Factors influencing non-adherence to tuberculosis treatment in a sub-district of the North West Province

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BCur

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ABSTRACT

BACKGROUND: Tuberculosis (TB) is a worldwide concern that leads the researcher to the identification of a research gap regarding non-adherence. Non-adherence in this study refers to missed doses of treatment among pulmonary sputum smear positive TB patients due to various reasons (National Department of Health (NDoH), 2014a:51; Tola *et al.* 2015b:2). Non-adherence to TB treatment is an acknowledged problem aggravating the health risks of TB patients, loved ones and the community. The high transmission of TB, exaggerated TB morbidity, increasing development of TB-drug resistance and TB related mortality (NDoH, 2014a:5; World Health Organisation (WHO), 2015a:4). The National Tuberculosis Management Guidelines (NTMG) 2014 state, that in order to effectively cure TB, every patient's cooperation is required to avoid non-adherence for the entire six (6) months of treatment (NDoH, 2014a:41).

DESIGN/DESIGN: A quantitative, cross sectional, descriptive research design was chosen to describe factors influencing adherence in pulmonary sputum positive TB patients in the Tlokwe sub-district. The researcher identified an internationally validated survey that could help measure these factors. The survey is known as the TB measuring adherence scale (TBMAS) and was used to collect data. The researcher also calculated the missed doses of patients who were non-adherent to treatment.

DATA ANALYSIS: The researcher employed descriptive and inferential statistics (Pearson's correlations and Cohen's effect sizes) in data analysis. The study population consisted of 63 available respondents during the time of data collection. The data from the TBMAS surveys was captured in an Excel sheet and was re-captured in second and third Excel worksheets. With the re-capturing of the data in three different Excel sheets, possible mistakes could be identified and corrected. Data were analysed by the North-West University's Statistical Consultation Services at the Potchefstroom Campus using SAS (SAS Institute Inc., 2016). Validity and reliability of the TBMAS was determined before any analysis was done to establish whether the results were reliable.

RESULTS: The researcher interpreted the data in order to answer the research question. The study was evaluated, limitations identified, and recommendations were made for practice, education, research and policy. The study was unable to answer the research question adequately or to reach the aim and objective. The study therefor did not identify the factors contributing to non-adherence to TB treatment in patients with pulmonary sputum positive TB in the Tlokwe sub-district.

The researcher then interpreted the data in order to answer the research question. The study was evaluated, limitations identified, and recommendations were made for practice, education, research and policy.

CONCLUSION: The conclusion is that respondents who did not adhere were also classified as to be adherent and thus the adherence group was contaminated by non-adherence respondents.

KEY CONCEPTS

Tuberculosis; pulmonary sputum positive TB; non-adherence factors; defaulter; Primary Health Care facilities; TB medication adherence scale; management; Xpert MTB/RIF; TB Professional Nurse

ABBREVIATION

AIDS:	Acquired immune deficiency syndrome
ART:	Anti-retro viral treatment
CDC:	Communicable disease coordinator
CHW:	Community health worker
DoH:	Department of Health
DOT:	Directly observed treatment
Dr KK district:	Doctor Kenneth Kaunda District
DRAT:	District Rapid Appraisal TB-tool
HIV:	Human immunodeficiency virus
HREC:	Health Science Research Ethics Committee
MDR:	Multi drug resistance
NDoH	National Department of Health
NHI:	National Health Insurance
NTMG:	National Tuberculosis Management Guidelines 2014
PDoH:	Provincial Department of Health
PHC:	Primary health care
SA:	South Africa
TB:	Tuberculosis
TB PN:	TB Professional Nurse
TBMAS	TB Medication Adherence Scale
WHO:	World Health Organization
XDR:	Extensive drug resistance

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CHAPTER 1

OUTLINE OF THE STUDY

1.1 INTRODUCTION

Tuberculosis (TB) is a worldwide concern that leads the researcher to the identification of a research gap regarding non-adherence. Non-adherence in this study refers to the interruption of TB treatment among TB patients due to various reasons (National Department of Health (NDoH), 2014a:51; Tola *et al.,* 2015b:2). Non-adherence to TB treatment is an acknowledged problem aggravating the health risks of TB patients, loved ones and the community. The high transmission of TB, exaggerated TB morbidity, increasing development of TB-drug resistance and brutal TB related mortality (NDoH, 2014a:5; World Health Organisation (WHO), 2015a:4). The National Tuberculosis Management Guidelines (NTMG) 2014 state, in order to effectively cure TB, every patient's cooperation is required to avoid non-adherence for the entire six (6) months of treatment (NDoH, 2014a:41). Literature and statistics enabled the researcher to formulate a problem statement regarding non-adherence to TB treatment. From the problem statement the research question and objective of the study was formulated. The researcher explained the conceptual framework for the research. The research design, methods, role of the researcher, accuracy, ethical considerations and dissertation layout followed. The chapter ends with a proposed budget, time line and summary.

1.2 BACKGROUND

TB is a universal devastating threat to the health of mankind since the 1990's (Munro *et al.,* 2007:1231; Naidoo *et al.,* 2013:2; Smeltzer *et al.,* 2010:567; Tola *et al.,* 2015b:1; WHO, 2015a:5). TB took 1.5 million lives globally in 2014 (WHO, 2015a:1) and is ranked the second highest cause of death in the world on the heels of the human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) (Tola *et al.,* 2015b:1; WHO, 2015a:1). In 2014, 28% of world-wide TB cases occurred in Africa – double the amount compared to the rest of the world (WHO, 2015a:2).

TB can be defined in short as a contagious disease caused by the bacillus – *Mycobacterium tuberculosis*. TB can affect various organs in the human body but attacks the lungs in 80% of cases and is then formally classified as pulmonary TB (Smeltzer *et al.,* 2010:567; NDoH, 2015a:6; WHO, 2015a:4). The emphasis of this study is therefore on pulmonary TB.

Pulmonary TB classically presents with cough, fever, unplanned weight loss and night sweats (NDoH, 2014a:12). However, health care workers are still obligated to confirm pulmonary TB with Xpert MTB/RIF sputum tests (NDoH, 2014a:19-23). The Xpert MTB/RIF is the recommended test world-wide since 2010 (WHO, 2015a:69). Once the Xpert MTB/RIF test

results return from the laboratory the diagnosis is revealed. The diagnosis is then either a positive or negative pulmonary sputum result for TB. The Xpert MTB/RIF is designed to test the sensitivity of the TB bacillus to Rifampicin simultaneously. Rifampicin is the primary drug used for treating pulmonary sputum positive TB (NDoH, 2014a:23). Pulmonary sputum positive TB has the reputation of being highly contagious. Therefore the NTMG (NDoH, 2015a:21) and the researcher felt urged to attend to these cases specifically.

Transmission of pulmonary sputum positive TB occurs among people when an infected victim coughs, sneezes, talks or sings into the surrounding air. The spread of TB flourishes in dark, poorly ventilated, cramped living spaces. The chances of infection are also determined by the amount of exposures to TB and the level of infectivity of the person spreading the TB bacilli. The TB nucleus can survive in the air for up to four hours and has ample time to infect other innocent prey that pass by and inhale this contaminated air (NDoH, 2015a:6). Developing countries such as Ethiopia and South Africa (SA) are especially predisposed to transmission of the TB epidemic (Gebremariam *et al.* 2010:1; Loveday & Vanleeuw, 2014:195; Naidoo *et al.,* 2013:2; Tola *et al.,* 2015b:1).

People in developing countries often reside in substandard housing with dark, poor ventilated, cramped living spaces providing favourable conditions for the TB bacillus to thrive and increase exposure times, therefore family and friends are the most affected secondary sufferers. In developing countries, poverty and overpopulation with limited access to sufficient resourceful healthcare, compounds the problem. Furthermore public transport and locations such as malls and shopping centres are overcrowded, providing excellent residence for the disease (Smeltzer *et al.,* 2010:567).

If TB remains untreated, one infected person with active TB can infect up to 15 people per year (NDoH, 2015a:6). People with compromised immune systems who are exposed to the nuclei are more prone to develop active pulmonary sputum positive TB than people with normal immune systems (NDoH, 2015a:6). HIV/AIDS, diabetes, the elderly, children below five (5) years of age, people on cancer chemotherapy, smokers, alcohol abusers and silicosis sufferers all have a higher risk of contracting the disease (NDoH, 2014a:51; NDoH, 2015a:6; Hattingh, *et al.* 2012:348). The WHO and NDoH estimates that people living with HIV/AIDS are 26-31 times more likely to develop TB than those that are HIV negative (Loveday & Vanleeuw, 2014:153; NDoH, 2015a:20; WHO, 2015a:78).

Africa is ranked the highest for TB and HIV/AIDS co-infection as 79% of cases are co-infected (Tola *et al.* 2015b:1). TB remains or continues to be the leading cause of death among people

living with HIV/AIDS in Africa (Loveday & Vanleeuw, 2014:195; Naidoo *et al.* 2013:2; Castelnuovo, 2010:320) and in SA (South African National Aids Council (SANAC), 2016:10). SA reported 7.4%-8.4% TB deaths (Loveday & Vanleeuw, 2014:169; SANAC, 2016:10) and 5.1% (23 203) HIV deaths in 2013 (Statistics South Africa (Stats SA), 2014:27). In 2014, the TB and HIV co-infection rate averaged 56.5%-60% in SA (Loveday & Vanleeuw, 2014:159; SANAC, 2016:10). SA continues to fight the battle against both these illnesses (Padayachee, 2014:175) and co-infection with one another spurs the fatality among TB and HIV/AIDS sufferers (SANAC, 2016:10). The researcher takes note of the enormous co-infection rate and initially planned to conduct the research among co-infection sufferers; however it seems that this study will be more appropriately addressed at PhD level as an outflow of this study.

During 2009 – 2012 SA ranked third in the world for TB incidence after India and China (Loveday & Vanleeuw, 2014:195; NDoH, 2015a:20; SANAC, 2016:10). SA had 328 897 notified TB cases that started anti-TB treatment in 2013 (NDoH, 2015a:22). Post 2013 SA proudly claimed sixth place in the world after India, China, Nigeria, Pakistan and Indonesia (SANAC, 2016:10). In 2014/15, a total of 450 thousand new TB cases were estimated of which 270 thousand were HIV/AIDS co-infected (SANAC, 2016:10). Unfortunately only 318 193 TB cases were noted in 2014 (SANAC, 2016:10). Kwa-Zulu Natal, Eastern Cape and Western Cape are the three provinces that have the highest incidence rates for TB in SA (NDoH, 2015a:22). The cure rate is used as an indicator to monitor the success of the NTMG.

Globally the cure rate of pulmonary sputum positive TB is 84% whereas in Africa the cure rate ranges between 54%-74% (Castelnuovo, 2010:320). The cure rate of pulmonary sputum positive TB improved from 57.6% in 2005 to 75.8% in SA during 2012 (NDoH, 2015a:20; SANAC, 2016:10). The expected pulmonary sputum positive TB cure rate agreed by WHO is 85% and the NTMG desires at least 80%. However, according to the NDoH statistics, SA does not succeed in these objectives due to three provinces that fell behind, of which North West is one (NDoH, 2015a:22).

Despite the fact that pulmonary sputum positive TB is a preventable, treatable and curable disease the transmission rate, morbidity rate, defaulter (non-adherence) rate, drug resistant rate and mortality rate is distressing, especially for the victims of TB in SA (Naidoo *et al.* 2013:2; Tola *et al.* 2015b:1; WHO, 2015a:4-5). The consequences of non-adherence results in high rates of transmission, prolonged morbidity, higher costs for curing multi drug-resistance (MDR) and extensive drug-resistant (XDR) TB or mortality (NDoH, 2014a:78; NDoH, 2015a:2; Naidoo *et al.* 2013:2).

Yin *et al.* (2012:1) and NDoH highlights that combating non-adherence is fundamental to the successful treatment and curing of TB which will prevent the abovementioned consequences (Department of Health (DoH), 2014:10; NDoH, 2014a:78). A patient who disregards the guidelines of prescribed TB treatment is also known as a defaulter. A defaulter is a patient who interrupts treatment for two months or more, intentionally or unintentionally (NDoH, 2014a:36). Non-adherence can be directly measured by the TB "defaulter rate", which is a TB indicator when compiling statistics. The NTMG agreed upon a defaulter rate of less than 5%. Only Kwa-Zulu-Natal and Limpopo Province had grasped these goals in 2013. North West Province however has the third highest "defaulter rate" (7.5%) in SA.

Non-adherence is driven by various motives, but one heart-wrenching fact is that patients in developing countries with insufficient daily food supply do not adhere to TB treatment because the side-effects of TB drugs on an empty stomach are intolerable (Loveday & Vanleeuw, 2014:195; Smeltzer *et al.* 2010:567; Tola *et al.* 2015b:2). Non-adherence are further escalated by lack of transport, limited access to Primary Health Care (PHC) facilities and a lack of education regarding key health problems, which prevent patients from addressing their TB symptoms at a PHC level (Loveday & Vanleeuw, 2014:195; Smeltzer *et al.* 2010:567; Tola *et al.* 2015b:2). These compounding factors led the WHO to create a strategy to help patients on TB treatment.

The WHO employed a global strategy to address non-adherence to TB treatment regimes in the 1990's named Directly Observed Therapy (DOT) (Yin *et al.* 2012:1). Gebremariam *et al.* (2010:1-6) accentuates that DOT strictly requires objective daily monitoring of the intake of TB drugs, however health care resources are too limited to perform DOT. Thus the role was handed over to committed family members and/or friends. Unfortunately DOT may jeopardise the jobs of family or friends and burden the breadwinners (Gebremariam *et al.* 2010:1-6). Another study revealed that DOT, the availability of the correct treatment regimen and better-quality drugs did not improve the non-adherence rate (Castelnuovo, 2010:323). Podwills *et al.* (2016) investigated DOT as a strategy to decrease non-adherence but conclude that the TB Professional Nurse (TB PN) should use their statistics (surveillance) to identify factors that lead to non-adherence in order to enhance the PHC facility pulmonary sputum positive TB cure rate. The NTMG was written to assist TB PNs in managing non-adherence however low cure rates and high defaulter rates are still major problems. There is no golden standard scale available for measuring the factors influencing non-adherence to TB treatment (Kastien-Hilka *et al.* 2016:5; Lavsa *et al.* 2011:90). However Yin *et al.* (2012) developed a scale that explores the factors that specifically influence non-adherence to TB treatment. Yin *et al.* (2012) identified the main

factors measured by the TB Medication Adherence Scale (TBMAS) as: communication with the TB health care worker, personal traits of an individual patient, the confidence that the patient has regarding the curing of TB, social support available to the patient, mood disorders that the patient might suffer from, the living habits of the patient, active coping behaviour by the patient, forgetfulness and the access to health care that the patient has. These consequently lead to a holistic and individualised patient centred management intervention that proactively identifies non-adherence traits and possibilities (Yin *et al.* 2012:4).

The ideal location for the TBMAS is in North West (one of the worst performing provinces in SA) with Dr Kenneth Kaunda District (Dr KK district) that cured only 59.4% of pulmonary sputum positive TB cases in 2012 (10% less than the previous year) after being selected as a priority National Health Insurance (NHI) district (NDoH, 2015a:22).

Additional to the selection of a NHI priority district, a District Rapid Appraisal TB-tool (DRAT) was piloted in Dr KK district during 2014/15. The DRAT monitored TB outcomes and quality on sub-district level but was found impractical due to the high amount of resources that it demands in terms of finance, manpower and time (Loveday *et al.* 2007:12-13). Neither NHI nor DRAT contributed to improving the main concern of non-adherence to TB treatment as raised by the quality assurance manager (Motsamai, 2016).

Successful treatment-and-cure of pulmonary sputum positive TB is dependent on the effective management of non-adherence for the entire six months of treatment (Naidoo *et al.* 2013:2; NDoH, 2014a:41-51). No research was found regarding the factors contributing to non-adherence to TB treatment as measured by TBMAS in PHC facilities in SA. Based on the background provided, the following problem statement and research objective was formulated.

1.3 PROBLEM STATEMENT

Non-adherence to TB treatment gave rise to high defaulter (non-adherence) rates in the Tlokwe sub-district of Dr KK health district and contributed to the undesirably low cure rate among pulmonary sputum positive TB patients (Mofokeng, 2016; NDoH, 2015a:22). The management of non-adherence is essential to ensure a higher cure rate of at least 80% instead of the current 59.4%. The non-adherence rate should be below 5% but is currently at 7.5% (NDoH, 2015a:22), therefore the researcher proposed to use the TBMAS of Yin *et al.* (2012), to determine which factors contribute exclusively to non-adherence with TB treatment among pulmonary sputum positive TB patients in the Tlokwe sub-district.

1.3.1 Research question

Which factors, according to the TBMAS survey, contribute mostly to non-adherence to TB treatment among pulmonary sputum positive TB patients in the Tlokwe sub-district, North West Province of South Africa?

1.3.2 Research aim

The **research aim** is to derive meaningful suggestions from the TBMAS scales to address the unique factors that contribute to non-adherence to TB treatment to be considered for implementation to the Tlokwe sub-district in order to improve the TB cure rate.

1.3.3 Objective

From the research aim the following objectives are provided for the research study:

- To determine the unique factors that contribute mostly to non-adherence to TB treatment among pulmonary sputum positive TB patients according to the TBMAS survey in the Tlokwe sub-district of the North West Province of South Africa.

- After you determined these unique factors what now? What happened with your suggestions? There is more than one objective derived from the aim

1.4 RESEARCHER ASSUMPTIONS

In the following section the meta-theoretical assumption is declared as well as the theoretical departure point.

1.4.1 Meta-theoretical assumptions

Polit & Beck (2012:720) define assumptions as true principles based on logic without the need of proof. In this study the researcher will base her study on ontological assumptions. Polit & Beck (2014:7) and LoBiondo-Wood & Haber (2006:134) explain ontological assumptions as a real world that exists, the nature of reality together with the laws of nature. It is therefore understood as the inescapable and ultimate reality that we are all part of. Each discipline has a boundary for meta-theoretical assumptions and nursing use four (4) concepts over many years namely: human being / man, environment, nursing and health (Brockopp & Hastings-Tolsma, 2003:97).

