is a determination of how well the instrument reflects the abstract concept being examined. The content validity of an instrument examines the extent to which the measurement includes all the major elements relevant to the construct being measured, in this instance treatment adherence and patient satisfaction (Burns & Grove, 2011:335). This was ensured by using two questionnaires from the literature, namely the Chaiyachati Patient adherence questionnaire and the Wouters Patient satisfaction with ART services questionnaire, both from previous studies (Chaiyachati et al., 2011; Wouters et al., 2008). Both these questionnaires were used in South Africa with HIV infected patients on ART. In addition to this, Dr Jannie Mouton and Dr Phillip Botha were consulted to ensure the content validity of the instruments. The readability and face validity of the questionnaire were assessed during the pilot study.

3.8.2 Reliability

Reliability is concerned with the consistency of the measurement method (Burns & Grove, 2011:332). Stability of an instrument is concerned with the consistency of repeated measures of the same attribute with the use of the same scale or instrument (Burns & Grove, 2011:333). Equivalence involves the comparison of two versions of the same paper-and-pencil instrument or of two observers measuring the same event (Burns & Grove, 2011:333). These both were ensured by using established questionnaires from the literature in which reliability, stability and equivalence were tested. The Cronbach's alpha coefficient was used to calculate the

internal consistency of the patient satisfaction scale in the instrument. The Cronbach's alpha was 0.78, an acceptable level (Grove et al., 2015:323) and similar to reliability measures reported by Wouters and colleagues (2008:4).

3.9 DATA COLLECTION

Ethical approval was obtained from the Health Research Ethics Committee of Stellenbosch University and the Western Cape Provincial Government. The Eden district municipality granted approval and the researcher contacted the respective clinics telephonically. The researcher confirmed with each clinic manager the days that would suit the clinic for data collection. The researcher and the fieldworkers collected data from the various clinics on different days and times, between September 2014 and March 2015.

During data collection, the researcher approached the professional nurse attending to HIV and ART care patients to assist with identifying prospective study participants. The professional nurse identified patients and then the researcher enquired about the patient's willingness to participate in the study. Those willing to participate were interviewed in a private consultation room. The researcher or fieldworker explained the purpose of the study, the participant's responsibility in the study and ensured that the participant knew participation was voluntary, anonymous, and that no compensation would be given. All information shared with either the researcher or fieldworker remained private and confidential and the participants were made aware that they could withdraw from the study at any time. The participants were informed while no harm would be done to them during the study, they may experience a level of emotional discomfort when answering questions.

Once the patient agreed to participate in the study, he/she would sign a consent form. Xhosa speaking participants were interviewed by a fieldworker, while English and Afrikaans speaking participants were interviewed either by a fieldworker or the researcher. The interviews lasted approximately ten minutes. The research team completed questionnaires for the participants to ensure that no information or question was missed or incomplete. The signed consent form and completed questionnaire were placed inside each other in an opaque envelope. At the end of each clinic visit, the researcher, with permission from the clinic manager, would use the completed questionnaire to obtain the HIV year of diagnosis, ART start date and last two viral loads. This information was obtained from either the patient folder or the computer program Tier.net available at the clinic. Tier.net is used by each clinic to log relevant information of all HIV infected patients in the specific clinic. Once this information was obtained the completed questionnaire and signed consent form were separated and kept in separate opaque envelopes.

Of the 361 participants asked to complete the questionnaire none refused and 41 did not meet the inclusion criteria. The chief reasons for participant exclusion were not being on ART for at least one year and not having attended the specific PHC clinic or ART adherence club for at least six months.

3.10 DATA ANALYSIS

3.10.1 Data preparation

The researcher firstly numbered the questionnaires from each clinic and checked each questionnaire for missing information before entering the data into Microsoft Excel program. The researcher then cross-checked all data entered into Microsoft excel for any errors and missing data. The data was then sent to the statisticians, Professor Daan Nel and Tonya Esterhuizen to be analyzed.

3.10.2 Descriptive statistics

Descriptive statistics are computed to reveal characteristics of the sample and to describe study variables (Grove et al., 2015:538). The descriptive statistical analysis made use of frequency distributions, measures of central tendency and standard deviations. A frequency distribution is a statistical procedure that involves listing all possible measures of a variable and tallying each datum on the listing (Grove et al., 2015:695). Measures of central tendency determine the center of a distribution of scores (mode, mean and median) (Grove et al., 2015:699). The standard deviation is a measure of dispersion that is calculated by taking the square root of the variance (Grove et al., 2015:710). Descriptive statistics was done for all variables of the questionnaire and was done with STATISTICA (version 12).

3.10.3 Inferential statistics

Inferential statistics are designed to allow inference from a sample statistic to a population parameter (Grove et al., 2015:696). Inferential statistics was done using SPSS statistical software program version 22. The tests used were Chi-squared, independent t-test, Fisher's exact test, Mann-Whitney U test and bivariate correlations.

A Chi-square test is used to analyze nominal data to determine significant differences between observed frequencies within the data and frequencies that were expected (Grove et al., 2015:688). On occasion in a comparison of the frequency of observations in a fourfold table the numbers are too small for the Chi-squared test and a Fisher's exact test is used (Swinscow & Campbell, 2002:95).

An independent t-test is a parametric analysis technique used to test for significant differences between the means of two independent samples when the data is normally distributed (Grove et al., 2015:581). A Mann-Whitney U calculation involves converting the data to ranks, discarding any variance or normality issues associated with the original values (Grove et al., 2015: 583).

Bivariate correlations were computed on the data, which measures the magnitude of linear relationships between two variables (Grove et al., 2015: 560). Correlational analysis provides two pieces of information about the data: the nature or direction of the linear relationship (positive or negative) between two variables and the magnitude of the linear relationship (Grove et al., 2015: 561). These correlations were done between certain demographic variables and either treatment adherence, patient satisfaction or viral load suppression.

3.10.4 Regression analysis

Regression analysis is a statistical procedure used for prediction and the purpose is to identify the factor or factors which predict or explain the value of a dependent (outcome) variable (Grove et al., 2015:570). The goal is to determine how accurately one can predict the value of an outcome (dependent) variable based on the value or values of one or more predictor (independent) variables (Grove et al., 2015:570). A multiple regression analysis was used to assess whether club or clinic attendance could predict patient satisfaction and logistic regression was used to assess whether the type of attendance could predict treatment adherence and viral suppression. These analyses were done in SPSS and the statistician controlled for clustering.

3.11 SUMMARY

This chapter provides the reader with detailed information regarding the research methodology of the study. Information regarding the aim of the study, the study design and the study population and sampling were all discussed. The validity and reliability of the study was supported in the chapter. Specific detail about the study instrument, the pilot study and data collection process was added and the chapter concluded with the data analysis process. The study findings will be examined in the next chapter.

CHAPTER 4: RESULTS

4.1 INTRODUCTION

In this chapter the researcher reports on all the data collected and results are presented using tables. The chapter follows the outline of the questionnaire (Appendix 5) used to collect the data and percentages are reported to the first decimal space. Firstly the biographical data is reported on.

4.2 SECTION A: BIOGRAPHICAL DATA AND HIV-RELATED INFORMATION

Biographical and Human Immunodeficiency Virus (HIV) related data was analysed with descriptive statistical analysis. A summary of the biographical data is provided in Tables 4.1 and 4.2. The data is tabulated to indicate the number of participants from clinics with clubs and clinics without clubs, which was combined to form the total clinic sample. The number of participants from Antiretroviral Treatment (ART) adherence clubs and the total number of participants are specified. The total sample is discussed in detail in order to provide a description of the participants. Differences between the clinic- and club groups are highlighted.

For the nominal data presented in Table 4.1, the Chi-square test was used to test for significant differences between the groups. The Fisher's exact test was used when one or more cells had expected values of less than five. The independent t-test was used for continuous data when the data was normally distributed and the Mann-Whitney U test when data was skewed (Table 4.2). A two sided level of significance of $\alpha < 0.05$ was used throughout and reported to the third decimal space.

Table 4.1: Biographical data: Nominal variables

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club P value
Gender (n=316)						0.832
Male	21 (20.2)	30 (26.3)	51 (23.4)	24 (24.5)	75 (23.4)	
Female	83 (79.8)	84 (73.7)	167 (76.6)	74 (75.5)	241 (76.3)	
Language (n=320)						0.031
Xhosa	53 (50)	45 (38.8)	98 (44.1)	57 (58.2)	155 (48.4)	
English	16 (15.1)	24 (20.7)	40 (18.0)	18 (18.4)	58 (18.1)	
Afrikaans	37 (34.9)	47 (40.5)	84 (37.8)	23 (23.5)	107(33.4)	
Employment (n=320)						0.006
Full-time	24 (22.6)	39 (33.6)	63 (28.4)	40 (40.8)	103 (32.2)	
Part-time	18 (17.0)	12 (10.3)	30 (13.5)	20 (20.4)	50 (47.8)	
Unemployed	64 (60.4)	65 (56.0)	129 (58.1)	38 (38.8)	167 (52.2)	
Number of other illnesses (n=320)						0.081
No other illnesses	78 (73.6)	77 (66.4)	155 (69.8)	77 (78.6)	232 (72.5)	
One other illness	22 (20.7)	34 (29.3)	56 (25.2)	20 (20.4)	76 (23.8)	
Two other illnesses	6 (5.7)	4 (3.4)	10 (4.5)	1 (1.0)	11 (3.4)	
Three or more other illnesses	0 (0)	1 (0.9)	1 (0.5)	0 (0)	1 (0.3)	
Feeling well (n=319)						0.269
No	18 (17.1)	12 (10.3)	30 (13.6)	9 (9.2)	39 (12.2)	
Yes	87 (82.9)	104 (89.7)	191 (86.4)	89 (90.8)	280 (87.8)	