- Humans

Human beings are unique with their own view and expectations of life. Some humans are influenced by the inheritance of their ancestors; others see themselves created by God and on earth for a specific time for a specific reason. Humans in this study are pulmonary sputum positive TB patients who individually have expectations for their own health and the TB PN. Their view regarding TB and the importance of adherence to TB treatment can have a negative or positive impact on the household, community and employment area where the TB patient stay and work. The TB PN has a commitment to ensure a healthy lifestyle in order to set an example for the community they are working in as well as to protect themselves from acquiring pulmonary sputum positive TB. The researcher believes furthermore that TB is a curable disease and if TB PNs provide detailed information during consultation to pulmonary sputum positive TB patients, it will enhance their understanding of the nature of the disease. TB is highly contagious and it is important to adhere to the taking of medication as prescribed, to adhere to follow up dates and to report side effects to the TB PNs. The condition can be cured within six months if the patient does not have resistance to any drug used in the treatment of TB.

- Health

Health refers to the harmony of the internal (the mind and soul) and external (physical, social and spiritual) environments. If these environments are not in harmony a person will be ill either mentally or physically. The communities the person interacts with can also be affected. Therefore, health changes in the internal and external environment of man can cause optimum or minimal health (Coetzee, 2010:15). In this study health refers to the health of pulmonary sputum positive TB patients and TB PNs. The TB patients' internal and external environment cannot be in harmony when they are suffering from TB and the contagious nature of the disease leads to the spread of pulmonary TB to others. The researcher also believes that optimum health can be attained through a well-balanced diet, at least eight hours sleep at night, healthy family relationships and friendships as well as emotional well-being, thus balancing the internal and external environments. It is essential for the TB PNs to ensure balancing of their internal and external environments for if they become ill, experienced TB PNs are lost and will leave a gap in the treatment of other TB patients as PNs are the backbone of the PHC level in South Africa.

- Nursing

A Professional nurse is a person who is registered with SANC in terms of section 31(1) (a) of the Nursing Act, 33 of 2005; who is qualified and competent to practice comprehensive nursing independently to the prescribed level and who is capable of assuming accountability for such practise. Nursing in this study refers to the management of pulmonary sputum positive TB patients in PHC facilities by TB PNs. These nurses are responsible for providing comprehensive care including treatment, management of side-effects, addressing psycho-social problems by referring to appropriate professionals in the multi-disciplinary team e.g. social worker or psychologist. Furthermore comprehensive nursing includes the education that the TB PNs should provide to their TB patients. With each visit at the PHC facility the TB PNs should enquire about any side-effects caused by TB drugs, problems with adherence and also do an assessment of the patients' emotional well-being. TB PNs should provide preventative interventions to the community, especially to the family of pulmonary sputum positive TB patients in order to reduce the spread of pulmonary sputum positive TB.

- Environment

Environment in this study refers to the PHC facility where the patient receives TB treatment, the consulting room of the TB PN and the atmosphere during consultation as well as the quality of service received at the PHC facility. The environment also includes the household, the community and the work environment of the TB patient and should as far as possible aid with the recovery process. These environments should be welcoming and safe for TB patients.

1.5. THEORETICAL DEPARTURE POINT

This study departs from a conceptual framework which was developed by the researcher as discussed below.

1.5.1. Conceptual framework

The framework of a study plays a very important role in the development of the research study (Burns & Grove, 2009:126). This study is based on a conceptual framework where the researcher develops the framework through identifying and defining concepts and proposing relationships between these concepts that assist in setting boundaries for the research. The conceptual framework (Brink *et al.* 2012:26; Kumar, 2014:57) is developed from concepts in the problem statement and background that will be used during this study. The conceptual framework explained that the focus of this study will be pulmonary sputum positive patients,

which either adhere or non-adhere to TB treatment received from TB PNs at PHC facilities in the Tlokwe sub-district. The classification of the non-adherent TB patient is explained as missed doses, defaulter and the consequences of developing Multi-drug resistant or Extreme drug resistant TB which contribute to a high morbidity rate. The other negative consequence is that it is highly contagious to close contacts (family members and patients with immune compromised diseases such as cancer) which lead to the diagnosis of new pulmonary sputum positive patients and contribute to an increase of pulmonary TB morbidity. Adherence to TB treatment by pulmonary sputum positive TB patients leads to an increase in the cure rate within six months of treatment and can contribute to reach the set target of 80%. The use of the TBMAS adherence survey aims to test whether TB patient's adherence can be influenced by certain factors. The conceptual framework is outlined in figure 1.1 below followed by a definition of the applicable concepts in Table 1.1.

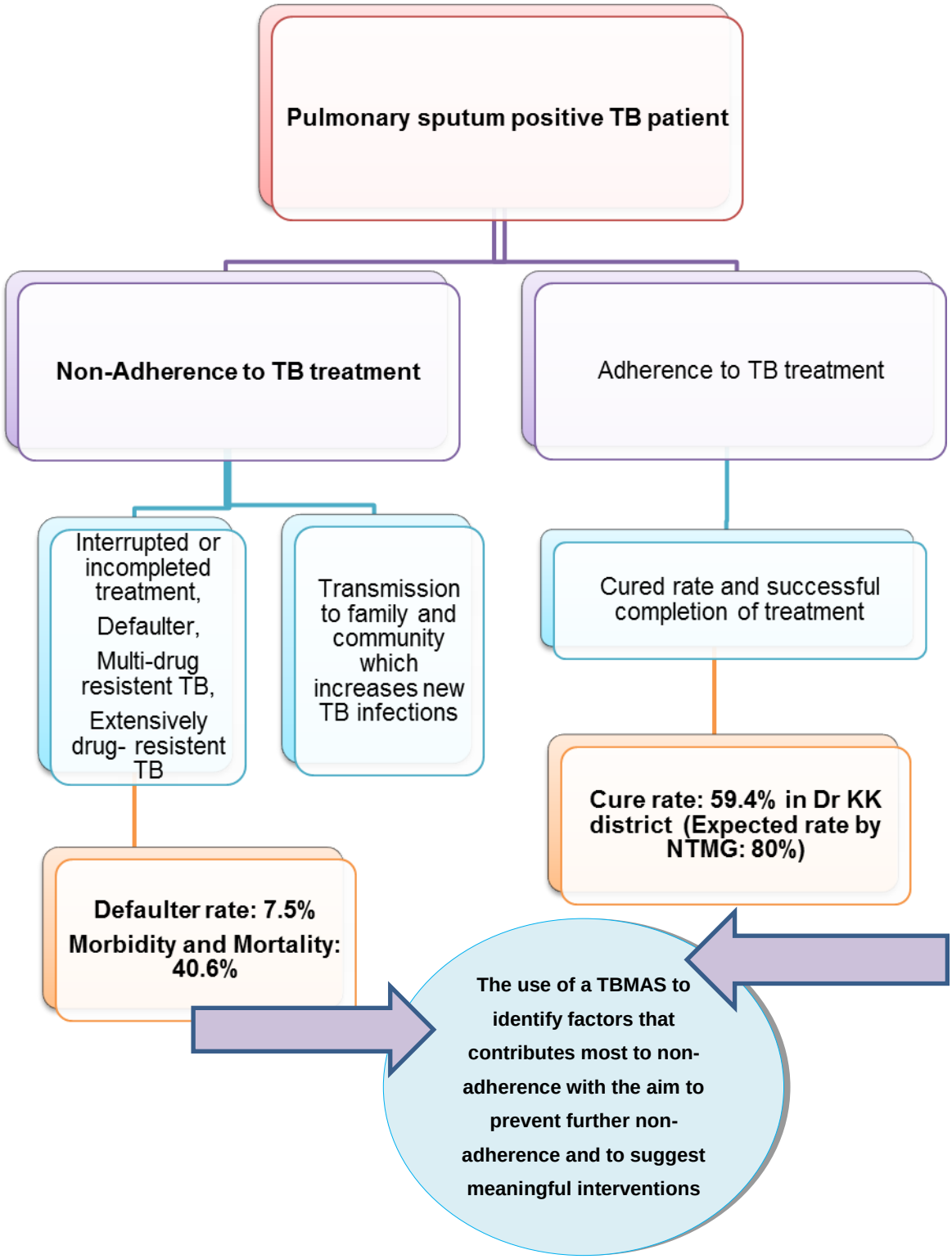

Figure 1.1: Conceptual framework for research study

A definition of key concepts is discussed in table 1.1 below.

Table 1.1: Key concepts applicable to study

TB	TB is a notifiable infection caused by *Mycobacterium tuberculosis* and primarily affects the lungs of humans but can also be found in other regions of the body (Brooker, 2010:796; NDoH, 2014a:8; NDoH, 2015a:6). In this research the focus is on pulmonary sputum positive TB patients due to the contagious nature thereof.
Non-adherence	Interruption or incomplete use of treatment; patient does not cooperate with the guidelines of treatment as explained by the TB PN (NDoH, 2014a:51; Tola *et al.* 2015b:2).
Defaulter	A patient who interrupts treatment for two months or longer (NDoH, 2014a:36).
Primary Health Care facilities	First level of health care service in a community where TB patients have access to a TB PN to render TB services and provide TB treatment to pulmonary sputum positive TB patients (Brooker, 2010:627).
TBMAS	An adherence scale that measures which factors contribute most to non-adherence to TB treatment (Yin *et al.* 2012:2).
Management	Management in the sub-district of PHC facilities refer to the effective and efficient organisation, accessibility and improvement of health care (Williams, 2014:41). Hattingh *et al.* (2012:174) defines management as the organisation but also as the coordination of activities, human resources and other resources according to policies for achieving objectives. In this context management refers to the effective and efficient organisation and coordination of TB objectives in accordance with the NTMG which in this case is mainly promoting adherence among pulmonary Xpert MTB/RIF sputum positive TB patients with the aim to improve TB outcomes.

Xpert MTB/RIF	The test that diagnoses pulmonary Xpert MTB/RIF sputum positivity of TB and simultaneously determines rifampicin sensitivity or resistance. The sputum is tested in a quality assured laboratory. A pulmonary sputum positive result indicates infection with TB – *Mycobacterium tuberculosis*. The approximate turnaround time is 48 hours before results are available to the TB PN to diagnose a patient and to immediately start treatment (NDoH, 2014a:22-32).
TB Professional Nurse	The TB PN is a qualified, registered, professional nurse according to the South African Nursing Councils' (SANC) regulation (SA, 2005:25) with the specific responsibility of co-ordinating and managing TB in a PHC facility. The TB PN provides TB patients with relevant TB information and a treatment plan as stipulated in the NTMG. The TB PN additionally clarifies instructions to a TB patient on how and when to self-administer treatment. If the TB PN suspects possible non-adherence in the future, the TB PN allocates a DOT supporter. A DOT supporter can be a friend, family member, employer or CHW. The TB PN corresponds with the DOT supporter regarding the patient's condition (possible side-effects of drugs or poor progress) and behaviour. This is especially helpful to the TB PN if the patient is unable to visit the PHC facility regularly. The TB PN also records all the data regarding the treatment plan in the patient's blue file, arranges tracing of contacts and defaulters, monitors side-effects of medication, arranges transfers and helps with appropriate appointments (NDoH, 2014a:59).

1.6. RESEARCH DESIGN

The research design is the tailored plan guiding the rigorous, ethical and scientific steps that the researcher will utilise to answer the research question. The design also supports the aim, objectives, data collection and data analysis process for the research study (Fouché *et al.* 2011a:142).

A quantitative, cross-sectional and descriptive design (Brink *et al.* 2012:112; Fouché *et al.* 2011:156; Maree & Pietersen, 2012a:152) will be applied using a survey to collect data that will

assist in describing the unique factors contributing mostly to non-adherence to TB treatment, in the Tlokwe sub-district (Yin *et al*. 2012). The final TBMAS validated by Yin *et al.* (2012:1) included in the survey are 30 items, scored on a 5-point Likert scale, and these items were loaded in nine (9) distinct factors that explained 65% of cumulative variance among respondents. Cronbach's alpha, the statistical component which tests the reliability of a survey, test-retest and split-half reliability were 0.87, 0.83 and 0.85 respectively. Thus the TBMAS survey is reliable to use and small adaptations were made to ensure applicability within the South African Context.

1.7. RESEARCH METHOD

The research method for this research study consists of a discussion regarding the population and sampling method, inclusion and exclusion criteria, data collection, data management, data analysis, reliability and validity (Klopper, 2008:69).

1.8. POPULATION AND SAMPLING

The **North West Province** is chosen purposely as it currently has the third highest defaulter rate (7.5%) in South Africa (NDoH, 2015a:20). The **Dr KK district** was purposively selected as the district that was labelled as one of the top three districts with the lowest ranking to reach the expected cure rate for pulmonary sputum positive TB in SA (see Background for statistics).

The Tlokwe sub-district is **purposely** selected as the outcomes according to the DRAT monitoring and the current statistics stated in the background was undesirable. The quality assurance manager assessed the TB indicators with the DRAT tool in the Tlokwe sub-district in 2015 and requested the researcher to conduct this study as it could identify the factors that contribute most to the non-adherence in the Tlokwe sub-district.

An **all-inclusive** selection **of PHC facilities** (N=9 & n=9). in the Tlokwe sub-district was chosen for the purpose of this study (Brink *et al.* 2012:134; De Vos *et al*. 2011:226) to ensure that the study represents the whole sub-district's pulmonary sputum positive TB patients.

The sampling method for selecting participants was **purposive sampling** (Brink *et al.* 2012:140). The researcher purposively chose all patients diagnosed with pulmonary sputum positive TB and that visited the PHC facility during the period of recruitment and data collection. Participants' inclusion and exclusion criteria follow in the next two paragraphs.

The **inclusion criteria** for this study are:

- All patients diagnosed with pulmonary sputum positive TB at any of the purposely chosen PHC facilities in the Tlokwe sub-district as this directly links with the research question. Although this does not mean that any patients will be required to disclose any other disease for the purpose of this study, such as HIV/AIDS, patients must not bear more than their fair share of burden during participation, thus no information were ask about HIV/AIDS. This is directly linked to the principle of distributive justice and respect (DoH, 2015:20);
- At any time period of treatment because TB treatment consist of two phases, the intensive phase which is the first two or three months of treatment and the continuation phase which followed after the patient sputum convert to negative with a Xpert test. The continuation phase is usually 4 months (NTMG, 2014).
- Patients who are willing to participate voluntarily and who sign the informed consent forms. The informed consent and inclusion criteria allow for self-determination and autonomy of participants (protect them from research they do not truly understand) before they participate and again affirmed on day of data collection (ongoing consent process) (DoH, 2015:16-20).
- Patients diagnosed by Xpert MTB/RIF test (pulmonary sputum positive TB) as these are the infectious patients.
- Patients 18 years and older as they are adults and need no parental permission.

The **exclusion criteria** (Brink *et al.* 2012:313) for this study are:

- Patients who are diagnosed with TB other than pulmonary sputum positive TB, such as TB in other organ systems (see section 1.11.1.2 Distributive justice and fairness) (DoH, 2015:16-20; NDoH, 2014a:13).
- Patients younger than 18 years of age

1.9. DATA COLLECTION

Data collection consists of the following sub-sections: the role of the researcher in recruitment of participants, the setting where the research will take place in, the data collection method and data collection survey. For a detailed discussion about recruitment of participants see Chapter 3, section 3.2.2.3.

1.9.1. Role of researcher in the recruitment of participants

The researcher involved the TB PN in each PHC facility to act as a gatekeeper. The gatekeeper was the facilitator between the researcher and the patient for the aim of this study.

The researcher equipped the gatekeepers with the needed information regarding the research aims and objectives of the study, the inclusion and exclusion criteria, the advertisement (see Addendum D: Advertisement) and how to explain the informed consent form (see Addendum A: Informed consent form). This assisted the gatekeeper in providing potential participants with an explanation of relevant information regarding the study (all patients diagnosed with pulmonary sputum positive TB). The gatekeepers provided the advertisement and an informed consent form inside the patient's booklet before leaving the consultation room to avoid questions, discrimination or stigma during PHC facility visits and to ensure respectful treatment among all patients (DoH, 2015:15).

Gatekeepers knew that there were no requirement to disclose HIV/AIDS status as this is irrelevant to the aim and objective for this study. It was unnecessary to exceed the fair share of harm and violation of the principles of justice and respect because disclosure was prohibited in this study.

1.9.2. Setting

The PHC facility changed to an appointment system for every service to reduce long waiting times which was very inconvenient for patients. This change assisted the researcher in planning a schedule. The space or room for data collection was private to ensure confidentiality during data collection. The researcher prevented stigmatisation by not receiving the patient in the TB consultation room (DoH, 2015:15). The TB PN sends the participants one by one to the researcher's space or room after their TB consultation was completed.

1.9.3. Data collection

The TBMAS survey was used for data collection. This survey was validated by Yin *et al.* (2012) (see Addendum B: Cover letter and survey). This survey was developed to determine contributory factors to non-adherence. The survey did not measure non-adherence as such, as the researcher used the TB register to determine whether the participant was adherent or not. The participant was classified as non-adherent when the TB record revealed days where the patient did not drink the TB medication or did not report at the PHC facility for an appointment. A detailed discussion of the TBMAS instrument follows in chapter 3.

1.9.4. Data management

Data was managed sensitively, privately, confidentially and anonymously to protect all participants including the PHC facilities (DoH, 2015:14). The **informed consent forms** (see Addendum A: Informed consent form) and surveys (see Addendum B: Cover letter and survey) were coded with numbers assigned to each PHC facility and participant. The researcher developed a record and wrote down each participant name next to a number and this number was written on the TBMAS survey as well as the number allocated to the PHC facility. These records will be available in a locked cupboard in the supervisor's office for audit purposes. No personal information regarding the participants and PHC facilities were divulged during data collection or revealed in the research study, research report or any journal article.

1.9.5. Data analysis

Descriptive statistics (Brink *et al.* 2012:179; Fouché & Bartley, 2011b:251) was used to describe the research findings of this study. Data analysis and results are described in Chapter 4. Cronbach's alpha coefficients were calculated to assure reliability of factors (constructs) measured in this study. The data analysis for this study was done under the supervision of a statistician from the North-West University consultation services to ensure **accuracy, correctness and precision** (DoH, 2015:14).

1.10. RIGOUR

Rigour in quantitative research refers to the truthfulness of the research outcomes achieved through maintenance of discipline, detail and accuracy (researcher completed the surveys on behalf of illiterate participants) throughout the research process (Brink *et al.* 2012:97). The researcher ensured that the outcomes of this study are valid by using an appropriate, rigorous, scientific and ethically approved research process (Botma *et al.* 2010:174). The same principles were applied in collection, analysis and reporting of data results. The statistical consultation services at the North-West University (NWU), Potchefstroom Campus assisted in minimising any threats to validity. External validity (Polit & Beck, 2004:201; Welman *et al.* 2005:125) was not achieved as the representative sample size of 80 surveys, which was calculated with the assistance of the statistician, were not obtained. However the statistician was satisfied that the time the researcher spend in the research field was long enough to ensure prolonged engagement as the participant took full time leave to conduct data analysis. Every possible opportunity within ethical boundaries was utilised to reach the available study population of 63 (n=63) for this study (see Addendum C: Statistical consultation).

1.11. ETHICAL CONSIDERATIONS

According to the DoH Research Ethical Guidelines (2015:3), ethical consideration in research is essential to ensure the research is conducted responsibly and ethically. The researcher considered these guidelines thoroughly and outlined the application thereof in the paragraphs below.

South Africa is a democratic country and this implies that no research is allowed without informed consent from any participant (DoH, 2015:6). The ethical guidelines followed by the researcher, holds in high regard, health care ethics in the health care environment where patients are involved and prioritise their interests, welfare and safety. This study relies on anonymous information about patients and thus underwent a formal ethics review.

1.11.1. Ethical principles

1.11.1.1. Beneficence versus harm

This study aimed to increase its benefits so that it will outweigh the risk of harm by using a rigorous research design; sound methodology and competent supervision (DoH, 2015:14) (see Chapter 3, sections 3.3.1, 3.2 & 3.3, Chapter 1, section 1.12.8).

1.11.1.2. Distributive justice and fairness

Patients did not bear more than a fair share of the burden of risk during participation. This is directly linked to the principle of distributive justice (DoH, 2015:20). This study did not place any undue burden on any population in Tlokwe sub-district and denied no one access to the information or benefits that the study's findings will produce. The researcher ensured this by disseminating honest and truthful (DoH, 2015:14) findings, results and suggestions derived from the study.

Dissemination was directed to participants and all other stakeholders. Dissemination of findings to participants was done by closed envelope containing a pamphlet reporting the findings and a health education leaflet advising patients on: how to prevent transmission of TB, how to improve adherence and what the consequences of non-adherence are. The researcher telephonically informed all participants that the CHW conducting home visits in their area will deliver it to their houses in a closed envelope after signing a confidentiality agreement. The PDoH, Dr KK district and the Tlokwe sub-district will be informed regarding the research results

and findings through a research report and peers will be informed through the publication of a peer reviewed article (Botma *et al.* 2010:6-27; Brink *et al.* 2012:42; Strydom, 2012:115-123).

1.11.1.3. Respect of human rights, autonomy and self-determination

The researcher ensured respect, autonomy and self-determination through excluding participants that were incapable of making choices such as under aged, intellectually disabled patients. Unnecessary participants were excluded as every participant's inclusion is justified based on fairness, scientific relevance and avoidance of unnecessary harm. The participants in this study were already vulnerable and adding the under aged and the intellectually disabled would have increased unnecessary exposure to additional harm (see Chapter 3, section 3.4.2 with motivation). The researcher also ensured this principle by a unique designed Informed consent form for use in this study. The Informed consent form (see Addendum A: Informed consent form) was designed to be understood by grade four level readers and explained to them in their home language by the gatekeeper to ensure the participant understood and was able to make an informed decision, to ensure self-determination and autonomy before signing for participation (DoH, 2015:15).

1.12. ETHICAL NORMS AND STANDARDS OF THE STUDY

1.12.1. Relevance and value

The relevance, study aim and objectives (DoH, 2015:15) of this study is well motivated in the background and problem statement (see Background and section 1). Despite many studies globally on TB medication adherence, the cure rate of pulmonary sputum positive TB is still between 54 – 74%. The value of this research is to identify unique factors that contribute to non-adherence in the Tlokwe sub-district. The study is clinically significant and limited to a sub-district area. If the research results identify specific factors leading to non-adherence, the cure rate of the sub-district can be improved by addressing those inherent factors.

1.12.2. Scientific integrity

The scientific integrity is built into the study's design and methodology (DoH, 2015:15) which are well reasoned to ensure results that answer the research question and aim of the study. (See Chapter 3 section 3.3 for detail).

1.12.3. Role player engagement

All key role players (permission of HREC, DoH, Dr KK district and Tlokwe sub-district, operational managers, gatekeepers, researcher and translators) that contributed to this study were identified and their involvement is crucial to ensure rigor of this study. The expertise of this study depended on the role of the gatekeeper, participants, translator, researcher and supervisor of this study (DoH, 2015:15).

1.12.4. Balance of risk benefit ratio

A risk is defined as the possibility of harm that can occur when a participant completes the survey in order to participate in the research (DoH, 2015:6). The estimated **risk level** for this study is **a medium,** as emotional discomfort may be caused during the disclosure of TB and possible HIV/AIDS status. Confession of non-adherence augments the risk of vulnerability of the participant. Please Note that HIV/AIDS status is not a requirement for participation of this study as this is irrelevant to this study and is firmly indicated in the informed consent form. The researcher prevented unnecessary disclosure of HIV/AIDS status (DoH, 2015:6-14). However, the knowledge gained by this study compensates for the risk of emotional harm that this study may hold when disclosing of TB or HIV/AIDS status and possible non-adherent behaviour. The researcher ensured that if **debriefing** is necessary, that it was handled **immediately** by a trained psychiatric nurse on duty at the PHC facility as arranged beforehand. Some **TB patients can be physically weak which contributes to vulnerability** and cannot wait in the clinic for a long time. Therefore data was collected directly after TB consultation with TB PN (DoH, 2015:14).

The intention of the study was not to deceive or coerce vulnerable members of society or any volunteers into participating but rather to ensure that justice and benefits are optimally received by participants to overrule the risks in the study. The researcher's intention is to help TB patients and not to harm them as TB is a national concern and mostly affects the poor. The researcher strived to protect the patients from any harm or discomfort in this study as far as possible (Botma *et al.* 2010:8; DoH, 2015:14-15). Deception toward participants was avoided by explaining truthfully to the participant that the aim of the study is to determine which factors contribute mostly to non-adherence to TB treatment among pulmonary sputum positive TB patients in the Tlokwe sub-district (De Vos *et al.* 2011:118).

Benefits for participation include:

There was no direct benefit for TB participants in this research. However their contribution can assist the sub-district to focus on those unique factors to improve the cure rate of pulmonary sputum positive TB patients. Thus their contribution can be seen as an indirect benefit. Other indirect benefits included:

- Remuneration for voluntary participation was ensured by providing refreshments and taxi fees after completion of TBMAS;
- Participants also received an educational leaflet about tuberculosis as a benefit (DoH, 2015:14-16-22).

1.12.5. Fair selection of participants

The selection of participants are justified and motivated in Chapter 3, section 3.4.2. Furthermore no discrimination was applied during selection of participants (DoH, 2015:16).

1.12.6. Informed consent

The Informed consent form briefed participants that they may volunteer and withdraw freely from the study without fear of reprisal or prejudice. **Voluntary** participation in this study was ensured through an advertisement and explanation provided by the gatekeeper or researcher (see Addendum D: Advertisement, Chapter 3, section 3.4.2 for detail (DoH, 2015:16).

1.12.7. Respect, privacy, anonymity and confidentiality

The respect, privacy, anonymity and confidentiality (DoH, 2015:17) applied in this study is discussed throughout but more specifically in Chapter 3, section 3.4.3. The researcher ensured **privacy** by handling the participant discretely at the PHC facility as discussed under data collection. **Confidentiality and anonymity** was ensured by coding TBMAS's and all hard copies were locked within a cupboard (DoH, 2015:14-17).

All members of the research team that require access to data is also required to sign a **confidentiality agreement** (researcher, translator and the statistician). The researcher at no time interfered with the way TB services were rendered at any PHC facility (DoH, 2015:14).

1.12.8. Competence and expertise of researcher

The supervisor of this study is experienced with successfully supervising Master students conducting quantitative research since 2010. The supervisor has taken part in a large,

international, five (5) year, research programme in 2009, dealing with quantitative and qualitative methods and attended a research internship in Kenya offered by the Canadian Institute for Health Research. The supervisor's area of expertise is Primary Health Care with sound knowledge and experience in tuberculosis. The researcher has experience working as a TB PN for the last year full time and has been keeping up to date with new developments in the field.

The Curriculum Vitae of the supervisor and researcher are included for HREC as proof of competence in the field of research and knowledge about TB. The researcher and supervisor are both knowledgeable with regard to TB services and have experience with the cultural background of the Setswana people in the Tlokwe sub-district (DoH, 2015:16).

1.13 PROPOSED STUDY LAYOUT

Chapter 1: Outline of the study

Chapter 2: Literature review

Chapter 3: Methodology

Chapter 4: Data collection and analysis

Chapter 5: Summary and suggestions to improve non-adherence, identification of gaps for further research and limitation of study.

1.14 SUMMARY

Chapter 1 introduced tuberculosis as a worldwide concern, which contributes to morbidity and mortality. Non-adherence to treatment regime is an identified topic of interest which requires attention with regards to effective management to cure TB, prevent interruption of treatment and decrease morbidity and mortality caused by TB. The proposed method to identify the factors contributing to non-adherence is utilising a validated TBMAS followed by a discussion of the research method. The researcher explained how ethical standards during the research will be ensured.

CHAPTER 2

LITERATURE REVIEW

2.1. INTRODUCTION

Adherence to medication is a big problem worldwide and causes increased costs, morbidity and mortality. For effectiveness of medication it is needed for adherence by taking treatment the prescribed way, collecting treatment in time, be present for all appointments, completing treatment for the prescribed period as well as taking every dose (Bazargan *et al.* 2017:2).

The literature review (Brink *et al.* 2012:70; Creswell, 2014:28; Kumar 2014:48) will embark from the method of search used to obtain peer reviewed scientific evidence regarding non-adherence to tuberculosis (TB) treatment. The most recent strategies of the WHO and the Sustainable Development Goals (SDG) post 2015, explains the overview of the international and national landscape of TB. Thereafter the landscape regarding the current management system of TB in SA will follow. The National and Provincial level of TB service delivery in SA is defined by the National TB Management Guidelines (NTMG), South African National Aids Council (SANAC), National strategic plan (NSP), National Health Act no. 61 of 2003 and the National Health Laboratory Service (NHLS). The management at District and sub-district level regarding TB service is discussed where after the management of TB at PHC facility level follows. The literature review further designates the existing literature regarding factors influencing non-adherence with TB treatment. The factors discussed correlates with the TB Medication Adherence Scale (TBMAS) which will be used to collect data in this study.

2.2. METHOD OF SEARCH

The researcher utilised the online Library guide of the North-West University's data bases and search engines (Ebsco-Host, Science Direct, and Advanced Google Scholar) to collect relevant, recent, accurate and reliable peer reviewed articles. The key words used to trace relevant articles were:

Tuberculosis or TB; TB treatment adher*/non-adher*/non-comply*/comply*; default*; interrup*; adher* scale; manag*; influence*, impact*; factor*; Primary Health Care/PHC Facilit*; pulmonary-, Xpert-, TB; sputum positive TB; outcome*; professional nurs*

All relevant articles were saved to the researcher's tablet, personal computer and memory stick. Some articles were printed and reflective notes were made to summarise important material. The guidelines and protocols formulated by the DoH originated from the Google Scholar search as it is government publications and widely available. Articles, national and international TB guidelines, reports regarding TB performance and new plans were opened to reveal headings and contents that helped with elimination of irrelevant articles. Irrelevant articles are regarded

as out-dated (older than eight years), irrelevant to the topic, suspicious of scientific and ethical nature or that are not available in English or Afrikaans. The researcher pursued the most recent and relevant material possible through the abovementioned, trusted databases and SA government publications. The researcher was able to obtain a great quantity of relevant, quality literature that was published after 2010. A few articles and government publications are matured, but when relevant matured articles were essential it was not completely eliminated. Although matured literature is used those studies delivered quality and worthy research findings that contribute and support this study's scientific grounds.

The following section draws the international and national TB landscape regarding the post 2015 WHO strategy and SDG's.

2.3. THE INTERNATIONAL AND NATIONAL TUBERCULOSIS LANDSCAPE

The international and national TB landscape consists of the roles and plans of the World Health Organisation (WHO) and the Sustainable Development Goals (SDG). The WHO and SDG have developed targets post 2015 regarding the global fight against the TB epidemic.

2.3.1 World Health Organisation (WHO)

The WHO is an agency in Geneva, Switzerland that provides leadership, monitoring and reporting of progress on health issues globally. The WHO is strongly involved with TB "prevention, care and control" (WHO, 2015b:1; WHO, 2015c:1). The core TB functions involve global leadership and monitoring of the international progress of TB. The WHO reports on global progress regarding TB outcomes and TB notification rates. The WHO also regularly develops updated, evidence based policies and guidelines to improve management of TB worldwide. Additional to the major contributions that the WHO makes regarding TB in the world, WHO also takes responsibility for supporting member countries, dissemination of research findings and engages in TB partnerships to facilitate National TB Programmes (NTP) (WHO, 2015a:xi-1; WHO, 2015b:1; WHO, 2015c:1). It is crucial that all member countries abide with the guiding principles of the WHO to achieve a world free of TB (WHO, 2015c:1). However the specific requirements among developed, developing and under developed countries differ, thus every country integrates the WHO guidelines into their specific NTP to suit the context of their country accordingly (Stakeholder Forum, 2015:2).

Once the Stop TB strategy was reinforced the WHO activated the End TB strategy in 2014 to prevent, care and control TB from 2015. The End TB strategy strives to end the TB epidemic by 2035 (Day & Grey, 2015:16; WHO, 2015a: x, 6-7; WHO & European Respiratory Society (ERS),

2015:20). Furthermore the aim is to achieve “a world free from TB” by eliminating all deaths and suffering related to TB illness (WHO, 2015a:7). The End TB strategy consists of three main pillars that work interchangeably (WHO, 2015a:7; WHO, 2015b:1; WHO & ERS, 2015:2).

Pillar 1: Integrated patient centred TB care and prevention

Integrated patient centred TB care and prevention is part of the strategy that focusses on early diagnosis and detection of TB and drug-resistant (DR) TB; strictly organised screening of TB contacts (family, friends, co-workers, health care workers (HCW) and high risk groups (HIV/AIDS, Diabetes, children under five, mine workers, smokers, communities living in poverty) (WHO, 2015b:2; WHO & ERS, 2015:2). The following listed key points summarise the strategy of pillar one.

- Treatment of all TB and DR TB as well as supporting patients
- Joint management referred to as integrated care of TB, HIV and other co-morbidities
- Preventative and proactive care such as vaccination against TB especially for new borns; Isoniasid Preventative Therapy (IPT) especially for highly exposed TB contacts and HIV diagnosed patients (WHO, 2015b:2; WHO & ERS, 2015:2).

Pillar 2: Bold policies and supportive systems for TB care and prevention

- Resource based support from government and political stakeholders are basic to ensure that health care services have available resources ready to prevent as well as identify cases as early as posible and manage TB effective and adequate in order to prevent new cases
- Collaboration of the community, public members and private sectors are cardinal to maintain the End TB strategy’s policies and support system
- Respect for worldwide health exposure policies are required by means of regulating notifications and registration frameworks, accurately administrating TB drugs and sustaining infection control
- Protect society, relieve poverty and manage causes of TB are indispensable (transmission, poverty, poor health care systems) (WHO, 2015b:2; WHO & ERS 2015:2).

Pillar 3: Intensified research and innovation to promote TB care and prevention

- Promotion of tools, interventions and strategies to manage the TB epidemic rapidly
- Implement reconstructed interventions and strategies (WHO, 2015b:2; WHO & ERS, 2015:2).

2.3.2. Principles of the interwoven TB pillars:

- Liability of government to monitor and evaluate TB care and prevention truthfully and honorably
- Strengthened partnership among the community and organisations available to civilians
- Protection and improvement of human and ethical rights and equality regarding TB care among the community
- Amendment of targets and strategies that establish partnerships nationally and internationally (WHO, 2015b:2; WHO & ERS, 2015:2).

Coordination of the three pillars and principles are pre-requisite to seal the “End TB” strategy by 2035 (WHO, 2015b:2; WHO & ERS, 2015:2). See figure one for interweaved blueprint of the End TB strategy, the researcher also added a cloud indicating how the strategy compliments the “ending” of non-adherence.

The Director of the Global TB Programme states: “Digital health will be critical in helping us reach our new global targets to the TB epidemic” Mario Raviglione (WHO & ERS, 2015:i). He further says that technology is a necessity and will assist in the management and prevention of TB if digital health is adapted (WHO, 2015a: x). The End TB strategy therefore introduces the ground-breaking digital health approach: information and communication technologies (Electronic- (eHealth) and Mobile health (mHealth)) that are more efficient and sustainable measures for management, treatment and prevention of TB. The digital health approach suggests the potential advancement of the Directly Observed Therapy (DOT) patient care strategy to eDOT or Video Observed Therapy (VOT) through mobile smart phones or Short Message Sending (SMS) usage for appointment reminders. The digital health approach is incorporated in the End TB strategy and its pillars (Chen *et al.* 2015:29; Liu *et al*. 2015:1; WHO & ERS, 2015:3). The following paragraphs and figure one indicates the three pillars of the End TB strategy and the principles that guide it.