Table 4.2: Biographical data: Continuous variables

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club p value
Age	(n=200)	(n=116)	(n=221)	(n=95)	(n=316)	0.989
Mean	39.1	37	39.4	39.4	39.4	
Median	30	39	40	39	39	
SD	9.5	9	9.2	9.4	9.3	
Minimum	19	23	19	22	19	
Maximum	68	65	68	66	68	
Educational level	(n=201)	(n=114)	(n=217)	(n=98)	(n=315)	0.902
Mean	9.1	9.3	9.2	9.1	9.2	
Median	10	10	10	10	10	
SD	2.8	2.8	2.8	2.7	2.8	
Minimum	1	1	1	1	1	
Maximum	12	12	12	12	12	
Monthly income	(n=198)	(n=114)	(n=214)	(n=98)	(n=312)	0.016
Mean	1240.2	1177.9	1034.5	1617	1217.4	
Median	400	800	0.0	1200.0	500.0	
SD	1748.7	1399	1331.8	2088.8	1627.6	
Minimum	0	0	0	0	0	
Maximum	11000	7000	7000	11 000	11 000	
Cost of travel	(n=204)	(n=116)	(n=222)	(n=98)	(n=320)	0.610
Mean	4.1	9	5.6	6.6	5.9	
Median	0	0	0	0	0	
SD	15.6	17.2	13.6	21.3	16.3	
Minimum	0	0	0	0	0	
Maximum	200	150	150	200	200	
Number of other illnesses	(n=204)	(n=116)	(n=222)	(n=98)	(n=320)	0.081
Mean	0.3	0.4	0.4	0.3	0.3	
Median	0	0	0	0	0	
SD	0.5	0.6	0.6	0.4	0.6	
Minimum	0	0	0	0	0	
Maximum	2	3	3	2	3	
Number of pills taken	(n=204)	(n=116)	(n=222)	(n=98)	(n=320)	0.440
Mean	3.4	4.2	3.8	3.4	3.7	
Median	3	3	3	3	3	
SD	2.4	3.6	3.2	2.3	2.9	
Minimum	1	1	1	1	0	
Maximum	12	30	30	10	30	

4.2.1 Language (n=320)

The language in which the questionnaire was completed was indicated on the questionnaire and added as a study variable. As seen in Table 4.1, the majority of the questionnaires were completed in Xhosa (n=155, 48.4%), then Afrikaans (n=107, 33.4%) and the least number of questionnaires were completed in English (n=58, 18.1%). There was a significant difference

between the clinic- and club group in terms of language ($X^2 [2] = 6.96, p = 0.031$). Xhosa speaking participants were more likely to be in a club and Afrikaans speaking participants were more likely to be in a clinic.

4.2.2 Age (n=316)

Table 4.2 shows that the mean age was 39.4 (SD 9.3) and median age of 39. The youngest participant was 19 years old and the oldest was 68 years.

4.2.3 Gender (n=316)

The majority of the participants were female (n=241, 76.6%) shown in Table 4.1. There were 75 (23.4%) males and in four questionnaires the gender was not indicated.

4.2.4 Educational level (n=315)

The median grade completed at school was grade 10 (Table 4.2). The lowest grade completed was grade 1 and the highest was grade 12.

4.2.5 Type of employment (n=320)

Table 4.1 shows that more than half of the participants were unemployed (n=167, 52.2%). The remaining participants were either employed full-time (n=103, 32.2%) or employed part-time (n=50, 15.6%). There was a significant difference between the clinic- and club group in terms of type of employment ($X^2 [2] = 10.21, p = 0.006$). Participants in the clubs were more likely to be employed full-time or part-time and participants in the clinic were more likely to be unemployed.

4.2.6 Monthly Income (n=312)

The mean monthly income was R1217.40 and the median income was R500. The highest monthly income earned was R11 000. Table 4.2 shows there was a significant difference between the clinic- and club group in terms of monthly income (Mann-Whitney U, $p=0.016$). The median monthly income in the club group was higher than in the clinic group.

4.2.7 Cost of traveling to the clinic (n=320)

The median cost of travelling was R 0 which indicated that at least half of the participants did not have any expense getting to the clinic or club (Table 4.2). The maximum amount spent by a participant was R 200. There was no significant difference in travel cost between the clinic- and club group. Although the cost is similar, patients in clubs may travel less frequently to the clinic, saving costs. This was however not specified in the questionnaire.

4.2.8 Number of other illnesses (n=320)

Participants were asked to indicate whether they have been diagnosed with any co-morbid illnesses. Reported co-morbid illnesses included: hypertension; diabetes; epilepsy; tuberculosis; asthma; gastric ulcer; cardiac illness; stress; glaucoma; arthritis; hypercholesterolemia and depression.

This variable was converted into the number of other illnesses; with possibilities being from no other illnesses to a maximum of three or more other illnesses. Table 4.1 shows that the majority of the participants had no other illnesses (n=232, 72.5%). The table further shows that 23.8% (n=76) had one other illness, 3.4% (n=11) had two other illnesses and 0.3% (n=1) had three or more other illnesses. The mean number of other illnesses in the clinic group was not significantly higher than in the club group (table 4.2) (Mann-Whitney U, p= 0.081), although participants in clinics tended to have more co-morbid illnesses. Participants with co-morbid illnesses are not eligible for transfer to a club yet according to the provincial guidelines and therefore are more likely to receive care in the clinic. This guideline was however not strictly applied since there were participants with co-morbid illnesses in clubs.

4.2.9 Number of pills taken daily (n=320)

The mean number of pills taken was 3.7 and the median was 3. The highest number of pills taken was 30 (Table 4.2).

4.2.10 Feeling well or not (n=319)

The majority of the participants reported feeling well on the day (n=280, 87.8%) with only 12.2% (n=39) reporting that they did not feel well.

4.2.11 Average log viral load (n=308)

The two most recent viral loads were combined to create an average viral load and this variable was dichotomized to report viral suppression. A participant was classified as viral load suppressed if the average viral load was below 400 copies/ml. The average viral load was then logged due to skewing in the data that revealed high standard deviations. The logged viral loads were more accurate to interpret. The average log viral load was 2.35 with a minimum of 1.43, a maximum of 6.52 and SD of 0.80. (Table 4.3). The majority of the participants had a suppressed viral load (n=259, 84.4%) and 15.6% (n=48) had non-suppressed viral loads. There was a significant difference between the clinic- and club group with regard to viral load suppression ($X^2 [1] = 22.55, p < 0.001$). The portion of participants who were viral load suppressed in the club was 98.9% compared to 77.7% in the clinic.

Table 4.3: HIV related information

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club P value
Viral suppression						<0.001
Yes	74 (75.5)	90 (79.6)	164 (77.7)	95 (99)	259 (84.4)	
No	24 (24.5)	23 (20.4)	47 (22.3)	1 (1.1)	48 (15.6)	
Average Log Viral Load	(n=99)	(n=113)	(n=212)	(n=96)	(n=308)	0.279
Mean	2.55	2.41	2.48	2.08	2.35	
SD	1.05	0.81	0.93	0.25	0.80	
Minimum	1.43	1.60	1.43	1.60	1.43	
Maximum	6.52	5.46	6.52	4.01	6.52	
HIV diagnosis	(n=90)	(n=103)	(n=193)	(n=93)	(n=286)	0.103
1 to 5 years ago	48 (53.3)	48 (46.6)	96 (33.6)	44 (47.3)	140 (49)	
6 to 10 years ago	35 (38.9)	38 (36.9)	73 (25.5)	44 (47.3)	117 (40.9)	
More than 10 years ago	7 (7.8)	17 (16.5)	24 (8.4)	5 (5.4)	29 (10.1)	
Years on treatment	(n=203)	(n=116)	(n=221)	(n=98)	(n=319)	0.002
Mean	4.9	4.6	4.5	5.4	4.8	
Median	4.5	4.1	4.0	5	4.3	
SD	2.4	2.4	2.3	2.4	2.4	
Minimum	1.1	1.2	1.1	1.6	1.1	
Maximum	11	10.7	11	11.2	11.2	

4.2.12 HIV diagnosis date (n=286)

HIV diagnosis date was used to calculate the number of years since HIV diagnosis. It was then categorized into three options namely 1-5 years since diagnosis, 6-10 years since diagnosis and > 10 years since diagnosis. The distribution amongst the options was 49% (n=140) for 1-5 years, 40.9% (n=117) for 6-10 years and 10.1% (n=29) for more than 10 years.

4.2.13 ART start date (n=319)

The Antiretroviral Treatment (ART) start date was used to calculate the number of years that a participant was on ART. The mean number of years on ART was 4.8 and the median was 4.3 as indicated in Table 4.3. The minimum number of years on ART was 1.1 and the maximum was 11.2 years. The mean number of years on ART in the club group were significantly higher than those in the clinic group ($t [317] = -3.1, p=0.002, 95\% \text{ CI } -1.4468 \text{ to } -0.3233$).

4.3 SECTION B: TREATMENT ADHERENCE

Patient adherence was measured using five questions. Five close-ended questions were used of which two measured adherence using a Likert scale and two measured the number of doses missed or taken late. The fifth question measured adherence with a visual analogue scale (VAS). The data is reported in Table 4.4 and Table 4.5.