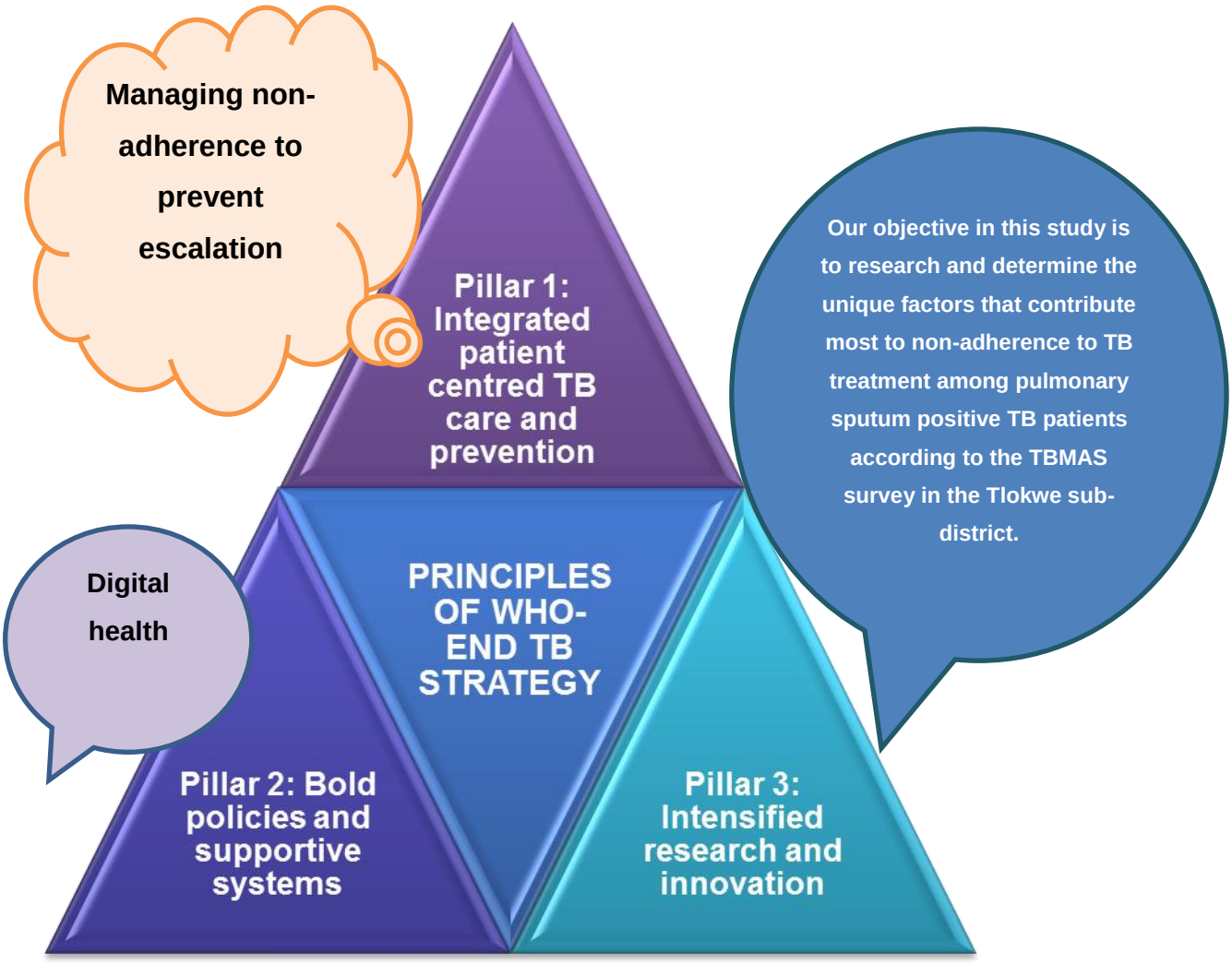

Figure 2.1: Interwoven relation between management of non-adherence and how this study contributes to these principles in the End TB strategy (WHO, 2015b:2; WHO & ERS, 2015:2).

2.3.3. Sustainable Development Goals (SDG)

The SDG is the state-of-the-art transcription of the Millennium Development Goals (MDG) entrenched in 2000. The millennium development goals stipulated important and effective standards to improve social circumstances and fights against global poverty, hunger, disease and other factors. The MDG stipulated eight goals to improve these circumstances (Sachs, 2012:1). However SA did not master the MDG target number six C regarding the reduction of TB related mortality. The global target was to reduce TB related deaths with 50% and SA had only reduced deaths by six% between 1999 and 2013 (Day & Grey, 2015:198).

The SDG aims to reform the global impression of social, economic and well-being components in developed and developing countries by 2030. The third SDG specifically focusses on “healthy lives and promotion of well-being for all at all ages” (Day & Grey, 2015:199). SDG number three reinforces the WHO’s aspiration to end TB by 2035 through global affiliation, searching for new vaccines and medicines for communicable diseases, such as TB eminently in developing countries (Day & Grey, 2015:199; Stakeholder Forum, 2015:13; United Nations, 2015:14). The SDG’s intent TB purpose is to end the epidemic by 2030 explicitly with zero new TB cases by providing medication and vaccines for TB. The current TB vaccine named Bacillus Calmette-Guerin (BCG) only protects one against TB meningitis and disseminated TB and is developed to protect children and not adults (NDoH, 2014a:9).

Another desire is to achieve quality health care service delivery in developing countries through universal health coverage (Day & Grey, 2015:198). The commitment of the SDG’s and WHO are in parallel to support one another (WHO, 2015b:2).

The following section provides the order in which TB is managed sequentially from national-, provincial-, district- and sub-district level in SA and results in a discussion of the facility level of TB management and service delivery which is the actual focus of this study.

2.4. NATIONAL AND PROVINCIAL LEVEL TUBERCULOSIS SERVICE DELIVERY SOUTH AFRICA

SA manages the TB epidemic from the national level by conforming to the National TB Management Guidelines (NTMG) invested by the Department of Health (DoH). The DoH is in collaboration with instructions of WHO, SDG, South African National Aids Council (SANAC), National Strategic Plan (NSP), the National Health Act no. 61 of 2003 and the National Health Laboratory Service (NHLS) (NDoH, 2014a:4).

2.4.1. National Tuberculosis Management Guidelines (NTMG)

The NTMG’s are constructed to practically manage and eradicate the TB epidemic in SA. The Director General for Health and the Minister of Health underlined a few aspects. Transmission of TB should be reduced, rapid detection of TB, prompt initiation of TB treatment, maintain patients’ adherence to TB treatment for an entire six to nine months to safeguard successful treatment without non-adherence and cure of TB, and to prevent people living with HIV/AIDS (PLW HIV/AIDS) from assimilating TB (NDoH, 2014a:3-4). The Minister of Health further stipulates that it is pivotal to successfully cure TB by eradicating non-adherence. The NTMG also portrays and directs health care workers on how to prohibit non-adherence with TB

treatment (NDoH, 2014a:51). The NTMG states that the following factors influence treatment outcomes:

Figure / Table 2.1 National TB Management Guideline factors influencing drug adherence (NDoH, 2014a:51)

Social and Economic Factors • Extreme poverty • Poor support networks • Unstable living circumstances • Substance abuse • Beliefs about TB and its treatment	**Health System Factors** • Poor health infrastructure • Poorly trained or supervised health care personnel • Low levels of accountability of health staff • Poor relationships with patients • Inadequate development of community based support for patients
Patient related factors • Stigma • Depression • Disempowerment • Poor knowledge about TB and the efficacy of treatment	**Therapy related factors** • Complex treatment regimens • Large pill burden • Adverse effects of medication • Long treatment duration.

The DoH continues to pursue a high cure rate in TB management by delegating National Tuberculosis Management Guidelines (NTMG) to the South African National Aids Council (SANAC).

2.4.2. South African National Aids Council (SANAC)

SANAC is a legal body empowered by the DoH to command objectives that manage (monitor and evaluate) main communicable programs such as HIV/AIDS, TB and Sexually Transmitted Deceases and develops SA policies and guidelines for these priority programs (NDoH, 2014b:6). SANAC also aims to combat violation of human rights, discrimination and stigma against HIV/AIDS, TB and STI (Sexually Transmitted Infections) (SANAC, 2016:12). Therefore SANAC developed the NSP, monitors, evaluates and reports on national performance regarding mentioned epidemics (NDoH, 2014b:30-38; NDoH, 2015a:62; SANAC, 2014: i-xiii). This authority enables SANAC to provide policies and guidelines to improve the performance which puts SA in line with the set targets as stated by WHO (Day & Grey, 2015:231; NDoH, 2015a:8-9; SANAC, 2016:iii,18). This is also stated in the national strategic plan which is discussed in the next section.

2.4.3. National strategic plan (NSP) regarding HIV/AIDS, TB and STIs 2014-2019

The NSP's plan for HIV/AIDS, TB and STI of 2014 – 2019 focuses greatly on prevention. All guidelines are developed under the supervisory capacity of SANAC as delegated by the Minister of Health. These conditions (HIV/AIDS, TB and STI's) often present as co-morbidities, especially with HIV/AIDS. While NTMG ensures policy development, research, innovation and programme implementation, the NSP incorporates international and regional obligations, commitments and targets regarding HIV/AIDS, TB and STI's as well as governmental development plans such as SANAC. SANAC revises all strategies five yearly accordingly to ensure that all strategies are aligned with the WHO as well as UNAIDS and that suggested plans can be followed through within the South African context (NDoH, 2014b:26; NDoH, 2015a:8; SANAC, 2014: xiii; SANAC, 2016:1).

SANAC's aims related to TB are to reduce TB infections, TB mortality and TB related stigma by 50% (NDoH, 2015a:30; SANAC, 2016:1; SANAC, 2014:xiii). The vision specifies "four zeros": zero new HIV or TB deaths, zero transmission, zero preventable deaths and zero discrimination toward HIV and TB (NDoH, 2014b:26; NDoH, 2015a:30; SANAC, 2016:1).

SANAC reports that TB continues to increase in SA according to the statistics of WHO, however they estimate slow progress by NSP toward the 50% reduction of TB related new infections and deaths. The TB registers further estimate a reduction in TB incidence and mortality corresponding with the increased number of HIV/AIDS patients on ART. TB fatality rate is estimated at an 8.4% according to the TB registers. SANAC believes there is much more to be done to reduce the rising incidence and mortality in TB when viewing the estimates by WHO, SA TB register and Stats SA (SANAC, 2014: xxii).

The objectives are to improve the integration with relevant inter-sectorial services and to address the social determinants of health; to improve access to community PHC facilities and quality services at PHC facilities (SANAC, 2016:1).

2.4.4. National Health Act (61 of 2003) and notification of TB as communicable disease

TB is a notifiable disease under the National Health Act (61 of 2003) (Mets *et al.* 2011:212) within seven days (Redelinghuys & Van Rensburg, 2010:252; South Africa, 2008:50). Under circumstances where a patient is unwilling to cooperate with treatment the state may follow action. Previously there has been a high court order by the Minister of Health to isolate and treat patients against their will until they were no longer infectious to the community. Four patients

had extensive drug resistant TB in the Western Cape under the following conditions (South Africa, 2013:28):

- It is a hazardous disease or health risk to the public (Ebola or drug-resistant TB)
- isolation and treatment without force is attempted first
- forceful isolation is the most justified manner to prevent spread of the disease
- it is highly likely that the disease will spread without intervention (South Africa, 2013:28).

2.4.5 National Health Laboratory Service (NHLS)

The NHLS is the public health laboratory and serves 80% of the population (NHLS, 2015:ii). The NHLS delivers valuable and sound service with regard to TB diagnosis in South Africa. The extensive availability of NHLS' GeneXpert testing assists tremendously in the rapid diagnoses of pulmonary sputum positive TB and susceptibility of rifampicin, one of the core drugs used to treat TB (NDoH, 2014b:5-11; NHLS, 2015:ii). There are 300 GeneXpert machines available which tested 1.2 million people during the 2013/14 period and achieved above target of 800 000 (SANAC, 2016:10). The GeneXpert is the WHO's preferred and recommended test for diagnosing pulmonary sputum positive TB and the possibility of MDR TB (Ardizzoni *et al.* 2015:1; Churchyard *et al.* 2014:245).

The NHLS' has an impressive turnaround time (TAT) of 48 hours for GeneXpert which determines diagnosis of pulmonary sputum positive TB and susceptibility to rifampicin simultaneously. NHLS collects GeneXpert samples at least once daily from PHC facilities and results are readily available to PHC facilities the following day. Access to results can be retrieved online or by SMS printers in the PHC facility if hard copies have not been delivered yet (NDoH, 2014b:5-11; NHLS, 2015: ii).

This section compiled a perspective landscape regarding the national level of TB management. The mediators between the national level and district/sub-district level are discussed in the following section and communicate regarding TB indicators.

2.5. DISTRICT/SUB-DISTRICT LEVEL TB SERVICE DELIVERY

The district and sub-district collaborators are mainly the Communicable disease coordinator (CDC) and data-capturer and they are chaperoned by the NTMG. They act as the team players that aid correspondence between the national and district/sub-district level and PHC facilities.

The NTMG are managed at district/sub-district level through the electronic TB register (ETR.net) tool which also analyses and validates the captured data. The ETR.net captures indicators electronically regarding registered TB patients, sputum conversion, treatment outcomes and facility profiles. The data is electronically transferred from sub-district to district level and then to Provincial level. At provincial level in-depth analysis is done prior to dispatch to the National level. Occasionally data is discharged to the district health information system (DHIS) which is regarded district/sub-district level (NDoH, 2014a:85-86).

Quarterly reports are communicated among district/sub-district level and provincial level regarding: the number of TB patients registered, sputum conversion rates, treatment outcomes for new and retreatment pulmonary sputum positive TB and all other types of TB patients, HIV indicators and management programme performance (in narrative form) (NDoH, 2014a:86).

The CDC and sub-district data-capturer/health information officer are responsible to ensure that the TB Register sheets (explained under facility level, next section) are collected in the first week of the new month. The sub-district data-capturer is responsible to ensure that all outstanding and new data is captured by the second week of the month. The CDC and sub-district data-capturer is responsible to ensure that the data is captured correctly and sent to District level. All districts' data-capturers and CDC's need to send TB data to Provincial level in the third week of the month, who in return sends it to National authorities (NDoH, 2014a:86).

2.5.1. Communicable disease coordinator (CDC)

The CDC's are responsible for updating PHC facilities with regard to new policies and guidelines like protocols for managing communicable diseases. The CDC is also responsible for investigating notified communicable diseases, to co-ordinate relevant and fast response to outbreaks as well as to prevent further outbreaks of the disease. TB and malaria are high priority communicable disease programs. The CDC needs sound knowledge of such programmes to conduct inspections and evaluation. The CDC also provides feedback to the TB Professional Nurse regarding the PHC facility's performance and supports adherence and monitoring of these programmes (Ethekwini Municipality, 2013:1).

In case of planned campaigns the CDC manages and coordinates events and ensures all points have enough equipment and resources. The CDC also ensures adequate training to staff involved in campaigns by arranging qualified volunteers and ensures valid statistical feedback of these campaigns. The CDC develops proactive strategies to manage contact with communicable diseases during campaigns (Ethekwini Municipality, 2013:1).

The CDC serves the PHC facility with updated guidance and advice from National authorities which are discussed in the next section.

2.6. PRIMARY HEALTH CARE FACILITY LEVEL: TB SERVICE DELIVERY

The PHC facility is an established public health care service and the location where first level of health care is rendered to pulmonary sputum positive TB and other patients (Van Rensburg, 2010:414-416). The PHC facility provides all necessary medication readily for the whole course of treatment to pulmonary sputum positive TB patients at no cost. After receiving medication the TB PN ticks off the amount of dosages given on a calendar-like format until the next visit. This also makes it easy to identify when patients are missing dosages as there is a universal calendar with the entire TB patient's data. Thus when a patient does not return on the date he/she should have, then the TB PN can start tracing the patient.

The tools used in the NTMG at PHC facility level are the TB identification and Follow-Up Register (GW 20/13), the National Health Laboratory (NHLS) Laboratory request form for sputum investigation, the blue clinic book (GW 201/12) that consists of essential patient information, green treatment card (GW 20/15), TB register (GW 20/11), Transfer form (GW 20/14) if a TB patient is transferred from one PHC facility to another PHC facility or hospital, TB symptom screening tool, Notifiable Medical Conditions Form and a TB daily diary.

At facility level a Cascade analysis is also conducted monthly to monitor and evaluate the performance of the facility in accordance with the NTMG. The Cascade analysis uses the following indicators: total PHC head count, number of patients screened for TB symptoms, number of patients found to have TB symptoms, number of patients with TB symptoms tested for TB, number of patients tested positive for TB and the number started on TB treatment.

After the Cascade analysis a cohort analysis is conducted to measure the amount of TB patients that have completed intensive phase (first two months) of treatment and the successful completion of the entire course of TB treatment (NDoH, 2014a:83-84).

The TB register (GW 20/11) is completed at facility level by using the information in the blue patient file (GW 201/12) and the green TB treatment card (GW 20/15) on a daily basis. After accurate completion of the TB register, the pink, yellow and green sheets are sent to the sub-district office for data capturing (leaving the blue sheet in the clinic) and for sending to district and provincial level for capturing and evaluation (NDoH, 2014a:86; Van Rensburg, 2010:414-427). The operational manager (OM) is the middle man responsible to ensure that data is

captured and sent timeously on requested dates between the PHC facility and to the sub-district CDC.

2.6.1. Operational manager (OM)

The OM is the highest level of authority in the PHC facility and all other staff answers to him/her, including the TB PN. The function of the OM is to provide the best possible care to patients while managing and organising the PHC facility regardless of the available resources and staff availability.

The OM is responsible to research and improve strategies that improve quality care of patients. The OM teaches, guides, leads and encourages staff to improve quality patient care by example, knowledge, experience, feedback about PHC facility performance, identification of gaps and to highlight good performance to enhance moral of staff (Meyer *et al.* 2014:6).

The OM is further also responsible for managing work and leave schedules; to assign patient care methods, supervision and delegation of staff; is accountable for legal and ethical issues in the PHC facility; has the responsibility to ensure that the work gets done; manage staff conflict; effective time management and ensures that all staff participate in decision making (Meyer *et al.* 2014:215-241). The TB PN is the mediator between the OM and the TB patient in the PHC facility.

2.6.2. TB Professional Nurse (TB PN)

The TB PN is the authorised TB “manager” in the PHC facility. The TB PN is responsible for managing TB patients according to the NTMG, under the supervision of the OM. The TB PN informs the patient after diagnosis with the necessary information regarding caption of TB, spread of TB and treatment course curing TB. The TB PN also explains the essence of treatment adherence and discusses the regime of treatment with the patient to enhance compliance and full cooperation. The TB PN informs the patient about the importance of contact identification and tracking. The patient’s close contacts are also screened and information is recorded in the patients blue file (GW 20/12). The TB PN is responsible for completing an assessment regarding symptoms of TB patients and contacts, investigation of contacts, risk assessment for co-morbidities and environmental assessments of living circumstances (NDoH, 2014a:38-39). The TB PN is the closest form of health authority that the TB patient has and thus advocates for the patient and acts as the channel between the multi-disciplinary team when needed (such as doctor, psychologist). The TB PN has the most influence due to the one-on-

one sessions during treatment and thus the TB PN plays a significant role in prevention of non-adherence.

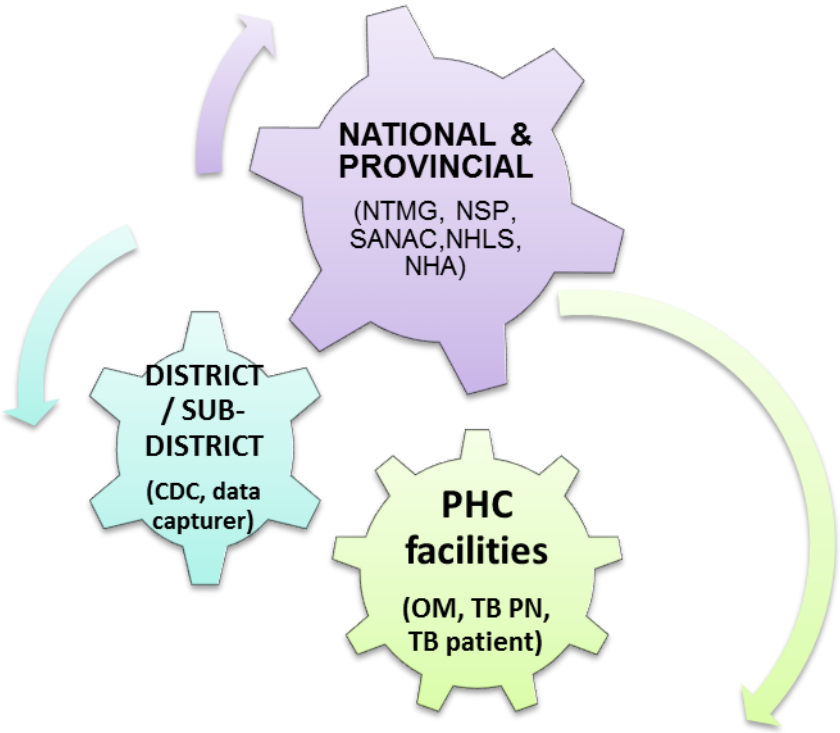

Figure 2.2: South African TB management landscape

The following section describes the factors influencing non-adherence among TB patients according to the TBMAS and it brings to light how important treatment adherence is to ensure pulmonary sputum positive TB are cured within 6 months.

2.7. FACTORS INFLUENCING NON-ADHERENCE WITH TB TREATMENT INTERRELATED WITH THE CONSTRUCTS OF THE TBMAS

The impact of non-adherence is emphasised in chapter one and the consequences are reinforced repetitively: development of MDR and XDR, prolonging morbidity, transmission of TB to loved ones and even death (Gebremariam *et al.* 2010:1-6). The TBMAS measures the level of agreement to statements according to certain factors e.g. the relationship with the health care worker. This section discusses the literature related to the factors measured by the TBMAS. The factors measured by the TBMAS are discussed in depth addressing nine constructs regarding: communication between the TB patient and the TB PN, personality traits-, confidence to cure TB-, social support -, possible mood disorders-, living habits-, the active coping behaviour-, forgetfulness- and the access to health care by the pulmonary sputum positive TB

patient. These factors are measured with the TBMAS by the researcher in the data collection phase and analysed during the data analysis phase (Chapter 4).

2.7.1. Communication between the TB patient and the TB Professional Nurse

Communication in this study refers to the physical communication between the TB PN and TB patient. This communication takes place in the PHC facility during consultation. The TB PN needs to discuss certain factors with each patient.

The factors that need to be discussed include the attitude of the TB PN towards the patient, whether the TB PN has described and explained the TB condition clearly. The questionnaire further measures whether the TB PN has described the method of taking medicine clearly, were side-effects discussed and did the TB PN lead the patient to believe that TB can be cured. These factors will be referred to as health education in this study.

According to Ibrahim *et al.* (2014:2), Oluwafunmilayo *et al.* (2017:265) and Zolnierek and DiMatteo, (2009:826) the attitude of the health care worker has an essential impact on the adherence of TB patients to TB treatment. A systematic review conducted by Van Hoorn *et al.* (2016:13) and additional literature concluded that effective communication (health education) had a positive effect on adherence, patient satisfaction and TB outcomes (Gebremariam *et al.* 2010:1-6; Jin *et al.* 2015:277; Nezenega *et al* 2013:1; Peltzer & Pengpid, 2015:26; Tola, *et al.* 2016:11; Tola, *et al.* 2015b:6; United States, 2014:13).

Additionally various authors revealed study results that indicate poor communication with TB PN's as experienced by patients and led to a high tendency of non-adherent behaviour. Unfortunately the communication with the TB PN in SA is poor which hampers a positive relationship according to Gebremariam *et al.* (2010:1-6).

Communication is such an important aspect in managing non-adherence that it evolved into expanded digital methods (eHealth and mHealth) for communication to continue during difficult circumstances. For detail on digital communication methods see (section 3.2.1). Various studies have explored the involvement and effect of electronic methods to facilitate communication between the TB PN and TB patient such as SMS's and video calls. Digital communication has proven to reduce the need for DOT and has improved adherence among TB patients (Chen *et al.* 2015:29; Liu *et al*. 2015:1; WHO & ERS, 2015:i).

2.7.2. Personality traits

A personality trait is a personal characteristic distinct to a person that is inherited or developed. It is the description of an individual's behaviour and personality (Brooker, 2010:785). In this study personal traits can manifest as patients who are neat and clean, strict to follow their plan, often seek the most effective way in doing things, one who often sets clear targets, organised and systematic to reach goals

Patients, who are unorganised and negligent in nature, tend to neglect their TB treatment and hence need strict support because they tend to default (Hipra *et al.* 2013:1; Kastien-Hilka *et al*. 2016:5). Thus it is important to identify possible negligent or forgetful behaviour so that proactive interventions could be arranged for such patients for example directly observed treatment (DOT) by a family member. Personal traits of negligent or forgetful patients often include substance abuse which hinders adherence (Craig *et al*. 2007:422; Kastien-Hilka *et al*. 2016:5). Negligence and substance abuse are often associated with prolonged treatment, drug resistance and missed appointments. Craig *et al*. 2007 and Hipra *et al.* 2013:1 suggest that these patients need more assistance in the treatment programme.

2.7.3. Confidence in curing TB

Confidence in curing TB in this study refers to the confidence that a patient has to completely cure TB, believing that his/her regimen in simple, feeling very confident in taking medication for an entire six months and feeling confident to tolerate side-effects.

The confidence of a patient to complete TB treatment has shown to play a great role in adherence. When a patient is not entirely confident about the complex series of events ahead, they tend to discontinue TB drugs prematurely. Patients especially tend to abandon TB drugs untimely (before six months are over) due to the pleasant experience of recovery (Ade *et al.* 2016:4; Tola, *et al.* 2015b:4; Tola, *et al.* 2016:11) which is associated with occurrence of non-adherence and treatment interruptions (Ade *et al.* 2016:4; Corless *et al.* 2007:1110; Kastien-Hilka *et al.* 2016:6; Tola *et al.* 2015b:6).

Oluwafunmilayo *et al.* (2017:266) also revealed in the study that patients who believed that the medication could cure TB adhered because they believed in their treatment. The confidence to cure TB is influenced by the understanding of TB regimens and how effective treatment is. When patients are knowledgeable and prepared for the burden they tend to be more confident in curing their TB (Tola *et al.* 2015b:4; Tola *et al.* 2016:11).

Ingersoll and Cohen, (2008) and Sawkin *et al.* (2015:3) found that when the regimen requires many daily dosages and is complex, patients also tended to be less adherent to treatment (Miller & DiMatteo, 2013:422).

Oluwafunmilayo *et al.* (2017:266) also discusses the factor of side-effects that influence adherence and believes that pre-medication counselling is necessary to help prevent patients from leaving their medication due to side effects. Side-effects had a negative impact on adherence and some patients completely end their treatment due to side-effects (Miller & DiMatteo, 2013:422; Oluwafunmilayo *et al.* 2017:266).

2.7.4. Social support

Social support is described as assistance received by others excluding health care workers. This network includes family, friends and co-workers (Corless *et al.* 2007:1108). Social support in this study refers to the satisfaction a patient has with the support between his/her family members, family members that remind them to take their medication, friends that remind them to do things and help from people around him/her.

A lack in social support could be recognised by homeless civilians, substance abusers and individuals who have no friends or family to remind or encourage them to take treatment. The absence of social support has been found to be associated with high levels of non-adherence (Craig *et al.* 2007:419-423; Kastien-Hilka *et al.* 2016:6). WHO says to manage non-adherence social support is essential (Van Hoorn *et al.* 2016:2; Tola *et al.* 2015b:6; WHO, 2015b:11).

Social support played a big role in adherence to treatment. Patients reported in Oluwafunmilayos' *et al.* (2017:265) study that family, friends and health care worker attitudes helped them with adherence. Scheurer *et al.* (2012:461) found that the most consistent type of support that was associated with adherence was "practical social support". Scheurer *et al.* (2012:461) further states that close family and friends are the best way of supporting patients with adherence to medication.

A lack of social support is one of the many reasons for defaulting treatment (Miller & DiMatteo, 2013:423).

2.7.5. Mood disorders

Mood disorders in this study refers to patients who sometimes feel depressed, feel frustrated and feel like giving up when they have done something wrong and who sometimes feel helpless and want help from others.

Kastien-Hilka *et al.* (2016) established in a systematic review that TB has a negative impact on a patient's mental health and can increase psychological distress. Psychological distress or mood disorders are possibly the result of facing a life threatening disease (Louwagie *et al*. 2014:501).The psychological distress associated with TB is well studied, but counselling in SA PHC facilities is not routinely carried out prior to TB treatment (Theron *et al.* 2015:2). Kastien-Hilka *et al.* (2016), Theron *et al.* (2015) and Tola *et al.* (2015a) studied the association of non-adherence with psychological distress related to TB in SA and the mood disorders most frequently reported were depression and/or anxiety. These authors discovered a high association with psychological distress and TB that resulted in higher non-adherent behaviour with TB treatment (Kastien-Hilka *et al.* 2016:4 Theron *et al.* 2015:1; Tola *et al.* 2015a:1; Tola *et al.* 2016:11). Psychological distress is not only neglected by the TB PN's but also by the DOT programme. Psychological distress is the greatest contributor of prolonged morbidity and causes higher chances of non-adherence. Studies were done and it was found that these results are consistent and may be due to memory and decisional impediment when patients become helpless and decide to give up their TB treatment (Tola *et al.* 2016:11).

2.7.6. Living habits

Living habits in this study refers to sleeping and waking regularly every day and having regular meals every day. Living habits are influenced by factors such as poverty (Kastien-Hilka *et al.* 2016:6), poor living circumstances (Tola *et al.* 2016:11), and substance abuse (Craig *et al*. 2007:422). This sub-category has been well explained in chapter one while explaining the general associated social circumstances of most TB patients and explains the favourable circumstances of transmission (See Chapter 1: Background). Patients who have regular meals on daily basis tend to be more adherent because they can tolerate side-effects better (Jin *et al*. 2016:278). Patients who don't have regular meals due to poverty tend to be non-adherent (Oluwafunmilayo *et al.* 2017:265).

2.7.7. Active coping behaviour

Active coping behaviour in this study refers to a patient's active involvement in pursuing knowledge on TB like asking the health care workers regarding their condition once they knew they were infected. (Tola *et al.* 2015b:4). Literature reveals that coping behaviour is the way in which a patient handles the stress (Corless *et al*. 2007:1108) of having a life-threatening illness. Behavioural factors leading to non-adherence are described as fear of stigma (Kastien-Hilka *et al.* 2016:6; Tola *et al.* 2016:11), feeling better after some time on treatment, or when abuse of

tobacco, alcohol or substance is prominent resulting in a careless attitude regarding their condition (Peltzer & Pengpid, 2015:26; Tola *et al.* 2015b:6).

Oluwafunmilayo *et al.* (2017:266) found that patients with a higher literacy level had a better understanding of the disease and it impacted on how they adhered to TB treatment. Once a patient seeks more information on TB they understood better and they tended to adhere better as well.

2.7.8. Forgetfulness

Forgetfulness in this study refers to forgetting to do important things that were planned to be done and whether a patient regards his/her memory as good. Forgetfulness is a patient related factor influencing non-adherence (Jin *et al.* 2016:278; Kastien-Hilka *et al.* 2016:5; Hipra *et al.* 2013:5). Regular meals act as a reminder to patients to take their tablets which assist adherence (Jin *et al*. 2016:278). According to Tola *et al.* (2016) forgetfulness can also be triggered by psychological distress when patients become hopeless.

2.7.9. Access to health care

Access to health care in this study refers to whether it is convenient to refill TB medicine and whether the PHC facility meets the need of a patient. Travelling long distances, lack of transport money can make appointments inconvenient (Ade *et al.* 2016:4; Corless *et al*. 2007:1110; Kastien-Hilka *et al.* 2016:6; Tola *et al.* 2015b:6; Tola *et al.* 2016:11). In cases where patients were referred from district hospitals to community PHC facilities patients defaulted in reaching the PHC facility that they were referred to. This could indicate poor communication between health care facilities. Patients feel inconvenienced when acquiring their treatment because the health care system has failed to transfer their medication (Jacobson *et al*. 2015:7-8).

2.8. SUMMARY

The second chapter introduced the literature used to form this study starting with the method of search. It described how scientific literature was obtained regarding non-adherence with tuberculosis (TB) treatment. The TB landscape is pictured as it is managed in SA and the collaborators to the TB management discussed. The researcher then explained the chain of command from top level management namely national to the lowest level of TB management namely the PHC facility and how things go about in each level. Finally the role of the TB PN was described as well as the contributing factors to non-adherence to treatment in TB patients. The

above mentioned factors are measured by the TBMAS and will be analysed accordingly in Chapter 4. In chapter 3 the methodology will be discussed.

CHAPTER 3

RESEARCH DESIGN AND RESEARCH METHODS

3.1 INTRODUCTION

In the previous chapter a literature review was conducted and the current TB landscape, nationally and internationally, was outlined. The factors contributing towards TB non-adherence according the TBMAS survey was discussed as well. Chapter 3 discusses the research methodology with reference to the research design and methods used to conduct the study regarding "factors influencing non-adherence with TB treatment in a sub-district in North West Province". The core design and research methods are outlined in Chapter 1. However, in this chapter a detailed discussion is portrayed. The research design, research question, population, sampling, inclusion and exclusion criteria, data collection, data analysis and results are captured in this chapter. The first section starts by verifying the choice of the chosen research design.

3.2 METHODOLOGICAL ASSUMPTIONS

Methodology is the science of determining the procedures for scientific investigation (Babbie, 2010:4). The methodological assumptions give direction to the methods within the study and are the logical application of scientific methods to the investigation of phenomena (Mouton & Marais, 1996:16). Methodological assumptions have their origin in science-philosophy and direct the research design as the researcher decides what the most suitable design is to address the research question (Klopper, 2008:67).

The researcher used ontology as a methodological assumption as it allowed formulation of a patterned set of assumptions about reality by utilising the TBMAS survey and non-adherence rate to formulate suggestions about factors that contribute mostly towards TB non-adherence in the Tlokwe sub-district.

3.3. METHODOLOGY

The research methodology refers to the research design chosen in order to answer the research question (Grey *et al*. 2017:683; Wood & Ross-Kerr, 2011:114-115). The research design is outlined in the paragraphs below.

3.3.1 Research design

The choice of a design was already made when the research question was formulated. This study uses a quantitative, cross-sectional and descriptive design which is described below.

3.3.1.1 Quantitative design

A quantitative approach in research uses methods that collect data systematically and objectively. In this study a survey was used to collect data systematically and was then analysed numerically. Quantitative research is used to describe and test relationships or to examine the cause and effect of relationships between variables. This data are then used to answer the research question with analysed statistical findings. Quantitative research is known for its predictability and stability. By controlling external influence the researcher minimises bias, but it is impossible to prevent all external influences. The main focus of a quantitative researcher is to produce reliable and valid results that can be generalised to a whole population (Borbasi & Jackson, 2016:105; Topping, 2015:163). The quantitative design aims to quantify a large amount of data, it is objective, rigid toward valid and reliable findings, it measures or classifies variables, it communicates data analytically and aims to generalise its findings (Kumar 2014:14). In this study the researcher used a survey to collect data and the numerical data are analysed in Chapter 4, from section 4.2.2. – 4.9. This data was used to generalise the entire Tlokwe sub-district's pulmonary sputum positive TB patients.

3.3.1.2 Cross-sectional design

A cross sectional design collects data once and the results are based on real time and not the past or future (Wood & Ross-Kerr, 2011:118). The data collected (with the survey) enables the researcher to associate certain characteristics with adherence or non-adherence. A cross-sectional design allows data collection once and in this study data was obtained from pulmonary sputum positive TB patients. A cross sectional design is similar to a Polaroid picture, the picture captured characteristics associated with adherence or non-adherence with one shot (Borbasi & Jackson, 2016:107; Burns & Grove, 2005:236; Goddard & Melville, 2013:39; Parahoo, 2006:469; Polit & Beck, 2014:162).

3.3.1.3 Simple descriptive design

Descriptive designs describe the analysed data in words or pictures or tables (Wood & Ross-Kerr, 2011:115). According to Gray *et al.* (2017:676) a descriptive design is developed with the intention to provide information about the prevalence of a variable or its characteristics in a data set, such as percentages, means and standard deviations. The purpose is to present findings on the current situation in the practical reality. Surveys are often used in descriptive designs (Borbasi & Jackson, 2016:108; Brink *et al.* 2012:113; Burns & Grove, 2005:233). During data analysis the statistical and descriptive relationships are described to answer the research

question (Wood & Ross-Kerr, 2011:115). In this study the researcher will answer the research question by describing the factors that contribute most to non-adherence in patients with pulmonary sputum positive TB in the Tlokwe sub-district.

3.4. RESEARCH METHODS

The research method is chosen to answer the research question. The steps followed to answer the research question are detailed below. Research methods for this study includes a discussion regarding the population and sampling methods, inclusion and exclusion criteria, data collection survey, data collection and analysis, data management, and reliability and validity.

3.4.1 Population and sampling

The target population is the amount of people that are theoretically available and to who the study population will be generalised (Wood & Ross-Kerr, 2011:152). Involving an entire population is not always feasible and thus sampling is done. Sampling allows the researcher to select a statistically representative sample of the population with regard to time and resources but also allows for generalisation (Burns & Grove, 2005:33; Polit & Beck, 2014:178). In the following paragraphs the researcher motivates why this research was done in North West Province, in the Dr KK district and why Tlokwe sub-district was selected for the research. The motivation of the study population as the focus of this research follows after Tlokwe sub-district motivation.