Table 4.4: Treatment adherence: Likert scale items

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club P value
Last missed dose						0.002
Within the week	7 (6.6)	15 (12.9)	22 (9.9)	9 (9.2)	31 (9.7)	
1-2 weeks ago	11 (10.4)	5 (4.3)	16 (7.2)	4 (4.1)	20 (6.3)	
2-4 weeks ago	3 (2.8)	3 (2.6)	6 (2.7)	4 (4.1)	10 (3.1)	
1-3 months ago	4 (3.8)	10 (8.6)	14 (6.3)	5 (5.1)	19 (5.9)	
More than 3 months ago	3 (2.8)	22 (19.0)	25 (11.3)	0 (0)	25 (7.8)	
Never	78 (73.6)	61 (52.6)	139 (62.6)	76 (77.6)	215 (67.2)	
Estimated adherence						0.660
Very Poor	1 (0.9)	2 (1.7)	3 (1.4)	0 (0)	3 (1.4)	
Poor	0	3 (2.6)	3 (1.4)	0	3 (1.4)	
Fair	1 (0.9)	6 (5.2)	7 (3.2)	1 (1.0)	8 (2.5)	
Good	12 (11.3)	21 (18.1)	33 (14.9)	14 (14.3)	47 (14.7)	
Very Good	34 (32.1)	23 (19.8)	57 (25.7)	30 (30.6)	87 (27.2)	
Excellent	58 (54.7)	61 (52.6)	119 (53.6)	53 (54.1)	172 (53.8)	

Table 4.5: Treatment adherence: doses taken late or missed and adherence percentage

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club p value
Total missed doses in last 7 days	(n=203)	(n=115)	(n=221)	(n=97)	(n=318)	0.243
Mean	0.4	0.5	0.5	0.3	0.4	
Median	0	0	0	0	0	
SD	0.9	1.4	1.2	0.9	1.1	
Minimum	0	0	0	0	0	
Maximum	7	7	7	7	7	
Total doses taken late	(n=202)	(n=114)	(n=220)	(n=96)	(n=316)	0.478
Mean	0.7	0.9	0.8	0.7	0.8	
Median	0	0	0	0	0	
SD	1.3	1.5	1.3	1.5	1.4	
Minimum	0	0	0	0	0	
Maximum	8	7	7	8	8	
% pills taken in last month	(n=203)	(n=116)	(n=222)	(n=97)	(n=319)	0.092
Mean	93	93.2	93.1	94.3	93.5	
Median	100	100	100	100	100	
SD	6.0	7.3	2.6	6.3	10.6	
Minimum	50	0	0	0	0	
Maximum	100	100	100	100	100	

4.3.1 Last missed dose (n=320)

A Likert scale was used to report the last missed dose. The participants' responses to this question were: never (n=215, 67.2%), more than 3 months ago (n=25, 7.8%), 1-3 months ago (n=19, 5.9%), 2-4 weeks ago (n=10, 3.1%), 1-2 weeks ago (n=20, 6.3%) and within the last week (n=31, 9.7%) as indicated in Table 4.4. There was a significant difference between the clinic- and club- group with regards to the last missed dose (Fisher's exact = 18.671, p = 0.002).

In order to conduct a more in-depth analysis of adherence, this variable was dichotomized to represent adherent or non-adherent; with adherent responses never having missed a dose and all other responses considered as non-adherent as suggested by Chaiyachati and colleagues (2011:165). This option was chosen as it had the best combination of sensitivity and specificity to detect treatment failure (Chaiyachati et al. 2011:166). The majority of the participants were found to be adherent (n=215, 67.2%) and 32.2% (n=105) non-adherent. There was a significant difference between the clinic- and club group with regards to last missed doses ($\chi^2 [1] = 6.88$, p = 0.009). A higher proportion of participants in the clubs reported to be adherent (77.6%) compared to the clinic (62.6%).

4.3.2 Total missed doses in last 7 days (n=318)

Table 4.5 shows that the median number of doses missed was 0. The maximum number of reported missed doses was 7 with no significant difference between the group responses.

4.3.3 Total doses taken late in the last 7 days (n=316)

The median number of doses taken late was 0 (Table 4.5). The maximum number of doses taken late was 8. There was no significant difference between the groups.

4.3.4 Percentage of pills taken in the last month (n=319)

The participants were asked to rate their adherence on a visual analog scale (VAS) where 100% indicated that they had taken all their pills in the last month and 0% meant that they did not take any pills. Table 4.5 shows that the mean percentage of pills taken was 93.5 (SD 10.6). The median was 100, indicating that most participants reported that they were fully adherent. There was no significant difference between clinic- and club participants.

4.3.5 Estimated adherence for the last month (n=320)

Estimated adherence was measured with a Likert scale. The majority of the participants reported an excellent adherence within the last month (n=172, 53.8%). The remainder reported adherence as very good (n=87, 27.2%), good (n=47, 14.7%), fair (n=8, 2.5%), poor

(n=3, 1.4%) and very poor (n=3, 1.4%). There was no significant difference between the groups as shown by Table 4.4.

This variable was dichotomized to represent adherent or non-adherent in order to conduct further analysis. Any response less than excellent and very good was considered as non-adherent. Eighty-one percent were found to be adherent and 19% non-adherent. This analysis did not indicate any significant differences between the clinic- and club participants.

4.4 SECTION C: PATIENT SATISFACTION

This section of the questionnaire used a five-point Likert scale with options ranging from very satisfied (1), satisfied (2), neither satisfied nor dissatisfied (3), dissatisfied (4) and very dissatisfied (5) (Wouters et al., 2008:3). The participant responses are summarized in Table 4.6. A satisfaction mean score was calculated in order to conduct further analyses of the data. A higher score indicated dissatisfaction and a lower score indicated satisfaction. The Cronbach's alpha coefficient for the 10 patient satisfaction items was 0.78, which is acceptable and similar to the original published reliability results (Wouters et al., 2008:4).

Table 4.6: Patient satisfaction

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club p value
Complaint procedure (n=291)						0.024
Very Satisfied	43 (48.3)	41 (36.6)	84 (41.8)	49 (54.4)	133 (45.7)	
Satisfied	16 (18.0)	33 (29.5)	49 (24.4)	20 (22.2)	69 (23.7)	
Neither satisfied nor dissatisfied	20 (22.5)	8 (7.1)	28 (13.9)	15 (16.7)	43 (14.8)	
Dissatisfied	6 (6.7)	28 (25.0)	34 (16.9)	4 (4.4)	38 (13.1)	
Very Dissatisfied	4 (4.5)	2 (1.8)	6 (3.0)	2 (2.2)	8 (2.7)	
Cleanliness (n = 319)						0.113
Very Satisfied	83 (79.0)	73 (62.9)	156 (70.6)	80 (81.6)	236 (74.0)	
Satisfied	12 (11.4)	31 (26.7)	43 (19.5)	14 (14.3)	57 (17.9)	
Neither satisfied nor dissatisfied	8 (7.6)	22 (1.7)	10 (4.5)	4 (4.1)	14 (4.4)	
Dissatisfied	1 (1.0)	8 (6.9)	9 (4.1)	0 (0)	9 (2.8)	
Very Dissatisfied	1 (1.0)	2 (1.7)	3 (1.4)	0 (0)	3 (0.9)	
Confidentiality (n=319)						0.207
Very Satisfied	91 (86.7)	66 (56.9)	157 (71.0)	81 (82.7)	238 (74.6)	
Satisfied	10 (9.5)	33 (28.4)	43 (19.5)	12 (12.2)	55 (17.2)	
Neither satisfied nor dissatisfied	3(2.9)	5(4.3)	8(3.6)	3(3.1)	11(3.4)	
Dissatisfied	1 (1.0)	9 (7.8)	10 (4.5)	1 (1.0)	11 (3.4)	
Very Dissatisfied	0 (0)	3 (2.6)	3 (1.4)	1 (1.0)	4 (1.3)	
Respect Shown (n= 319)						0.162
Very Satisfied	88 (83.8)	86 (74.1)	174 (78.7)	86 (87.7)	260 (81.5)	
Satisfied	8 (7.6)	17 (14.7)	25 (11.3)	10 (10.2)	35 (11.0)	
Neither satisfied nor dissatisfied	4 (3.8)	7 (6.0)	11 (5.0)	2 (2.0)	13 (4.1)	
Dissatisfied	3 (2.9)	4 (3.4)	7 (3.2)	0 (0)	7 (2.2)	
Very Dissatisfied	2 (1.9)	2 (1.7)	4 (1.8)	0 (0)	4 (1.3)	
Information About HIV/AIDS (n= 318)						0.438
Very Satisfied	91 (87.5)	84 (72.4)	175 (79.5)	83 (84.7)	258 (81.1)	
Satisfied	10 (9.6)	27 (23.3)	37 (16.8)	10 (10.2)	47 (14.8)	
Neither satisfied nor dissatisfied	3 (2.9)	2 (1.7)	5 (2.3)	3 (3.1)	8 (2.5)	
Dissatisfied	0 (0)	2 (1.7)	2 (0.9)	1 (1.0)	3 (0.9)	
Very Dissatisfied	0 (0)	1 (0.9)	1 (0.5)	1 (1.0)	2 (0.6)	
Information about ART (n= 319)						0.434
Very Satisfied	89 (84.4)	89 (76.7)	178 (80.5)	81 (82.7)	259 (81.2)	
Satisfied	11 (10.5)	19 (16.4)	30 (13.6)	9 (9.2)	39 (12.2)	
Neither satisfied nor dissatisfied	4 (3.8)	5 (4.3)	9 (4.1)	4 (4.1)	13 (4.1)	
Dissatisfied	1 (1.0)	2 (1.7)	3 (1.4)	4 (4.1)	7 (2.2)	
Very Dissatisfied	0 (0)	1 (0.9)	0 (0)	0 (0)	1 (0.9)	