The **North West Province** is chosen purposely as it currently has the third highest defaulter rate (7.5%) in South Africa (NDoH, 2015a:20). The purpose of selecting **Dr KK district** was that the district was labelled as one of the top three districts regarding non-performance to the expected cure rate for pulmonary sputum positive TB in SA (see Chapter 1, section 1.1.).

The North West Province consist of four Districts namely: Ngaka Modiri Molema District (north), Bojanala-Platinum District (east), Dr Ruth Segomotsi Mopati District (west) and Dr KK District (south) (Dr KK District Municipality, 2011:6-15; North West Dr KK District Profile 2016:3). Figure 3.1 below provides an overview of all the districts of the North West Province.

Figure 3.1: Map of North West Province

The Dr KK district is divided in four sub-districts namely Matlosana, Tlokwe, Ventersdorp and Maquassi Hills sub-districts. Most of the population resides in the Matlosana and Tlokwe sub-districts which are both urban. The remaining population is rural however all four of the sub-districts are mining zones (Dr KK District Municipality, 2011:6-15; North West Dr KK district profile, 2016:3). See figure 3.2 above for the map of the Dr KK district's sub-district division. This study was conducted in the Tlokwe sub-district. **The Tlokwe sub-district** was deliberately selected as the outcomes according to the District Rapid Appraisal TB-tool (DRAT) monitoring and the current statistics stated in the background were undesirable. The quality assurance manager assessed the TB indicators with the DRAT tool in the Tlokwe sub-district in 2015 and requested the researcher to conduct this study as it could identify the factors that contribute most to the non-adherence in the Tlokwe sub-district (see Chapter 1: section 1.2).

Figure 3.2: Map of Dr KK districts' sub-district division

The Tlokwe sub-district consists of nine Primary Health Care (PHC) facilities namely:

- Mohadin Clinic
- Steve Tshwete Clinic
- Promosa Community Health Care Center (CHC)
- Lesego Clinic
- Top City PHC
- Boiki-Tlhapi CHC
- Boskop Health Clinic
- Potchefstroom Clinic
- Potchefstroom Gateway Clinic

An all-inclusive selection of PHC facilities in the Tlokwe sub-district was chosen for the purpose of this study (Brink *et al.* 2012:134; De Vos *et al*. 2011:226) to ensure that the study represents the whole sub-district's pulmonary sputum positive TB patients. All PHC facilities equal nine (N=9 & n=9).

The population refers to all people in the selected research area that meets the inclusion criteria of the study (Borbasi & Jackson, 2016:121; Polit & Beck, 2014:178; Wood & Ross-Kerr, 2011:152). The type of sampling used in this study is non-probable sampling which is unusual for a quantitative study but due to the essential information that the specific patients can provided, the researcher purposely chose the participants as they could provide the relevant data necessary for this research (Borbasi & Jackson, 2016:123; Hunt & Lathlean, 2015:174; Polit & Beck, 2014:168). The sample requires data from pulmonary sputum positive TB patients and they are not common to the whole population (Wood & Ross-Kerr, 2011:114) thus the sample was chosen purposively.

The sampling method for selecting participants was **purposive sampling** (Brink *et al.* 2012:140). In other words the researcher purposively chose all patients diagnosed with pulmonary sputum positive TB who visited the PHC facilities in the data collection period. The inclusion and exclusion criteria were discussed in Chapter 1, section 1.8.

Before the research study could be conducted an appointment was made with the statistical consultation services of the North-West University. During the consultation session with the statistician the research question and objective against the background were evaluated and it was determined whether the research question could be answered with the suggested survey in conjunction with the TB register to determine non-adherence. The statistician assisted the researcher with minor adjustments, allowed by the developers of the survey, in order to ensure that the survey can be used within the South African context. The statistician calculated the required number of surveys that were necessary to complete according to the number of constructs and items in the survey to ensure validity and reliability of the study. The minimum required number of completed surveys was calculated to be n=80. The statistical consultation services provided the researcher with a confirmation letter of approval to proceed, which she attached as an addendum for ethics approval from the Health Science Research Ethics committee (HREC), (see Addendum C: Statistical consultation services).

3.4.2 Recruitment of participants

After conceptualisation and approval by the Health Research Ethics Committee (HREC) the researcher presented the research by means of a PowerPoint presentation at the North West Province DoH, Dr KK Health District management committee because the sub-district managers are part of this committee. After approval was granted by the Provincial Department of Health (PDoH), Dr KK district and Tlokwe sub-district managers, the researcher pursued goodwill permission from all operational managers (OM) at the nine PHC facilities. Thereafter the TB

PN's/CHW were approached for recruitment to act as gatekeepers during this research study. The recruitment and consent of the TB PN's/community health workers (CHW) to participate as gatekeepers were crucial to the success of this study.

Gatekeepers were trained to assist in recruitment of participants because they have access to TB files and will know the pulmonary sputum positive TB patients. The gatekeepers' (who were Setswana speaking and able to translate the advertisement and informed consent form) role were to provide information to the participants about the research study, to give them an advertisement as well as explaining and providing them with informed consent forms (See Addendum's A and D).

Once participants were certain of participation they signed the informed consent with two witnesses and were informed on the advertisement to send a short message service (SMS) or please call me to the researcher. The cell number was provided on each advertisement (See addendum D). The researcher phoned each interested participant and made arrangements regarding an appointment date and time when the participant visit the PHC facility for a TB follow up visit. The phone communication additionally assisted in excluding problems such as loss of income due to participation. Participants who were employed had the option of participating at a 24 hour open PHC facility of their choice.

Another role of the researcher was the recruitment of translators from English to Setswana for cases that need translation during the completion of the TBMAS. The translators were (was) arranged to be available on the data collection date at the PHC facility if they were needed for data collection. The researcher also requested the service of the psychiatric nurse in each PHC facility to assist in cases where emotional discomfort was experienced on completion of TBMAS. Each PHC facility had a psychiatric nurse available and the researcher referred any patient with emotional discomfort to him/her immediately. Once all logistics were in order, data collection commenced.

3.4.3 TBMAS as data collection survey

Surveys are most common in survey research. A survey allows the researcher to collect data according to a standard procedure and to make inferences with the sample population. Surveys have a list of statements which can be positive or negative for the participant to answer and have form of a scale that is used to measure the variables (Alford, 2014:155). The TBMAS was developed in China and validated there by Yin *et al.* 2012. Surveys generally have a scale to

measure the value of a variable. Scales assign numerical values to responses (Borbasi & Jackson, 2016:125; Hickman & Disler, 2016:127).

The TBMAS has been standardised and underwent rigorous psychometric analysis to ensure its reliability and validity (Jones & Rattray, 2015:414; Yin *et al.* 2012:2). The TBMAS Cronbach's Alpha was averaged 0.87 (including all the factor scores) when Yin *et al.* (2012) conducted validation of this scale. The content validity is supported by the statistical significant correlations found between the TBMAS nine factors measured by instrument and the non-adherence ratio of the TB patient as found in pharmacy records of TB patients (Yin *et al.* 2012:3). It should be noted clearly that the TBMAS on its own do not measure adherence as such but the factors that mainly contribute to non-adherence. Patients were classified as non-adherence and correlations were done to determine which of the factors contribute most to non-adherence.

Using a survey has its advantages and disadvantages. See table 1 below for the latter.

Table 3.1: Advantages and disadvantages of a SURVEY/TBMAS

ADVANTAGES	DISADVANTAGES
• Self-administered surveys have low cost and are economical for data collection purposes (Alford, 2014:155; Hickman & Disler, 2016:125) • Surveys allow respondents to ask questions during completion of the questionnaire which improves completion and contributes to the reliability of answers (Alford, 2014:155) • Questionnaires are easy to administer and if literacy level of respondents are taken in consideration e.g. in case of a low literate population a graphic scale assisted instead of a numeric scale and a trained researcher was present to assist respondents in completion of the scale which increased the reliability	• It is unlikely that the researcher will reach a large area unless electronic surveys are used (Alford, 2014:155) • Questionnaires are unable to measure change (Hasson *et al.* 2015:256) • Respondents could respond in a way that they believe the researcher wants them to respond (Hasson *et al.* 2015:256) • Trained interviewer needed if the study population is for instance totally illiterate or the study population is part of a high risk group e.g. HIV/AIDS patients (Maree & Pietersen, 2012:158) • High risk of bias by the interviewer (Maree & Pietersen, 2012:158)

ADVANTAGES	DISADVANTAGES
(Hickman & Disler, 2016:125; Hasson *et al.* 2015:256) • A widely distributed sample could be included with the questionnaire, in this study pulmonary sputum positive TB patients were in different stages of treatment could easily be included in the study population (Hickman & Disler, 2016:125) • Anonymity was assured by allocating a numerical value to questionnaires instead of names immediately after completion of the survey (Hickman & Disler, 2016:125) • Questionnaires have the ability to describe the study population with only one contact session (Hasson *et al.* 2015:256) • High response rates can be achieved if study population agrees to complete it voluntary, depending on time available to complete the survey and user friendliness (Maree & Pietersen, 2012:158) • Respondents do not need to be literate to complete the survey if a trained facilitator is present to answer questions for respondents (Maree & Pietersen, 2012:158)	

3.4.4. ***Data Collection***

Data collection involves interaction with participants during the completion of surveys. The choice of a survey as data collection tool was chosen during the proposal stage of the study. The researcher collected data with the TBMAS (see Addendum B) and afterwards uses the TB blue file to determine adherent status in the different PHC facilities in the Tlokwe sub-district during September and October 2017. The TBMAS had a graphic-Likert combination scale that also assisted in simplifying the completion of the TBMAS. The TBMAS identified the possible reasons and personality traits which correlate with non-adherent behaviour. There were 63 surveys completed, thus the study population consist of 63 respondents.

Data was also collected for the sake of identifying participants who are adherent and non-adherent as mentioned in the blue TB file of the patient. The TB register validated the information identified in the blue TB file. The universal TB register was used and compared to individual TB blue patient files to ensure accuracy. The universal TB register points out where dosages have been missed by a TB patient. The patients who have missed medication dosages or follow up dates were regarded as non-adherent and those with no record of missing dates or dosages were regarded as adherent for the purpose of this study. The non-adherents were calculated to be nine and the remaining 54 were adherent at the time of data collection.

3.4.5 Data analysis

Data analysis was done in consultation with the statistician and is discussed in chapter 4, section 4.3

3.4.6. Data management

Data was managed **sensitively, privately, confidentially and anonymously** to **protect** all participants including the PHC facilities (DoH, 2015:14).

The informed consent forms (see Addendum A: Informed consent form) and TBMAS survey (see Addendum B: Cover letter and survey) were coded with numbers assigned to each PHC facility and participant. The researcher took the list of all the participants, the assigned number of the PHC facility and the participant for safe keeping. This list was electronically saved on the supervisor's computer to allow password protection. This serves to ensure that the names of PHC facilities and participants are kept confidential and private. This will only be available for audits or queries from HREC regarding a specific participant. No personal information regarding

the participants and PHC facilities was divulged during data collection or revealed in the research study, research report or any journal article.

To ensure confidentiality, only the researcher and supervisor have access to these copies. Informed consent forms and completed TBMAS scales were saved as hard copies in a locked cupboard in the supervisor's office. Only the researcher and supervisor have access to data. All research data (hard copies and electronic back up's) will be saved for a period of five years. Data is only available for audit purposes and not for secondary use. After a period of five years hard copies will be destroyed by means of a shredder.

3.5 VALIDITY AND RELIABILITY

This section regarding validity and reliability are thoroughly discussed in Chapter 4, section 4.3.1.1 and 4.3.1.2.

3.6. ETHICAL CONSIDERATIONS

SA is a democratic country and this demands that no research is allowed without informed consent from the relevant authorities, approval by HREC, PDoH and Tlokwe sub-district manager which first needed to approve the research. Goodwill permission was obtained from the Operational managers and TBPNs and CHW who act as translators. The ethics regarding participants were outlined in Chapter 1, section 1.11 in detail and according to standards set by the DoH (Department of Health (DoH), 2015:6). Figure 3.3 illustrates the priorities of ethical considerations to conduct a study with integrity and scientifically correct research.

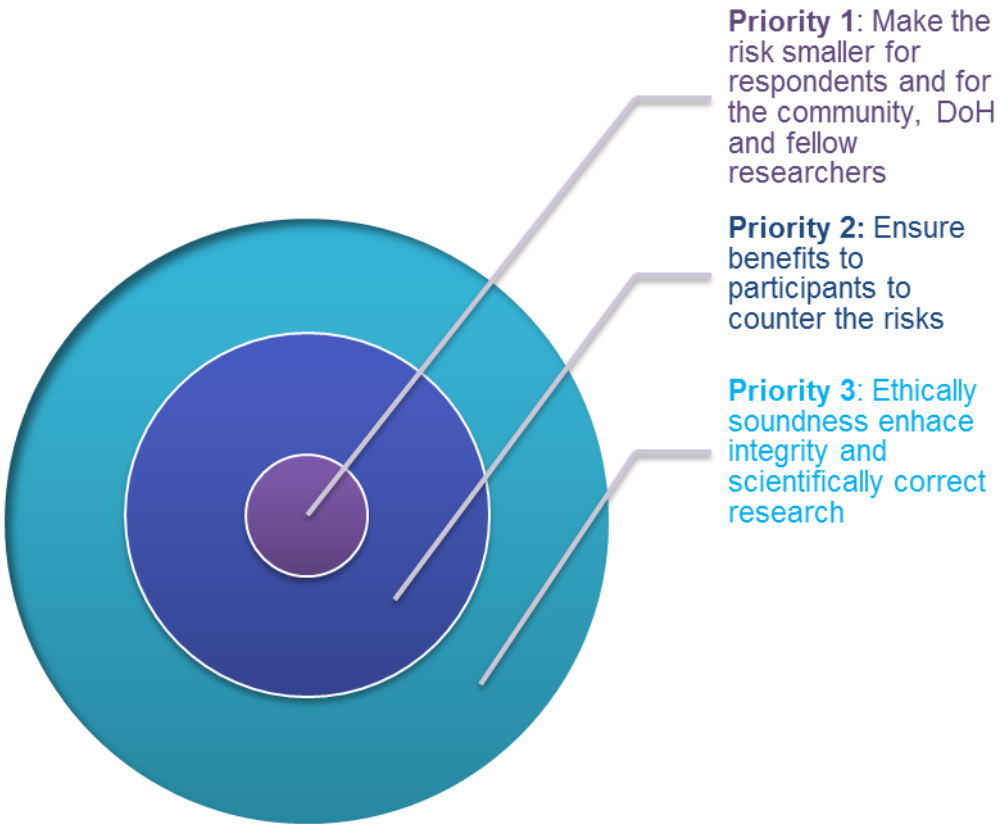

Figure 3.3: Priorities of the researcher regarding the risks and benefits for respondents

3.7. SUMMARY

This Chapter outlined the methodology, research methods and data collection. This Chapter further names validity and reliability, process of data collection, data analysis and ethical considerations and refer to where they are described in detail. This Chapter leads to Chapter 4 where data analysis is described in detail and shows how the data answered the research question

CHAPTER 4:

DATA ANALYSIS AND RESULTS

4.1 INTRODUCTION

The previous chapter provides detail about the research methodology. This chapter explains in detail data analysis and results in order to answer the research question. Before any data can be interpreted the validity and reliability of the TBMAS was determined. The researcher then analyses and describes demographic data. Descriptive statistics provide an overview of TBMAS constructs. A Comparison was done between the TBMAS constructs and the TB adherence and non-adherence groups. The chapter ends with a summary.

4.2. DATA ANALYSIS AND RESULTS DISCUSSION

The study population consisted of 63 available respondents during the time of data collection. The data from the TBMAS surveys was captured in an Excel sheet and was re-captured in second and third Excel worksheets. With the re-capturing of the data in three different Excel sheets, possible mistakes could be identified and corrected. Data were analysed by the North-West University's Statistical Consultation Services at the Potchefstroom Campus using SAS (SAS Institute Inc., 2016). Before any analysis on a checklist can be done it is important to determine the reliability and validity of the TBMAS survey to establish whether the results were reliable. Without reliable data no analyses can be done as the data will be useless. The reliability and validity of the TBMAS checklist are discussed below, followed by descriptive statistics.

4.2.1. Validity and reliability of the TBMAS

4.2.1.1 Validity

Validity of surveys depends on its ability to measure what it is meant to measure correctly and accurately (Borbasi & Jackson, 2016:129; Jones & Rattray, 2015:461). This study relies highly on content validity. Content validity determines whether the TBMAS surveys represent all the components of the constructs that needs to be measure (Brink *et al*. 2007:160). In other words does the TBMAS represent all factors that contribute to TB non-adherence? This is tested with the judgment of experts and in this research was ensured by the supervisor, and clinical experts in the Primary Health Care (PHC) field such as the TB coordinator and the statistician. These experts assisted initially before the study began to ensure that the TBMAS and "missed doses" (used to classify adherent and non-adherent groups) are valid to use when answering the research question. When experts determine the content validity of a survey, the items under a construct provide answers between the construct and comparison groups. In this study the TBMAS factors were compared between adherence versus non-adherence groups and will be

discussed below. It should be noted that Exploratory Factor Analyses was not done because an international validated survey was used in this study and the items under each construct explain the construct on a master student level.

4.2.1.2 Reliability

Cronbach's alpha coefficients were used to determine the reliability of the TBMAS constructs. The reliability of the TBMAS refers to the consistency of scores obtained by the researcher during data collection (Babbie, 2010:150). To determine the reliability of the TBMAS survey, a Cronbach's alpha coefficient was calculated for each construct. According to Field (2011:642) a Cronbach's alpha of 0.6 indicates acceptable reliability. If the reliability estimates are 0.80 and above the TBMAS are acceptable and under 0.60 reliability of the TBMAS are unacceptable.

Table 4.1: Constructs and Cronbach alpha coefficients

TBMAS Construct	Study population (n)	Cronbach alpha coefficient
Communication with the TB PN	63	0.76
Personal traits of TB patients	63	0.85
Confidence in curing TB by patient	63	0.75
Social support for TB patient	62	0.75
Mood disorders	62	0.68
Living habits*	62	0.13
Active coping behaviour*	62	0.41
Forgetfulness*	62	-1.01
Access to health care	63	0.69

*Living habits, active coping behaviour, forgetfulness are not reliable according to Field (2005:668).