Table 4.6 Patient satisfaction (continued)

Variable	Clinic with club n=106 (33.1)	Clinic without club n=116 (36.3)	Total clinic n=222 (69.4)	Club n=98 (30.6)	Total n=320 (100)	Total clinic vs club p value
Opportunity to ask questions (n= 318)						0.560
Very Satisfied	81 (77.9)	82 (70.7)	163 (74.1)	79 (80.6)	242 (76.1)	
Satisfied	17 (16.3)	23 (19.8)	40 (18.2)	16 (16.3)	56 (17.6)	
Neither satisfied nor dissatisfied	4 (3.8)	6 (5.2)	10 (4.5)	1 (1.0)	11 (3.5)	
Dissatisfied	0 (0)	4 (3.4)	4 (1.8)	1 (1.0)	5 (1.6)	
Very Dissatisfied	2 (1.9)	1 (0.9)	3 (1.4)	1 (1.0)	4 (1.3)	
Language used (n= 318)						0.648
Very Satisfied	92 (87.6)	88 (75.9)	180 (81.4)	83 (85.6)	263 (82.7)	
Satisfied	10 (9.5)	19 (16.4)	29 (13.1)	13 (13.4)	42 (13.2)	
Neither satisfied nor dissatisfied	3 (2.9)	5 (4.3)	8 (3.6)	1 (1.0)	9 (2.8)	
Dissatisfied	0 (0%)	2 (1.7)	2 (0.9)	0 (0)	2 (0.6)	
Very Dissatisfied	0 (0%)	2 (1.9)	2 (0.9)	0 (0)	2 (0.6)	
Hours facility is open (n= 317)						0.029
Very Satisfied	68 (65.4)	68 (59.1)	136 (62.1)	72 (73.5)	208 (65.5)	
Satisfied	14 (13.5)	24 (20.9)	38 (17)	17 (17.3)	55 (17.4)	
Neither satisfied nor dissatisfied	11 (10.6)	14 (12.2)	25 (11.4)	4 (4.1)	29 (9.1)	
Dissatisfied	9 (8.7)	8 (7.0)	17 (7.8)	2 (2.0)	19 (6.0)	
Very Dissatisfied	2 (1.9)	1 (0.9)	3 (1.4)	3 (3.1)	6 (1.9)	
Waiting Time (n= 319)						<0.001
Very Satisfied	28 (26.7)	24 (20.7)	52 (23.5)	71 (72.4)	123 (38.6)	
Satisfied	21 (20.0)	29 (25.0)	50 (22.8)	16 (16.3)	66 (20.7)	
Neither satisfied nor dissatisfied	13 (12.4)	19 (16.4)	32 (14.5)	1 (1.0)	33 (10.3)	
Dissatisfied	29 (27.6)	23 (19.8)	52 (23.5)	4 (4.1)	56 (17.6)	
Very Dissatisfied	14 (13.3)	21 (18.1)	35 (15.8)	6 (6.1)	41 (12.9)	

4.4.1 Complaint procedure (n=291)

Most of the participants reported that they were very satisfied with the complaint procedure (n=133, 45.7%). The remaining participants reported as follows: satisfied (n=69, 23.7%), neither satisfied nor dissatisfied (n=43, 14.8%), dissatisfied (n=38, 13.1%) and very dissatisfied (n=8, 2.7%). A significant difference was noted between the club- and clinic group (Fisher's exact =1 0.97, $p = 0.024$). More club participants were satisfied with the complaint procedure than the clinic participants as shown by Table 4.6.

4.4.2 Cleanliness of the facility (n=319)

Table 4.6 shows that the majority of the participants were very satisfied with the cleanliness of their respective facilities (n=236, 74.0%). The remaining portion was as follows: satisfied (n=57, 17.9%), neither satisfied nor dissatisfied (n=14, 4.4%), dissatisfied (n=9, 2.8%) and very dissatisfied (n=3, 0.9%). There was no significant difference between clinic and club participants.

4.4.3 Confidentiality of the medical information (n=319)

Seventy-four percent of the participants (n=238) were very satisfied that their medical information was kept confidential (Table 4.6). A total of 25% were either satisfied (n=55, 17.2%), neither satisfied nor dissatisfied (n=11, 3.4%), dissatisfied (n=11, 3.4%) or very dissatisfied (n=4, 1.3%) respectively. There was no significant difference between club- and clinic group.

4.4.4 Respect shown by the Health Care Worker (HCW) (n=319)

More than 90% of the participants in total were either very satisfied (n=260, 81.5%) or satisfied (n=35, 11%) that the health care worker (HCW) was respectful towards them. The remaining participants reported the following: neither satisfied nor dissatisfied (n=13, 4.1%), dissatisfied (n=7, 2.2%) and very dissatisfied (n=4, 1.3%). Table 4.6 shows that there was no significant difference between club- and clinic group.

4.4.5 Health information about HIV/AIDS (n=318)

Table 4.6 shows that the majority of the participants were either very satisfied or satisfied with the health information given about HIV/acquired immune deficiency syndrome (AIDS) (n=258, 81.1%), (n=47, 14.8%). Less than 5% of participants were neither satisfied nor dissatisfied (n=8, 2.5%), dissatisfied (n=3, 0.9%) and very dissatisfied (n=2, 0.6%) with the health information given. There was no significant difference between club-and clinic group as seen on Table 4.6.

4.4.6 Information about ART medication (n=319)

The majority of the participants were very satisfied with the information they received about their ART medication (n=259, 81.2%). Table 4.6 shows that the remaining participants were as follows: satisfied (n=39, 12.2%), neither satisfied nor dissatisfied (n=13, 4.1%), dissatisfied (n=7, 2.2%) and very dissatisfied (n=1, 0.9%). Table 4.6 indicates that there was no significant difference between the club- and clinic group.

4.4.7 Opportunity to ask questions (n=318)

Less than 10 participants in total were either very dissatisfied or dissatisfied with the service with regards to opportunity to ask questions (n=4, 1.3%) (n=5, 1.6%). Eleven participants (3.5%) were neither satisfied nor dissatisfied. Table 4.6 shows that the rest were either satisfied or very satisfied (n=56, 17.6%), (n=242, 76.1%). There was no significant difference between the groups.

4.4.8 Language used to during consultation (n=318)

Overall the participants were very satisfied or satisfied with the language used during consultation (n=263, 82.7%), (n=42, 13.2%). Only thirteen participants in total were either very dissatisfied, dissatisfied or neither satisfied nor dissatisfied (n=2, 0.6%), (n=2, 0.6%), (n=9, 2.8%). Table 4.6 shows that there was no significant difference between club- and clinic group.

4.4.9 Hours that the facility is open (n=317)

The majority of the participants were very satisfied with the hours that the facility is open (n=208, 65.5%) and fifty-five (17.4%) were satisfied. The remaining participants responded as follows: neither satisfied nor dissatisfied (n=29, 9.1%), dissatisfied (n=19, 6.0%) and very dissatisfied (n=6, 1.9%). There was a significant difference between the club- and clinic group (Fisher's exact = 10.38, p=0.029). The club participants were more satisfied with the hours that the facility was open than the clinic participants.

4.4.10 Waiting time (n=319)

Although the majority of the participants were either very satisfied or satisfied with the waiting time at the facility the responses were fairly evenly spread. Table 4.6 indicates the responses: very satisfied (n=123, 38.6%), satisfied (n=66, 20.7%), neither satisfied nor dissatisfied (n=33, 10.3%), dissatisfied (n=56, 17.6%) and very dissatisfied (n=41, 12.9%). There was a significant difference between club- and clinic group (Fisher's exact = 77.51, p< 0.001). The club participants were more satisfied with the waiting time at the club than the clinic participants were.

4.4.11 Satisfaction mean score (n=320)

A mean score for satisfaction was calculated from all the questions related to services received (sections 4.4.1 to 4.4.10). The mean satisfaction score was 1.5 (SD 0.5) and the median 1.4. The minimum score was 1 which reports that the participant was very satisfied with services received. The maximum score was 4.3 indicating that this participant was dissatisfied with the service.

4.4.12 Complaints about service (n=308)

An additional question was asked about whether the participants had any complaints about the service. The majority of the participants had no complaints about the service they received (n=252, 81.2%) and 56 (18.2%) had complaints. Participants were asked to provide any further comments about their complaints through an open-ended question.

Participant comments were then analyzed thematically. The major themes were waiting time (n=22), hours facility is open (n=3), respect (n=3), service (n=5), support (n=1), confidentiality (n=3), medication administration (n=8) and facility logistics (n=4).

The majority of complaints were about the waiting time (n=22, 39%). Many patients complained that they have to wait very long as illustrated by the following statements: *“It is because of the time we must wait for the long time” (participant 104); “If I just come to take my pills I have to wait for a long time” (participant 38)*. One participant stated that the long waiting time caused dissatisfaction: *“We have to wait very long and are very unhappy” (participant 49)*. Another participant indicated that the reason for the long waiting time was not communicated clearly: *“I feel I wait very long and don’t understand why” (participant 314)*.

There were compliments from club participants about the service received (n= 3, 5%). These compliments related to convenience, the quality of the service and the time: *“The club works very well for me.” (Participant 56); “I really like the time. It is very convenient for me.”(Participant 67); “They provide good service in the club. The evening club works better for me. I prefer to collect my tablets in the evening.” (Participant 216)*.