In this study reliability was increased by using the graphic-Likert combination scale to improve respondents understanding (see Addendum B). The graphic-Likert scale provided the participant with five options to respond to in each item on the scale. Graphics were indicated with the use of different cartoon facial expressions. If the TB patient strongly disagreed with the statement then the sad face was marked with a cross. If the TB patient strongly agreed with the

item a smiley face was ticked. The Likert scale's first response is 1 and refers to a strong disagreement and gradually rises to option 5 which refers to a strong agreement with the item (Brink *et al*. 2012:150; Delport & Roestenburg, 2011a:171-206; Fouché & Bartley, 2011b:253). The conclusion can be made that all the constructs test reliable except for living habits, active behaviour and forgetfulness. Thus the researcher will interpret reliable constructs as a whole but those constructs that had an unreliable outcome will be analysed item by item.

4.2.2 Descriptive statistics

Data analysis was a fundamental step in the research study. Collected data needed to be organised with the aim to formulate conclusions that can answer the research question. The data needs to be analysed with reasonable attention to the extent that the reader can get a clear picture regarding the data (Hickman & Disler, 2016:132; Lacey, 2015:27). Data analysis will be described according to descriptive.

4.2.2.1 Demographic data

Frequency tables were drawn to describe the demographic variables among the study population. Demographic data describes the characteristics of the research study population. Each respondent completed demographic data which were included in the TBMAS surveys. Many literatures suggest that demographic factors such as age, gender and chronic illness influence adherence (Rolnick *et al.* 2013:55). The researcher summarises the demographic data collected from this study below in tables, followed by pie charts and discussions.

Table 4.2: Age group of TB respondents

Age	Number indicating survey answer	Frequency	Percentage
18- 25	1	5	7.94%
26-30	2	5	7.94%
31-40	3	21	33.33%
41-65	4	30	47.62%
65+	5	2	3.17%

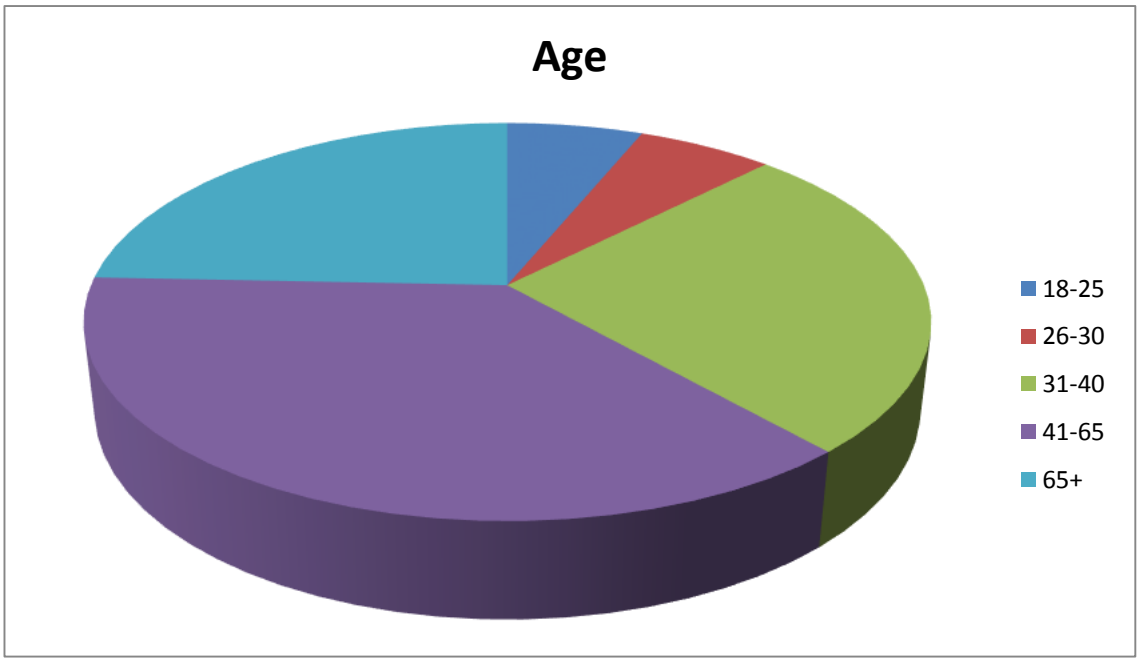

Figure 4.1 Pie chart representing the age group of study population

The available study population age affected by pulmonary sputum positive TB represents 80.95% in the age group 31 and 65 years.

Table 4.3: Gender of TB respondents

Gender	Number indicating survey answer	Frequency	Percentage
Male	1	42	66.67%
Female	2	21	33.33%

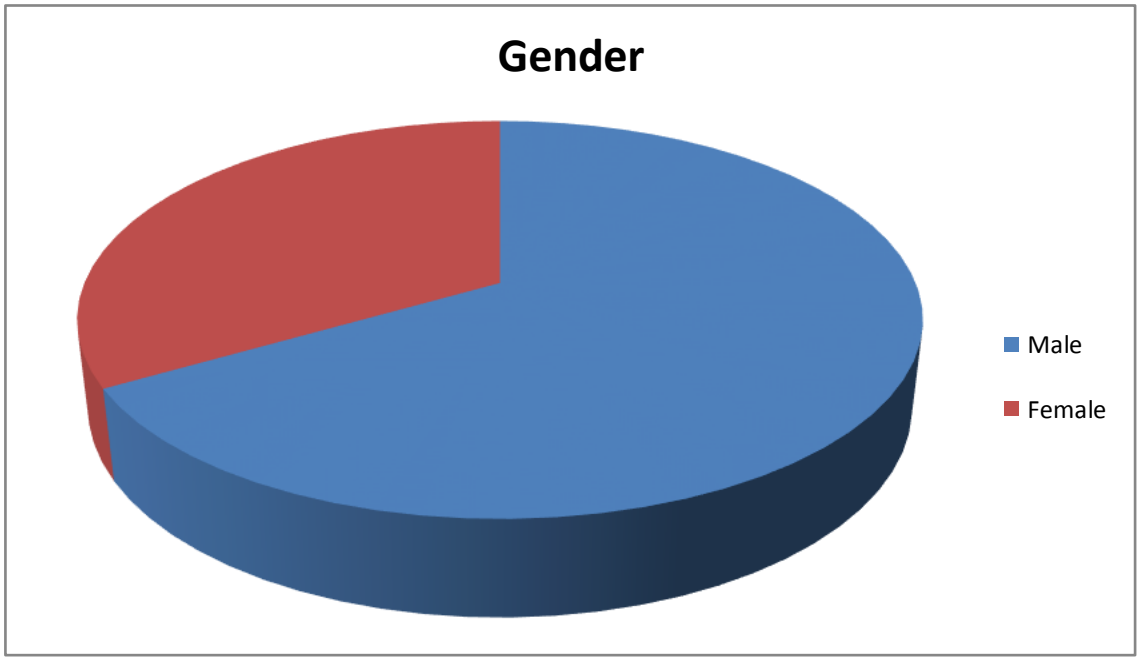

Figure 4.2: Pie chart representing the gender of study population

The gender of the available study population indicate that males are twice as susceptible to be affected by pulmonary sputum positive TB as females

Table 4.4: Duration that respondents are on TB treatment

Duration on TB treatment	Number indicating survey answer	Frequency	Percentage
1 month	1	9	14.29%
2 months	2	10	15.87%
3 months	3	13	20.63%
4 months	4	7	11.11%
5 months	5	7	11.11%
6 months	6	11	17.46%
7 months	7	1	1.59%
8 months	8	5	7.94%

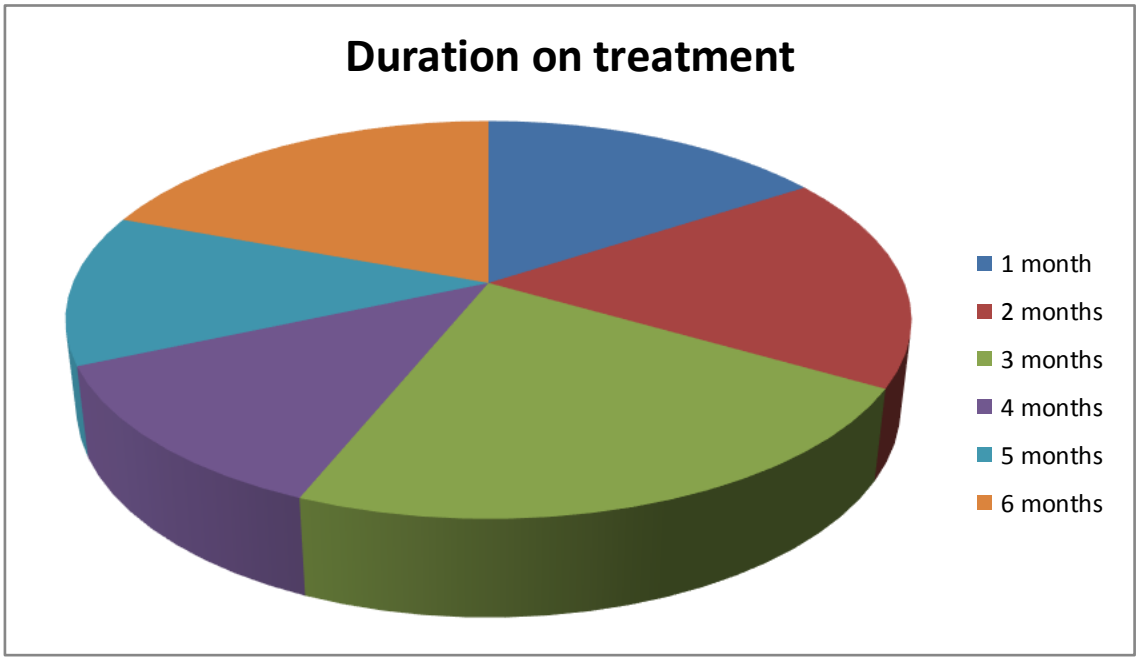

Figure 4.3: Pie chart representing the length on TB treatment of study population

The length on TB treatment of the available study population indicate that most of the affected pulmonary sputum positive TB sufferers have been on treatment for 3 months followed by those that have been on treatment for 6 months.

Table 4.5: Amount of previous TB treatments

How many previous treatments	Number indicating survey answer	Frequency	Percentage
One	1	18	28.57%
Two	2	3	4.77%
Three	3	2	3.17%
More than 3	4	1	1.59%
None (First time on TB treatment)	5	39	61.90%

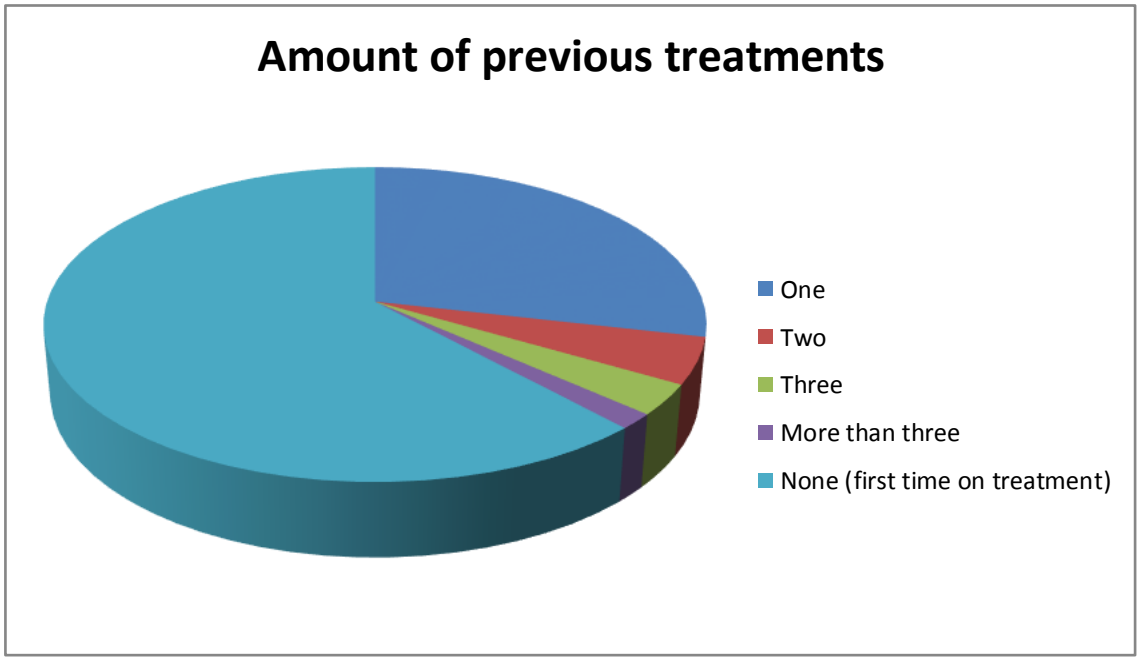

Figure 4.4: Pie chart representing the amount of new and previous TB treatments for the available study population

The percentage of the available study population on first time TB treatment supersedes all the other re-infections by 24%, followed by first time re-infections on 29%.

Table 4.6: Literacy level of TB respondents

Literacy level	Number indicating survey answer	Frequency	Percentage
Did not attend school	1	12	19.05%
Grade 1-4	2	1	1.59%
Grade 5-7	3	12	19.05%
Grade 8-11	4	24	38.10%
Matric	5	13	20.62%
Diploma or degree	6	1	1.59%

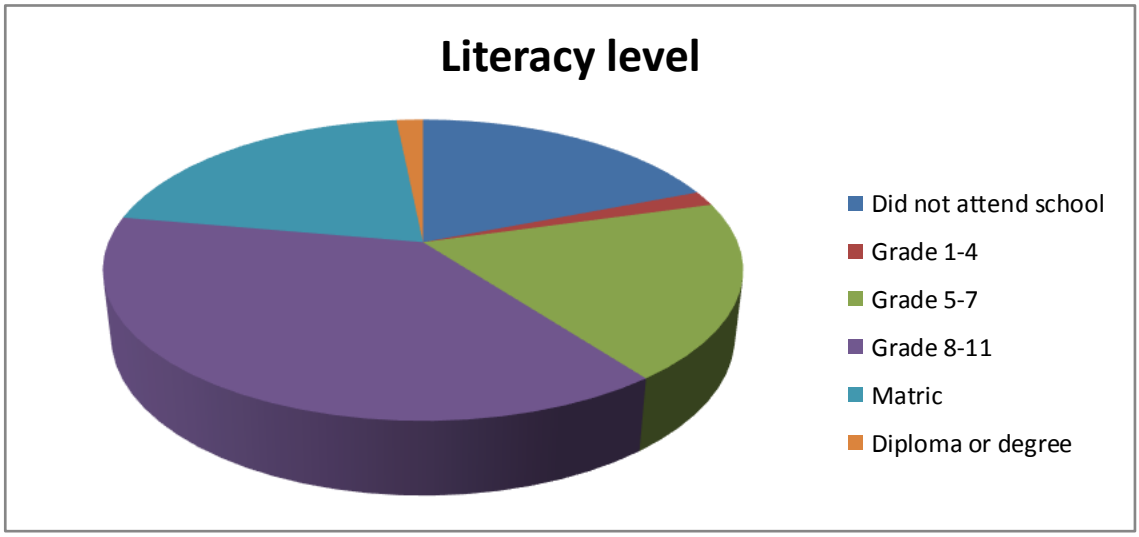

Figure 4.5: Pie chart representing the literacy level for the available study population on TB treatment

The literacy level of the available study population indicates that more than 60% of respondents have an education level of grade 8 and higher.

Table 4.7: Total of TB respondents suffering from another chronic illness

Chronic illness	Number indicating survey answer	Frequency	Percentage
Hypertension (High blood)	1	7	11.11%
Diabetes	2	3	4.76%
Asthma	3	1	1.59%
COPD (Chronic obstructive pulmonary disease – please ask the researcher to check your health card)	4	3	4.76%
None	5	49	77.78%

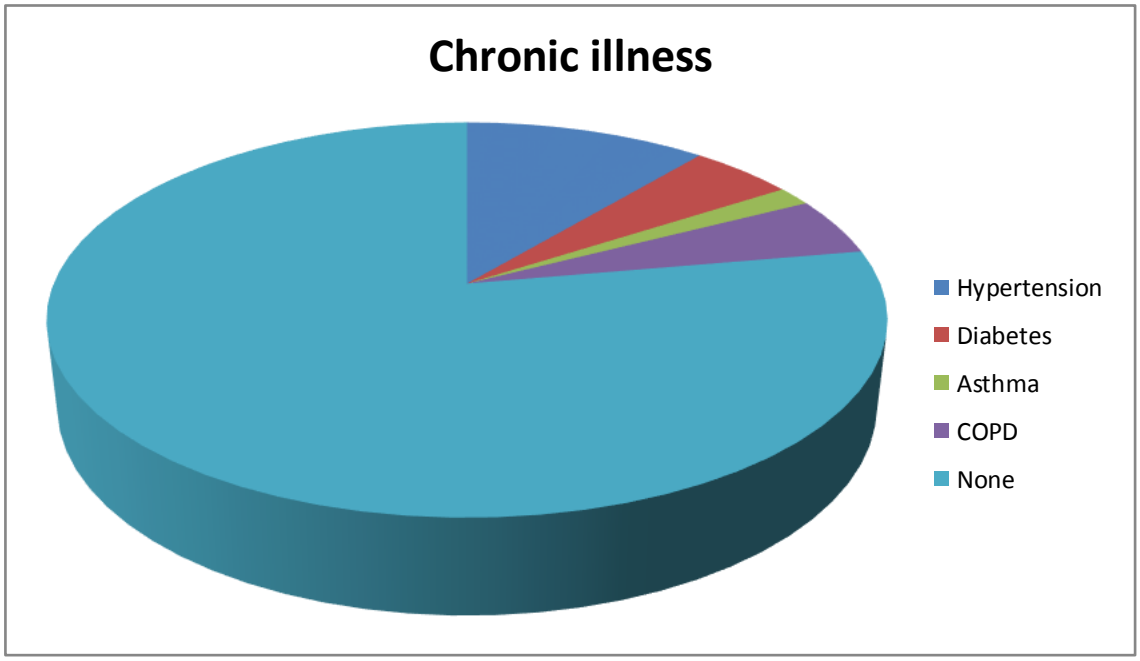

Figure 4.6: Pie chart representing the respondents suffering from chronic illnesses other than TB

Only 22% of TB pulmonary sputum positive patients suffer from other chronic illnesses as depicted in the pie chart above.