4.5 BIVARIATE CORRELATIONS

Variables were correlated to determine relationships between certain demographic variables, treatment adherence and patient satisfaction.

A significant correlation was found between the participant’s age and the number of illnesses ($r=0.291$; $p=0.01$) and age and the number of pills taken per day ($r=0.227$, $p=0.01$). However the correlation was weak and may be of no clinical significance. Older patients were more likely to have more illnesses and took more tablets.

Age was negatively correlated with the level of education ($r=-0.385$, $p=0.01$). Older patients therefore had lower levels of education. Between age and feeling well or not and age and number of years on ART there were weak positive correlations ($r=0.136$, $p=0.05$) respectively ($r=0.152$, $p=0.05$). Income was correlated with the cost of travel to the clinic ($r=0.323$, $p=0.01$), level of education ($r=0.191$, $p=0.01$) and employment status ($r=0.731$, $p=0.01$).

Adherence (last missed dose and estimated adherence) was negatively correlated with the number of pills taken per day ($r=-0.142$, $p=0.05$; $r=-0.164$, $p=0.01$). Both adherence measures used in the correlation were coded as 0 = non-adherent and 1 = adherent. The more pills participants had to take, the less adherent they tended to be.

Both adherence measures (last missed dose and estimated adherence) were negatively correlated with the satisfaction mean score ($r=-0.137$, $p<0.05$; $r=-0.225$, $p<0.001$). The satisfaction mean score was coded as very satisfied = 1 and very dissatisfied = 5. Patients with a greater level of satisfaction therefore tended to be more adherent.

The patient satisfaction score was correlated with whether the patient felt well or not ($r=0.221$, $p=0.01$). Feeling well was coded as 1 and not feeling well as 2. Patients who felt unwell were more likely to be dissatisfied.

Viral suppression was coded as 1 = yes and 2 = no. Viral non-suppression was therefore correlated with income ($r=0.142$, $p=0.05$), number of other illnesses ($r=0.15$, $p=0.01$); number of pills taken per day ($r=0.194$, $p=0.01$), total missed doses in the last seven days ($r=0.126$, $p=0.05$), level of education ($r=-0.117$, $p=0.05$), employment ($r=0.152$, $p=0.01$), last missed dose ($r=-0.137$, $p=0.01$) and estimated adherence in the last month ($r=-0.191$, $p=0.01$).

Participants who had more illnesses and had to take more pills were more likely to not have suppressed viral loads. Participants with a higher level of education were more likely to have viral load that is not suppressed. Being unemployed (coded as 3) vs being employed full time (coded as 1) were correlated positively with not being viral load suppressed.

Higher patient adherence (based on the last missed dose and estimated adherence measures coded as 1 = adherent and 0 = non-adherent), was negatively correlated with a non-suppressed viral load.

4.6 HYPOTHESES TESTS

The null hypotheses were that stable HIV infected patients receiving care in ART adherence clubs have equal levels of treatment adherence and satisfaction as patients receiving care in Primary Health Care (PHC) clinics.

The hypothesis was tested in two ways. Firstly, treatment adherence was analyzed with logistic regression analysis by creating a model with satisfaction mean score, type of attendance (club vs clinic) and other variables. Then patient satisfaction was analyzed with multiple regression analysis by creating a model made up of various variables including type of attendance (club vs clinic) and treatment adherence amongst others.

A simple linear regression provides a means to estimate the value of a dependent variable based on the value of an independent variable. Multiple regression analysis is an extension of a simple linear regression in which more than one independent variable is entered into the analysis (Grove et al., 2015:570). Logistic regression analysis is done when a predictor or predictors of dichotomous dependent variable need to be tested (Grove et al., 2015:576).

Variables were included in the model if significant differences were found between the clinic- and club groups during the exploratory analysis. The model which explained the highest percentage of variance in the dependent variable was used. All analyses for hypothesis testing was statistically adjusted for clustering. Cluster sampling is used for heterogeneous population and uses the natural clusters of population units that have similar characteristics (Grove et al., 2015:360). There were thirteen clusters and each cluster represented each clinic that was used.

4.6.1 Treatment adherence

Treatment adherence was measured with five questions as validated by a previous study (Chaiyachati et al., 2011:166). The two questions that showed the highest sensitivity and specificity to detect non-adherence were the estimated adherence in the last 30 days and last missed dose (Chaiyachati et al., 2011: 166). These variables were dichotomized as described in Chaiyachati et al. (2011:166) and discussed in sections 4.3.1 and 4.3.5. Estimated adherence in the last 30 days was used first to create a model to test the hypothesis (Table 4.7). Non-adherence was coded as 0 and adherence as 1.

Table 4.7: Logistic regression model on estimated adherence (non-adherent vs adherent)

Estimated adherence (n=320)	(Pseudo R ² = 0.057)			
	Odds Ratio	p value	95% Confidence Interval	
Attendance: Club	1.015	0.972	0.415	2.484
Language*: Afrikaans	0.392	0.021	0.177	0.866
English	0.383	0.043	0.151	0.970
Satisfaction mean score	0.471	0.019	0.252	0.882
*Xhosa used as the reference group				

There was no significant difference between clinic and club participants with regards to estimated adherence (Table 4.7). The Afrikaans and English groups were less likely to be adherent than the Xhosa group (OR = 0.392, p=0.021, 95% CI 0.177 to 0.866; OR = 0.383, p

= 0.043, 95% CI 0.151 to 1.970). The odds of being adherent was more likely in participants that were satisfied (OR = 0.471, $p = 0.019$, 95% CI 0.252 to 0.882). The explained variance in estimated adherence was only 5.7% with this model as indicated by the R^2 of 0.057. The hypothesis was tested with a second measure of adherence namely the last missed dose (Table 4.8). Non-adherence was coded as 0 and adherence as 1.

Table 4.8: Logistic regression model on adherence (last missed dose – non-adherent vs adherent)

Adherence (last missed dose)(n=306)	(Pseudo $R^2 = 0.139$)			
	Odds ratio	p value	95% Confidence Interval	
Attendance: Club	1.21	0.592	0.590	2.520
Language*: Afrikaans	0.231	0.009	0.0765	0.698
English	0.363	0.052	0.131	1.008
Years on ART	0.893	0.052	0.797	1.000
Satisfaction score	0.346	0.006	0.162	0.737
Viral Suppression: Yes	2.194	0.021	1.124	4.280
*Xhosa used as the reference group				

The last missed dose revealed no significant difference between clinic and club participants (Table 4.8). The Afrikaans (48.6%) group was less likely to be adherent than the Xhosa (80.6%) group (OR = 0.231, $p = 0.009$, 95% CI 0.0765 to 0.698), but there was no significant difference between the English (65.5%) group and the Xhosa group. The odds of being adherent was more likely in the participants that were satisfied (OR = 0.346, $p = 0.006$, 95% CI 0.162 to 0.737). The number of years on ART had no significant effect on adherence. The explained variance (13.9%) in this model was slightly higher than in the first model (R^2 of 0.139).

4.6.2 Patient satisfaction

Table 4.9 indicates that the analysis showed that higher levels of (mean) satisfaction were predicted with club attendance than with clinic attendance after adjusting for the presence or contribution of every other variable in the model ($\beta = -0.261$, $p = 0.006$, 95% CI -0.431 to -0.091). The total variance explained was 18.7% ($R^2 = 0.187$).

Higher levels of satisfaction could be predicted in the English group than the Xhosa group ($\beta = -0.17$, $p = 0.003$, 95% CI -0.270 to -0.070). Lower scores indicated a higher level of satisfaction. There was no significant difference in satisfaction between the Xhosa group and the Afrikaans group. Further, lower levels of (mean) satisfaction were predicted with not feeling well than with feeling well when every other variable is adjusted for ($\beta = 0.363$, $p = 0.013$, 95% CI 0.091 to 0.636). Higher levels of satisfaction are expected with participants that are not viral load suppressed ($\beta = -0.164$, $p = 0.025$, 95% CI -0.304 to -0.023).

Table 4.9: Multiple regression model on mean satisfaction score

Satisfaction mean score (n=305)		(R ² = 0.187)		
	Coef.	p value	95% Confidence Interval	
Attendance: Club	-0.261	0.006	-0.431	-0.091
Language*: Afrikaans	-0.066	0.440	-0.247	0.114
English	-0.170	0.003	-0.270	-0.070
Number of other Illnesses	0.089	0.035	0.007	0.170
Years on ART	-0.037	0.032	-0.070	-0.003
Last missed dose	0.047	0.002	0.021	0.073
Feeling well: No	0.363	0.013	0.091	0.636
Viral Suppression: No	-0.164	0.025	-0.304	-0.023
*Xhosa was used as the reference group				

4.6.3 Further analyses of data: Viral suppression

Data on participants' viral load was collected as a guide for adherence since it is expected that patients who are adherent to their medication will have a suppressed viral load (Peltzer et al., 2010: 1). A logistic regression model was used to determine if there was a difference between the clinic- and club participants (Table 4.10).

Table 4.10: Logistic regression model for viral suppression

Viral Suppression (n=294)	(Pseudo R ² = 0.196)			
	Odds Ratio	p value	95% Confidence Interval	
Attendance: Club	25.38	0.001	3.694	174.421
Language*: Afrikaans	0.300	0.017	0.112	0.804
English	0.408	0.110	0.136	1.224
Income	1.000384	0.036	1.000	1.000
Education level	1.091	0.085	0.987	1.206
Years on ART	0.878	0.130	0.742	1.039
*Xhosa used as the reference group				

The odds of being viral load suppressed was more likely in the club participants than the clinic participants (OR = 25.38, p = 0.001, 95% CI 3.69 to 174.42). The confidence interval was very wide since only 1 of 96 club members was not viral load suppressed. The odds of being viral load suppressed was more likely in the Afrikaans group than the Xhosa group (OR = 0.3, p = 0.017, 95% CI 0.112 to 0.804).

With reference to income, the model shows that every 1 unit (Rand) increase in income resulted in an odds ratio of 1.000348 or a 0.038% increase in viral load suppression. Since the Rand units are such small units, the OR and CI are tiny in terms of absolute risk. The explained variance in this model was 19.6%.

4.7 SUMMARY

The study findings show that the club participants were more likely to be employed and to have higher mean monthly income compared to the clinic participants. The club participants had a lower mean number of illnesses than the clinic group. Participants in the clubs were more likely to have suppressed viral loads and to be longer on ART. The findings show that the club participants were more satisfied with the service received than the clinic participants. Interestingly the findings show that participants who were satisfied were more likely to be adherent on treatment. Further discussion and interpretation of the findings will follow in the next chapter.

CHAPTER 5: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The previous chapter reported on all the study findings. These will now be used to draw certain conclusions, make recommendations from the data and highlight study limitations.

5.2 DISCUSSION

The aim of the study was to investigate whether stable Human Immunodeficiency Virus (HIV) infected patients on Antiretroviral Treatment (ART) who receive care in ART adherence clubs are more adherent and more satisfied than patients receiving care in Primary Health Care (PHC) clinics. The data analyses showed that there were various differences between the ART adherence club and the PHC clinic participants. The first study objective was to determine the level of treatment adherence in the ART adherence club and PHC clinic participants, is discussed next.

5.2.1 Treatment adherence

Treatment adherence is defined as the extent to which a patient's behaviour corresponds with agreed recommendations from a health care provider. This was measured with Treatment adherence questionnaire validated by Chaiyachati and colleagues (2011:165). The findings for treatment adherence reported in 4.3 showed that the majority of the participants in both groups were adherent. However, the club group had slightly better adherence levels with both the last missed dose (club-77.6% vs clinic-67.2%) and estimated adherence (club-54.1% vs clinic-53.8%). Despite high levels of self-reported adherence 15.6% were found to not have suppressed viral loads. The Chaiyachati and colleagues sample (2011:165) had 9% with viral loads not suppressed and in comparison this is high. However, for the whole Eden district only 4.6% were not viral load suppressed. This supports suggestions that self-reported adherence perform poorly to identify treatment failure (Chaiyachati et al., 2011:163).

The bivariate correlations revealed two correlations with treatment adherence. Treatment adherence had a negative correlation with number of pills taken. The negative correlation implies that large pill burdens decrease treatment adherence which confirms an earlier study in ART (Chesney, 2000:s172). The use of fixed-dose combination pills (single pill combination) in South Africa will reduce the pill burden for HIV infected patients (South Africa, 2015:14). The second correlation was with satisfaction score which implies that higher levels of

satisfaction relate to better adherence to treatment consistent with previous research (Dang et al., 2013:4).

Treatment adherence was analysed with two regression models using “estimated adherence in last 30 days” and “last missed dose.” Chaiyachati and colleagues (2011:165) found that the Likert scale item, “estimated adherence in last 30 days” performed the best so it was used. The researcher included “last missed dose” as it showed significant differences ($p=0.002$). Both models found that club and clinic attendance could not influence adherence, but that satisfaction mean score did influence adherence. This will be discussed further in 5.2.3.

5.2.2 Patient satisfaction

As defined in chapter 2, patient satisfaction describes a patient’s general orientation towards a total experience of health care and a degree to which the service is meeting the patient’s expectations and needs. Patient satisfaction was measured with an established patient satisfaction survey designed by Wouters et al. (2008:10). The instrument had an acceptable reliability in this study population with a Cronbach’s alpha coefficient of 0.78, this was similar to the Cronbach’s alpha coefficient reported by the original authors (Wouters et al., 2008:4).

5.2.2.1 Interpretation of patient satisfaction based on previous research

The majority of the participants were satisfied with the care they received in both the ART adherence clubs and the PHC clinics. This corresponds with recent satisfaction studies done in South Africa specifically with HIV/acquired immune deficiency syndrome (AIDS) programs, that conclude that in general patients are satisfied with the care they receive (Wouters et al., 2008:10; Dang et al., 2012:5; Chimbindi et al., 2014:12). Significant differences between ART adherence clubs and PHC clinics were found with complaint procedure, hours facility is open and waiting time (Fisher’s exact = 10.97, $p=0.024$; Fisher’s exact = 10.38, $p=0.029$; Fisher’s exact = 77.51, $p< 0.001$). The interpretation of these follows.

The study findings showed that the PHC clinic participants were less satisfied with waiting time. This is supported in previous studies done (Anderson et al., 2007:3; Chimbindi et al., 2014:15; Wouters et al., 2008:1). For policy-makers and managers this is valuable as studies done on patient support groups for HIV infected patients reported that patient support groups reduced the waiting time for patients (Bemelmans et al., 2014:971). With specific reference to the South African model, it is argued that the ART adherence clubs had better outcomes as a result of shorter waiting times (Luque-Fernandez et al., 2013:2). This supports the finding that the ART adherence club group was significantly more satisfied than the PHC clinic group with regards to waiting time and should not be overlooked.

ART adherence clubs meet outside of busy clinic times which are generally early mornings or late afternoons as they are convenient for working patients (Luque-Fernandez et al., 2013:2). The demographic data supports this as the club group had a higher percentage of employed participants. The total full-time and part-time employed participants was 61% compared to 42% in the PHC clinic group. The difference between the ART adherence club and PHC clinic group specifically referring to hours that the facility is open is supported by this finding. The convenience of meeting times are very attractive for burdened health care workers (HCW) as this decongests clinics. Employed patients are often conflicted by regular work attendance and inconvenient clinic times. For these patients missing work regularly to attend the clinic for treatment may result in less pay and possibly retrenchment. ART adherence clubs provide patients with a workable solution to this realistic problem. The compliments reported by participants attending the ART adherence club further confirms this as the following participant explained: *"I really like the time. It is very convenient for me."* HIV/AIDS programs and PHC clinic managers may consider reviewing facility times to meet patient needs.

The researcher failed to find any literature to specifically explain the difference between the groups with regards to complaint procedures. The open-ended question responses did not allude to any explanation either. Future qualitative research on ART adherence may reveal reasons for this.

The regression model for patient satisfaction showed significant differences for language, number of other illnesses, years on ART and feeling well or not. With regards to feeling well or not some support from the literature was found. A 2002 study on patient experiences and satisfaction with health care found an association between satisfaction and health status, similar to feeling well or not (Jenkinson, Coulter, Bruster, Richards & Chandola, 2002:335). This study suggests that feeling well or not does influence a patient's experience of care and services received, but the correlation was weak (Jenkinson et al., 2002:337). No other literature to clarify and support the links between patient satisfaction and language, number of illnesses and years on ART could be found at the time of review.

The total mean satisfaction score (mean 1.5, SD 0.5) for this study is very similar to the mean satisfaction scores of the South African study from which the questionnaire was formed, which support the findings (mean 1.38, SD 0.48) (mean 1.48, SD 0.55) (mean 0.53, SD 1.43) (Wouters et al., 2008:5). In general, it suggests that HIV infected patients are satisfied with the service and/or care they receive.

5.2.2.2 Interpretation of patient satisfaction based on theory

The conceptual framework of the study proposed that if contextual components of care provision such as who, where and how are improved, this could positively affect patient satisfaction. These contextual components were related aspects of who provides care, how care is provided and where care is provided as described in chapter 1. Two aspects of where care is provided namely: facility times and waiting time, did show a significant difference. The club group was more satisfied with both these aspects of where care is provided. The regression model further supported this as the club group was more likely to be satisfied than the clinic group. These are only two of the contextual components of patient satisfaction which can be explored to improve overall patient satisfaction. If overall patient satisfaction is improved by these this may provide insight into the relationship between patient satisfaction and treatment adherence. This will be discussed further in 5.2.3.

5.2.3 Comparison and link between treatment adherence and patient satisfaction

As stated in 5.2.1, both regression models found that patient satisfaction did influence treatment adherence. This confirms what previous studies have shown: satisfied patients are more likely to be adherent (Dang et al., 2013:5; Barbosa et al., 2012:46; Preau et al., 2012:437-438). In the first study, Dang and colleagues (2013:5) specifically aimed to examine the link between treatment adherence and patient satisfaction with use of a structural equation model. The study used estimated adherence in the last 30 days, as was used in this study, to measure adherence and found 74% responded excellent or very good. This was then used to create a structural model along with other variables, such as retention in care, viral suppression and patient satisfaction. The designed model confirmed that patient satisfaction is positively related to retention in care and adherence to ART, both outcomes for HIV/AIDS programs ($p= 0.001$) (Dang et al., 2013:5).

The above provides further evidence that ART adherence clubs may positively affect HIV outcomes whereby the more satisfied ART patient is more likely to be adherent to treatment. A systematic review found five studies reported that increased adherence was associated with patient support group participation like ART adherence clubs (Bateganya et al., 2015:372). ART adherence clubs provide a practical measure for HIV/AIDS programs to improve and maintain adherence of stable HIV infected patients that should be implemented into more HIV/AIDS programs. HIV/AIDS programs could improve treatment adherence by improving the patient's experience of care and services received with the use of patient satisfaction surveys.

5.2.4 Viral suppression

Viral suppression was not stated in the objectives of the study. As self-reported treatment adherence is not a very accurate measure of treatment adherence. Viral suppression and treatment adherence are closely linked and therefore was used to strengthen the study findings. A viral load below 400copies/ml was deemed an acceptable viral load and was used to distinguish between viral suppression and non-viral suppression.

Bivariate correlations with viral suppression suggest that patients with more co-morbidities and large pill burdens are more likely to not be viral load suppressed. This finding is consistent with a recent study (Nachega, Parienti, Uthman, Gross, Dowdy, *et al.*, 2014:1303). Reduced pill burdens do link to improved viral suppression as was seen with treatment adherence in 5.2.1.

The logistic regression model showed that the club participants were more likely to have a suppressed viral load than the clinic participants. This may present a slightly skewed picture as in order to be part of the ART adherence club a patient needed to have a suppressed viral load. A component of the inclusion criteria was club attendance for a minimum of 6 months. The fact that club participants remained viral load suppressed post 6-month membership does provide further evidence that club patients exhibit suppressed viral loads. This finding is supported by the Luque-Fernandez and colleagues study that found that club participation is strongly associated with viral load suppression (2013:4).

Interestingly, in the club group this study had a lower percentage of non-viral suppression (n=1, 1%) compared to the Luque-Fernandez study (n=14, 3%) (Luque-Fernandez *et al.*, 2013:4). However, in the clinic group non-viral suppression was higher in this study (n=47, 22.3%) than the Luque-Fernandez study (n=214, 9%) (Luque-Fernandez *et al.*, 2013:4). This is consistent with another South African study that found that urban residents were almost three times more adherent than rural residents (Peltzer *et al.*, 2010:5). There may be unique challenges to adherence in the rural setting that requires further investigation.

5.3 STRENGTHS AND LIMITATIONS OF THE STUDY

A high quality study focuses on a significant problem, demonstrates sound methodology, produces credible findings and provides a basis for additional studies (Burns & Grove, 2011:419).

As the HIV infected population continues to grow, sufficient evidence is needed to guide HIV/AIDS programs and the health care system to provide both access and care for ART patients. ART adherence clubs is a new model of care for HIV/AIDS programs and is still in

the implementation phase. The cross-sectional design of this study provides HIV/AIDS program developers and managers with valuable information for this model of care in a rural setting, about the levels of treatment adherence and satisfaction levels of patients as process unfolds.

The sample of the study was large enough to detect significant differences between the groups suggesting a sufficient sample size. The sample was collected from 13 clinics from different towns in the Eden district thereby increasing the representativeness and generalization of the study findings to other areas and population groups in South Africa.

The study was the first in South Africa to examine patient satisfaction in ART adherence clubs and reveals essential new information for the further roll-out of ART adherence clubs in South Africa. The evidence found regarding patient satisfaction and ART adherence clubs is valuable for PHC clinics with high HIV infected patient volumes.

Convenience sampling was used to acquire study participants, allowing biases to exist and thereby limiting the study. The ability to generalize the study findings to the larger HIV infected population is thus limited. The researcher attempted to control these biases as far as possible by recruiting participants on different days and at different times during clinic hours.

A further potential shortfall of this study may be the causal nature of adherence. Club participants are more likely to be adherent as adherence is a requirement for club inclusion. This would create a false positive adherence in the club participants for the study. Club managers may have selected well adherent patients for the club. As this form of bias remains largely uncontrollable, the researcher attempted to curb this by using participants with a six month minimum attendance.

Self-report measures of treatment adherence by patients proved to be another important potential shortfall as patients may overestimate their own adherence. The researcher attempted to control for this by using established adherence measures.

The researcher and field workers were not employed at the clinics or known to any of the participants and this was used to control for a possible Hawthorne-effect. This suggests that participants could answer truthfully and accurately.

The researcher discovered that in the translation to Afrikaans and Xhosa certain concepts of the questionnaire may have lost their meaning or may have been understood differently in the different languages. The misunderstanding of certain concepts specifically with treatment adherence and patient satisfaction may have influenced study findings to a certain degree.

This was seen in the regression analyses that showed significant differences between Xhosa and English with mean satisfaction score. Both treatment adherence regression models revealed differences between Xhosa and English and Xhosa and Afrikaans with regards to adherence. These differences could be interpreted as concepts in the questionnaire being understood differently in three languages. The researcher ought to have included ethnic group differences when gathering biographical data in the questionnaire. The differentiation between ethnic groups may have provided insightful information about treatment adherence and patient satisfaction differences between these groups.

5.4 RECOMMENDATIONS

5.4.1 Recommendations for practice

ART adherence clubs have shown to be an efficient, effective and feasible model of care for stable ART patients and specifically in the rural setting (Luque-Fernandez et al., 2013:1). PHC clinics with high patient loads could make use of ART adherence clubs to not only reduce patient loads in PHC clinics, but to improve patient satisfaction of their ART patients. The researcher suggests that ART adherence club implementation should continue to expand and establish ART adherence clubs in other parts of the Western Cape and South Africa. For PHC clinics in the Eden district that have not established ART adherence clubs, this should be done. For the seven clinics that have established ART adherence clubs regular patient satisfaction surveys should be done to evaluate and improve existing ART Adherence clubs. These club managers could implement interventions based on patient satisfaction surveys to improve individual components of patient satisfaction and overall patient satisfaction. ART adherence clubs have been established in Cape Town for other groups such as adolescents, families and patients with co-morbidities. These could be explored in the rural setting of the Eden district (Luque-Fernandez et al., 2013:2,8).

5.4.2 Recommendations for future research

The wealth of knowledge that could be gathered from a qualitative review of patient experiences in ART adherence clubs would be very valuable for the further implementation of ART adherence clubs in South Africa. This knowledge could help to fully understand what patient experiences are in ART adherence clubs and assist to further improve their experiences. Further research of patient satisfaction and treatment adherence levels in an urban setting of ART adherence club patients would provide knowledge for that setting. ART adherence clubs have proven to be beneficial for patients and the experience of nurses and counsellors would be valuable in supporting further roll-out of this model of care. The link

between patient satisfaction and treatment adherence should be researched further to uncover the direct pathways that govern the relationship between these two.

5.5 DISSEMINATION

A poster presentation of the study was done at the Annual Academic Day and Provincial Health Research Day for 2015 at Stellenbosch University medical campus. The study findings will be presented to the Eden district management and the Western Cape Government. The abstract of the study will be submitted for the Southern African HIV Clinicians Society Conference in 2016 and the International AIDS conference 2016. An article of the study will be submitted for publication in a peer-reviewed journal.

5.6 CONCLUSION

The comparison of treatment adherence and patient satisfaction of HIV infected patients revealed more than just the differences between ART adherence clubs and PHC clinics. This comparison has strengthened the link between patient satisfaction and treatment adherence that exists. The study has added to the empirical evidence that ART adherence clubs are an effective model for delivering ART to the ever growing population of HIV infected people.

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APPENDICES

Appendix 1: Ethical approval from Health Research Ethics Committee



UNIVERSITEIT-STELLENBOSCH-UNIVERSITY
JOU KENNISSENT OOR + JOUF WISWISSEDE PLEKKE

Approval Notice Response to Modifications- (New Application)

24-Jun-2014
De Jager, Gabi GA

Ethics Reference #: S14/03/055

Title: Patient satisfaction and treatment adherence of stable HIV infected patients.

Dear Ms Gabi De Jager,

The **Response to Modifications - (New Application)** received on 06-Jun-2014, was reviewed by members of Health Research Ethics Committee 2 via Expedited review procedures on 24-Jun-2014 and was approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: 24-Jun-2014 -24-Jun-2015

Please remember to use your **protocol number** (S14/03/055) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rdc and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: www.sun.ac.za/rdc

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:

HREC Checklist

Supervisor declaration

Protocol

Information sheet

Appendix 2: Amendment Letter from Health Research Ethics Committee



UNIVERSITEIT-STEPLENBOSCH-UNIVERSITY
Job Enrichment out of your knowledge partner

Ethics Letter

22-Jul-2015

Ethics Reference #: 514/03/055

Title: Patient satisfaction and treatment adherence of stable HIV infected patients.

Dear Ms Gabi De Jager,

The HREC approved the submitted amendment.

The researcher would like to add clinics that do not yet have ART Adherence clubs to the study population.

If you have any queries or need further help, please contact the REC Office 219389207.

Sincerely,

REC Coordinator
Mertrude Davids
Health Research Ethics Committee 2

Appendix 4: Participant information leaflet and consent form

TITLE OF THE RESEARCH PROJECT:

Patient satisfaction and treatment adherence of HIV infected patients in adherence clubs and clinics in the Eden district within the Western Cape

REFERENCE NUMBER: S14/03/055

PRINCIPAL INVESTIGATOR: Gabi de Jager

ADDRESS: 13 Grysbok Avenue, George, Western Cape

CONTACT NUMBER: 0733554167

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- *The study will be conducted at seven PHC clinics in the Eden district. 15-20 participants from your clinic and/or 15-20 participants from the adherence club will be recruited. A total of approximately 350 participants will be recruited.*
- *The study will investigate if there is a difference in patient satisfaction and treatment adherence of clinic patients and adherence club patients. The researcher wishes to know if adherence clubs can improve the care of ART patients provided by clinics.*
- *An Adherence clubs consists of 15-30 ART patients who meet as a group every two months either at the primary health clinic outside of busy times or in the community to receive their medication.*
- *The researcher will clearly explain the purpose of the study and the details regarding participation with respect to voluntary consent. The researcher will complete the research questionnaire with you and it will take approximately 10-20 minutes.*
- *Participants will be randomly selected from the clinic and the adherence club to participate.*

Why have you been invited to participate?

- *The researcher has invited you to participate in the study to investigate your level of satisfaction with the service provided by either the clinic or the adherence club and to determine your level of adherence to Antiretroviral Treatment.*

What will your responsibilities be?

- *You will be responsible for answering questions from the research questionnaire openly and honestly.*

Will you benefit from taking part in this research?

- *You will not benefit directly from participating in the study, but the findings of the study will help to benefit future patients.*

Are there in risks involved in your taking part in this research?

- *You will not be harmed at all by taking part in the study, but you may feel uncomfortable or nervous about answering some of the personal questions about your illness. You must also understand that you will be asked many questions and it will take approximately 10-20 minutes to complete the questionnaire.*

Who will have access to your medical records?

- *Your medical records will remain confidential and protected. Only the research staff and clinic or adherence club staff will have access to your information.*

Will you be paid to take part in this study and are there any costs involved?

- *No you will not be paid to take part in the study.*

Declaration by participant

By signing below, I agree to take part in a research study entitled (*insert title of study*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) On (*date*) 2014.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) On (*date*) 2014.

.....
Signature of investigator

.....
Signature of witness

Declaration by interpreter

I (*name*) declare that:

- I assisted the investigator (*name*) to explain the information in this document to (*name of participant*) Using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) On (*date*)2014

.....
Signature of interpreter

.....
Signature of witness

Appendix 5: Patient satisfaction and adherence questionnaire

English	<input type="checkbox"/>
Afrikaans	<input type="checkbox"/>
Xhosa	<input type="checkbox"/>

Section A: Basic Biographical Information

Please complete the entire questionnaire by marking your answer with X where applicable.

1. Type of attendance

Clinic	<input type="checkbox"/>
Club	<input type="checkbox"/>

2. Age

3. Gender

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>

4. What is the highest grade in school that you completed?

5. Employment

Work Full-time	<input type="checkbox"/>
Work Part-time	<input type="checkbox"/>
Unemployed	<input type="checkbox"/>

6. Monthly Income R.....

7. Cost of traveling to the clinic / club R.....

8. Do you have any other illnesses? For example Diabetes Mellitus, Hypertension, Asthma or TB

9. How many pills do you take every day?

10. Are you feeling well today?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

11. Two most recent HIV viral loads and date:

Date..... Viral Load.....copies/ml

Date..... Viral Load.....copies/ml

12. When were you diagnosed with HIV?

13. When did you start taking ART?

Section B: Patient Adherence

Please mark your answer using X

1. When was the last time you missed taking your medication?

Within the last week	5	
1-2 weeks ago	4	
2-4 weeks ago	3	
1-3 months ago	2	
More than 3 months ago	1	
Never	0	

2. During the last 7 days, how many times, in total, did you miss taking one or more of your antiretroviral pills?.....time(s)

3. During the last 7 days, how many times, in total, did you take one or more of your antiretroviral pills more than two hours late?.....time(s)

4. Please put a cross on the line below at the point showing your best guess about how many antiretroviral pills you have taken in the last month? We would be surprised if this is 100% for most people. 0% means you have taken none of your pills; 50% means you have taken half of your pills; 100% means you have taken every single pill.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
None					Half					All

5. How would you rate your adherence for the last 30 days? (Circle one)

a) Very Poor

b) Poor

c) Fair

d) Good

e) Very Good

f) Excellent

Section C: Patient Satisfaction

Please rate the ART services you receive in terms of the following and mark your answer using X:

		Very Satisfied	Satisfied	Neither Satisfied nor Dissatisfied	Dissatisfied	Very Dissatisfied
1.	<u>Complaint Procedure</u> I know how to make a complaint	1	2	3	4	5
2.	<u>Cleanliness of the Facility</u> The facility is clean	1	2	3	4	5
3.	<u>Confidentiality of medical information</u> My personal medical information is kept private	1	2	3	4	5
4.	<u>Respect shown by the Health Care worker</u> The Health Care Worker treats me with respect	1	2	3	4	5
5.	<u>Health Information about HIV/AIDS</u> Health information is given to me about HIV/AIDS	1	2	3	4	5
6.	<u>Information about ART medication given by the Health Care Worker</u> Information is given to me about my ART medication	1	2	3	4	5
7.	<u>Opportunity to ask questions</u> I'm given an opportunity to ask questions	1	2	3	4	5
8.	<u>Language used during consultation</u> The Health Care Worker uses language that I can understand	1	2	3	4	5
9.	<u>Hours that the facility is open</u> The facility is open during convenient times	1	2	3	4	5
10.	<u>Waiting time</u> The waiting time at the facility is appropriate	1	2	3	4	5

6. Do you have any complaints about the service you receive?

Yes	
No	

7. Please explain

.....

.....

.....

Appendix 6: Personal communication with Sandra Smit

Sandra Smit <Sandra.Smit@westerncape.gov.za> Hi Gabi Sien aangeheg soos versoek. -
Patients with detectable viral loads = 632
Total Adult patients in clinics = 14757
Total adult patients in clubs = 1747
Groete Sandra -----Original Message---

To
Gabi De Jager
Jul 27 at 2:28 PM
Hi Gabi

Sien aangeheg soos versoek.

- Patients with detectable viral loads = 632
- Total Adult patients in clinics = 14757
- Total adult patients in clubs = 1747

Groete
Sandra

-----Original Message-----
From: Gabi De Jager [mailto:gabi_defreitas@yahoo.com]
Sent: 16 July 2015 11:19 AM
To: Sandra Smit
Subject: Adherence club Research

Appendix 7: Declaration of technical editing



To whom it may concern

This letter serves as confirmation that I, Lize Vorster, performed the Technical Formatting of Gabi de Jager's thesis. Technical formatting entails complying with the Stellenbosch University's technical requirements for theses.

Yours sincerely

Lize Vorster
Language Practitioner

A handwritten signature in black ink, appearing to read 'Lize Vorster', is written over a simple line drawing of a pen nib.

Vygie street 9, Welgevonden Estate, Stellenbosch, 7600 * e-mail: lizevorster@gmail.com * cell: 082 856 8221

Appendix 8: Declaration of language editing

PO Box 31973

Newton Park

Port Elizabeth

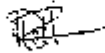
6055

24 November 2015

To Whom It May Concern:

This letter confirms that I, Philippa Holtz, assisted with the language editing of this thesis for submission to the University of Stellenbosch for Gail Ann de Jager.

Yours sincerely



Phillipa Holtz
BSc (Hons) & PGCE

Appendix 9: Data dictionary

Variable Description	variable type	Level of measurement	Codes
Language	Integer	Ordinal	Xhosa=1 Afrikaans=2 English=3
Type of attendance	Integer	Nominal	Clinic=1 Club=2
Age	Integer	Continuous	
Gender	Integer	Nominal	Female=1 Male=2
Education level	Integer	Continuous	
Employment		Ordinal	full-time=1 part-time=2 unemployed=3
Income	Integer	Continuous	
Cost of travelling to the clinic	Integer	Continuous	
Number of other illnesses	Integer	Ordinal	none=0 1 other illness=1 2 other illnesses=2 3-4 other illnesses=3
Number of pills taken every day	Integer	Continuous	
Feeling well or not	Integer	Nominal	yes=1 no=2
Last Viral load	Integer	Continuous	
Second last Viral Load	Integer	Continuous	
Average Log Viral Load	Integer	Continuous	
Viral Suppression	Integer	Nominal	Yes=1 No=2
HIV diagnosis year	Integer		
ARV start date	Integer		
Years on ART	Integer	Continuous	
Last missed dose	Integer	Ordinal	never=0 more than 3 months =1 1-3 months =2 2-4 weeks=3 1-2 weeks=4 within last week=5
Adherent yes or no based on last missed dose	Integer	Nominal	0=not adherent 1=adherent
Total missed doses in last 7 days	Integer	Continuous	
Total doses in last 7 days taken late	Integer	Continuous	
Percentage of pills taken in last month	Integer	Continuous	

Variable Description		Level of measurement	Codes
Estimated adherence rate in month	Integer	Ordinal	Very poor=1 poor=2 fair=3 good=4 very good=5 excellent=6
Adherent yes or no based on estimated adherence	Integer	Nominal	0=not adherent 1=adherent
Complaint Procedure Cleanliness of facility Confidentiality of medical information Respect shown by HCW Information given about HIV/AIDS Information about ART given by HCW Opportunity to ask questions Language used during consultation Hours that facility is open Waiting time	Integer	Ordinal	1=very satisfied 2=satisfied 3=neither satisfied nor dissatisfied 4=dissatisfied 5=very dissatisfied
Mean Satisfaction score	Integer	Continuous	
Do you have any complaints	Integer	Nominal	yes=1 no=0

Appendix 10: Permission to use questionnaire

[Wouters Edwin <edwin.wouters@uantwerpen.be>](mailto:edwin.wouters@uantwerpen.be)

['Gabi De Jager'](#)

Jan 4 at 11:49 AM

Dear Gabi,

If you refer to our paper and our team as the developers of the scale, you are certainly welcome to use our satisfaction scale. We are certainly also interested in the results of your study, so please share them :-).

If we can be of any assistance, just let us know.

Good luck with your study.

Best regards,
Edwin Wouters

Prof. dr. Edwin Wouters
Centre for Longitudinal & Life Course Studies
University of Antwerp
Belgium
&
Centre for Health Systems Research & Development
University of the Free State
South Africa