As seen in the tables above the demographic data are summarised in numbers (frequency and percentages). The most prevalent age group affected by pulmonary sputum positive TB was between the ages of 41-65 years, while the second most were between 30 and 41 years of age. There were more men affected than women in the study population, 66.67% were male respondents. Most respondents were on treatment for three, six and two months. The most of the respondents were on treatment for the first time (61.90%). Few of them were on treatment more than once. Regarding the literacy level, most participants had completed grade 8-11 (38.10%), of which the second biggest group had completed matric (20.62%). The percentage of respondents with other chronic illnesses other than pulmonary sputum positive TB are 22%. All respondents live in an urban area.

According to literature these abovementioned demographics have an influence on adherence as follows. According to Rolnichs' *et al.* (2013), those younger of age were more prone to non-adherence than older patients (Krueger *et al.* 2015; Barclay *et al.* (2007). Rolnichs' *et al.* (2013); Manteuffel *et al.* (2014) and Granger *et al.* (2009) indicate that males were more adherent than females. Patients who were on TB treatment before had strong association with missed doses and appointments thus resulting in prolonged treatments. Missed doses are added at the end of

treatment e.g. if patient missed doses in the intensive phase, these doses are add at the end of the intensive phase, thus increase the time being on the treatment (Craig *et al.* 2007:422).

4.3 INTERPRETATION OF TBMAS BY USING PEARSON CORRELATION

Pearson correlations show the linear correlation between the constructs. For example if there is a good correlation, when the one increases the other also increases and if one decreases the other decreases. Pearson's correlation coefficients were calculated to determine if linear relationships existed. A Pearson coefficient correlation is usually reported between -1 and 1 if inferential statistics are used. However in this study only descriptive statistics are reported thus the use of Cohen's effect size was used to calculate strength of correlations and the values range of 0.1 represents a small strength of correlation where 0.3 is a noticeable strength of correlation and 0.5 is a practically significant correlation (Cohen, 1988). Cohen's effect sizes for correlations used the Rho value and absolute values are reported. Table 4.8 represents and interprets the Cohen effect size or strength of Pearson correlation with the factors of the TBMAS.

Table 4.8: Pearson correlations between constructs of the TBMAS Survey for whole study population

Constructs	1. Communication with the TB PN	2. Personal traits	3. Confidence in curing TB	4. Social support	5. Mood disorders	6. Living habits	7. Active coping behaviour	8. Forgetfulness	9. Access to health care
Communication with the TB PN	1.00	0.53	0.59	0.54	-0.39	0.30	0.21	-0.23	0.36
Interpretation: **Communication (1) and personal traits (2) have a practically significant positive correlation (0.53).** **Communication (1) and confidence in curing TB (3) have a practically significant positive correlation (0.59).** **Communication (1) and social support (4) have a practically significant positive correlation (0.54).** **Communication (1) and mood disorders (5) have a negative correlation (-0.39) with a medium effect in practice.** **Communication (1) and sleep and wake up regularly every day (6) have a positive correlation (0.30) with a medium effect in practice.** **Communication (1) and active coping behaviour (7) does not correlate (0.21) with each other.** **Communication (1) and forgetfulness (8) does not correlate with each other (-0.23).** **Communication (1) and access to health care (9) have a positive correlation with a medium effect in practice (0.36).**									
Personal traits	0.53	1.00	0.46	0.57	-0.40	0.20	0.38	-0.20	0.32
Personal traits (2) and confidence in curing TB (3) have almost a correlation with practical significance (0.46). **Personal traits (2) and social support (4) have a practically significant positive correlation (0.57).** **Personal traits (2) and mood disorders (5) have a negative correlation (-0.40) with a medium effect in practice.** **Personal traits (2) and living habits (6) do not correlate (0.20) with each other.** **Personal traits (2) and active coping behaviour (7) have a positive correlation with a medium effect in practice (0.38).** **Personal traits (2) and forgetfulness (8) do not correlate with each other (-0.20).** **Personal traits (2) and access to health care (9) have a positive correlation with a medium effect in practice have a noticeable correlation (0.32).**									

Constructs	1. Communication with the TB PN	2. Personal traits	3. Confidence in curing TB	4. Social support	5. Mood disorders	6. Living habits	7. Active coping behaviour	8. Forgetfulness	9. Access to health care
Confidence in curing TB	**0.59**	**0.46**	**1.00**	**0.46**	**-0.46**	**0.34**	**0.34**	**-0.34**	**0.28**
Confidence in curing TB (3) and social support (4) have almost a correlation with practical significance (0.46). **Confidence in curing TB (3) and mood disorders (5) have a negative correlation (-0.32) with a medium effect in practice.** **Confidence in curing TB (3) and living habits have a noticeable correlation (0.34) but it is not practically significant.** **Confidence in curing TB (3) and active coping behaviour (7) have a positive correlation with a medium effect in practice (0.34).** **Confidence in curing TB (3) and forgetfulness (8) have a negative correlation (-0.34) with a medium effect in practice.** **Confidence in curing TB (3) and access to health care (9) do not correlate with each other (0.28).**									
Social support	**0.54**	**0.57**	**0.46**	**1.00**	**-0.32**	**0.18**	**0.37**	**-0.33**	**0.24**
Social support (4) and mood disorders (5) have a negative correlation (-0.32). **Social support (4) and living habits (6) have a small correlation (0.18).** **Social support (4) and active coping behaviour (7) have a noticeable correlation (0.37).** **Social support (4) and forgetfulness (8) have a negative correlation (-0.33) with a medium effect in practice.** **Social support (4) and access to health care (9) do not correlate with each other (0.24).**									

Constructs	1. Communication with the TB PN	2. Personal traits	3. Confidence in curing TB	4. Social support	5. Mood disorders	6. Living habits	7. Active coping behaviour	8. Forgetfulness	9. Access to health care
1. Mood disorders	-0.39	-0.40	-0.46	-0.32	1.00	-0.14	-0.39	-0.44	-0.36
Mood disorders (5) and living habits (6) do not correlate with each other (-0.14). Mood disorders (5) and active coping behaviour (7) have a negative correlation (-0.39) with a medium effect in practice. Mood disorders (5) and forgetfulness (8) have a negative correlation (-0.44) with practical significance. Mood disorders (5) and access to health care (9) have a negative correlation (-0.36) with a medium effect in practice.									
Living habits	0.30	0.29	0.44	0.18	-0.14	1.00	0.14	-0.34	0.18
Living habits (6) and active coping behaviour (7) have no correlation (0.14). Living habits (6) and forgetfulness (8) have a negative correlation (-0.34) with a medium effect in practice. Living habits (6) and access to health care (9) have no correlation (0.18).									
Active coping behaviour	0.21	0.38	0.34	0.37	-0.18	0.30	1.00	-0.24	0.06
Active coping behaviour (7) and forgetfulness (8) have no correlation (-0.24). Active coping behaviour (7) and access to health care (9) have correlation (0.06).									

Constructs	1. Communication with the TB PN	2. Personal traits	3. Confidence in curing TB	4. Social support	5. Mood disorders	6. Living habits	7. Active coping behaviour	8. Forgetfulness	9. Access to health care
2. Forgetfulness	**-0.23**	**-0.20**	**-0.34**	**-033**	**0.49**	**-0.34**	**-0.24**	**1.00**	**-0.17**
Forgetfulness (8) and access to health care (9) have no correlation (-0.17).									
Access to health care	**0.36**	**0.32**	**0.28**	**0.24**	**-0.36**	**0.27**	**0.06**	**-0.17**	**1.00**

Medium and large effect sizes support findings that the constructs of TBMAS correlates with each other either positively or negatively and that only in a few instances no correlations were found. A reason therefor can be that the data collected was for a specific population in a specific geographic area. The findings are thus not as representative as reported in other studies.

4.4 INTERPRETATION OF TBMAS ACCORDING TO COHENS EFFECT SIZES

The TBMAS survey consisted of nine (9) constructs and a total of 30 items. The study population who completed this survey were from nine (9) PHC facilities situated in the Tlokwe sub-district of the Dr Kenneth Kaunda district in North West Province. Descriptive statistics simplifies data by statistical tests and analysis in order to report in numbers and interpret findings in a practical way. In this study SAS (previously Statistical Analysis System) was used to analyse data (SAS Institute Inc., 2016), however currently the abbreviation is used and not the wording anymore. As a result of the fact that no random sampling was done, interpretation of TBMAS constructs, and Pearson correlation, different constructs of the TBMAS and a comparison between the adherence versus non-adherence groups according to TBMAS constructs means were done according to Cohen's effect sizes (Cohen, 1988). Effect sizes indicate practical significance – that is the extent to which a difference is large enough to have an effect in practice (Steyn, 2009). Thus no inferential statistics were interpreted, although p-values are reported as if random sampling was done.

The mean refers to the average obtained by computing the sum of the items falling under each construct and dividing it by the number of items under the same construct (Babbie, 2010:429; Hickman & Disler, 2016:136; Lacey, 2015:27; Walters & Freeman, 2015:497). The respondent could give a rating of between 1 and 5 of which 1 refers to a strong disagreement, 2 refers to disagreement, 3 refers to neutral feeling, 4 refers to agreement and 5 refers to strong agreement. The interpretation of the mean value score will depend on the phrasing of words of each item under the construct. Because this study focused mainly on adherence versus non-adherence, more attention will be given to the interpretation of that aspect in order to answer the research question.

To analyse data, the variables need to be measureable in numerical form of nominal, ordinal, interval or ratio (Hickman & Disler, 2016:132). Nominal variables have been assigned to numbers but have no rank worth, for example in this study gender refers to male and a number one was assigned to male respondents. Female respondents received a number two to indicate differences between gender (Hickman & Disler, 2016:133). The interpreting of surveys starts with the analysis of each construct according to the adherent or non-adherent group, (n) value, the mean, standard deviation, p-value and its d-value followed by a discussion. The study population for the adherent group were n=54 respondents and non-adherent were n=9.

The standard deviation is the average difference between the values of variables dispersed from the mean (Hickman & Disler, 2016:136). Thus the standard deviation indicates the

difference in respondents responded on the surveys for a specific construct or variable. The smaller the deviation the more concentrated the data is around the mean. As a result of the fact that no random sampling was done in this research, interpretation of comparisons between group means were done according to Cohen's effect sizes, d-values (Cohen, 1988). Effect sizes indicate practical significance – that is the extent to which a difference is large enough to have an effect in practice (Steyn, 2009). The following guidelines were used for d-values regarding differences between means:

- Small effect: d = 0.2;
- Medium effect (noticeable with the naked eye): d = 0.5;
- Large effect (practically significant): d ≥ 0.8 (Cohen, 1988).

The *P*-value represents the significance of an item. A *p*-value needs to be under 0.05 to be significant. A *p*-value resembles that the difference between variables is not by chance (Hickman & Disler, 2016: 137). Thus the *p*-value should be low to indicate significant difference between the adherent group and the non-adherent group.

Table 4.9: Descriptive statistics and effect sizes on the TBMAS constructs for the adherent group and non-adherent group

Construct	Group Adherent=1 Non-adherent=2	N	Mean	Standard deviation	p-value when random sampling is accepted	d-value $^{\Delta}$
1. Communication with the TB PN	**1**	**54**	**4.14**	**0.72**	**0.86**	**0.06$^{\Delta}$**
	2	**9**	**4.18**	**0.58**		
As seen above there is a medium effect (d=0.06) which means the difference between the adherent and non-adherent group differs slightly. The mean of both groups were averaged at 4 which represents agreement to the construct. The spread or distribution of data is measured by the standard deviation. A higher standard deviation means that data is more dispersed, while a lower standard deviation means that the data is more consistent (Babbie, 2010:432; Bruce *et al.* 2008:62) The standard deviation was low which indicates that there was no major deviations from the mean value and that the average is fairly justified. The *p*-value for communication was high which indicates low significance between the two groups (adherent and non-adherent) in other words there is not much difference in the responses regarding communication with the TB PN between the adherent group and the non-adherent group. The two groups responded very similar despite the fact that one group is adherent and the other not. This is a contradictory finding (see chapter 2, section 2.7.1. regarding literature of communication with the TB PN).						

Construct	Group Adherent=1 Non-adherent=2	N	Mean	Standard deviation	p-value when random sampling is accepted	d-value Δ
2. Personal traits	**1**	**54**	**3.65**	**1.02**	**0.91**	**0.04**
	2	**9**	**3.68**	**0.90**		
As seen above there is a small effect between the adherent and non-adherent group (d=0.04). The mean of both groups were averaged adherent group (mean=3.65) and non-adherent group (mean=3.68) indicates minimal difference between the two groups. The p-value is insignificant thus the adherent and non-adherent group did not differ much in terms of personal traits. According to literature reviews males are more adherent than females with regard to adherence and this finding is thus contradictory with scientific findings. An explanation will be given at the end of this table (see chapter 2, section 2.7.2. for literature regarding personal traits).						
3. Confidence of TB patient in curing TB	**1**	**54**	**4.39**	**0.61**	**0.91**	**0.03**
	2	**9**	**4.41**	**0.41**		
As seen above there is small effect according to Cohen effect sizes (d=0.03) between the adherent and non-adherent groups, meaning that the adherence group and non-adherent group does not differ from each other in their confidence in curing TB. The adherent group (mean=4.39) and non-adherent group (mean=4.41) have the same value which indicates that there is no difference as well. The mean, standard deviation and p-value indicates the same conclusion. According to literature reviews this finding is a contradictory finding (see chapter 2, section 2.7.3. for literature regarding confidence of curing TB)						
4. Social support	**1**	**54**	**3.75**	**1.05**	**0.17**	**0.33**
	2	**9**	**4.11**	**0.61**		
As seen above the Cohen effect sizes (d=0.33) is small and thus there is no difference between the adherent and non-adherent groups regarding social support. The mean value of the adherent group (mean=3.75) and non-adherent group (mean=4.11) indicates as well not a difference. According to literature review this finding is contradictory (see chapter 2, section 2.7.4).						
5. Mood disorders	**1**	**54**	**2.88**	**1.22**	**0.50**	**0.22**
	2	**9**	**3.14**	**1.05**		
As seen above there are a small effect according to Cohen's d-value (d=0.22). This means that the adherent and non-adherent groups does not differ at all with regards to mood disorders. The mean value of the adherent group (mean=2.88) and non-adherent group (mean=3.14) indicates the same result. According to literature review this finding contradictory as well (see chapter 2, section 2.7.5).						

Construct	Group Adherent=1 Non-adherent=2	N	Mean	Standard deviation	p-value when random sampling is accepted	d-value [Δ]
6. Living habits **I sleep and wake up regularly every day**	**1**	**54**	**3.49**	**1.40**	**0.04***	**0.52[Δ]**
	2	**9**	**4.22**	**0.83**		
As seen above there is a medium effect according to Cohen's d-value. The groups slightly differs from each other according to the mean value between adherent group (mean=3.49) and non-adherent group (mean=4.22). This interpretation corresponds with the t-value, see the explanation at the bottom of this table. According to literature review this finding is contradictory (see chapter 2, section 2.7.6).						
I have meals regularly every day	**1**	**54**	**4.13**	**1.19**	**0.19**	**0.35**
	2	**9**	**4.55**	**0.52**		
As seen above the Cohen effect sizes (d=0.35) are small and thus there is no difference between the adherent and non-adherent groups regarding regular meals every day. The mean value of the adherent group (mean=4.13) and the non-adherent group (mean=4.55) reveals the same result. According to literature review this finding is contradictory (see chapter 2, section 2.7.6).						
7. Active coping behaviour **I actively pursued knowledge on TB when I knew I had been infected**	**1**	**54**	**2.77**	**1.56**	**0.11**	**0.57[Δ]**
	2	**9**	**3.66**	**1.41**		
As seen above there is a medium effect according to Cohen's d-value (d=0.57) meaning that there is a slight difference between the adherent and non-adherent groups. The mean value of the adherent group (mean=2.77) and the non-adherent group (mean=3.66) confirm the small difference. According to literature review this finding is contradictory (see chapter 2, section 2.7.7).						
I often ask the health care worker about my condition since I know I have been infected	**1**	**54**	**4.07**	**1.07**	**0.34**	**-0.34**
	2	**9**	**3.55**	**1.50**		
A negative effect (d=-0.34) is not scientific of any value, thus to interpret the mean will be incorrect.						

Construct	Group Adherent=1 Non-adherent=2	N	Mean	Standard deviation	p-value when random sampling is accepted	d-value [Δ]
8. Forgetfulness **I sometimes forget to do important things I planned to do**	**1**	**54**	**2.75**	**1.42**	**0.96**	**0.02**
	2	**9**	**2.77**	**1.30**		
As seen above there are small Cohen effect size (d=0.02) between the adherent and non-adherent group, meaning that the adherent and non-adherent group does not differ from each other. The mean value of the adherent group (mean=2.75) and the non-adherent group (mean=2.77) indicates the same. According to literature reviews this finding is contradictory (see chapter 2, section 2.7.8).						
My memory is good	**1**	**54**	**4.16**	**1.01**	**0.70**	**-0.14**
	2	**9**	**4.00**	**1.22**		
A negative effect (d=-0.14) is not scientific of any value, thus to interpret the mean will be incorrect.						
9. Access to health care	**1**	**54**	**4.06**	**0.98**	**0.80**	**-0.09**
	2	**9**	**3.94**	**1.35**		
A negative effect (d=-0.09) is not scientific of any value, thus to interpret the mean will be incorrect.						

Note- 1 = Adherent; 2 = non-adherent

* Statistically significant at 0.05 level according to t-test results for non-adherence group

[Δ] Medium effect in practice

[Δ Δ] Large effect in practice and also practically significant

4.4.1 Conclusion statement about contradictory findings

A Further literature search indicates that medication adherence can be monitored by pill counts. A pill count is easy to conduct but indicates only that pills were removed out of the container however there is no proof that the pills and the correct amount of pills were taken. Self-reported adherence is when TB patients informs the TB PNs on how many doses they missed but it is the least reliable method to determine adherence. By taking contradictory findings in this study

into account this study supports previous findings that TB PNs tend to overestimate their patients' adherence. Meaning that there is a possibility that respondents who did not adhere were also classified as to be adherent and thus the adherence group was contaminated by non-adherence respondents. More time should be spend with TB patients to inform them about the side-effects of TB medication, what can be done to address it and that it is difficult to take TB treatment for a six month period because pulmonary sputum smear positive TB patients tend to feel better after a time on treatment and become reluctant in daily use of drugs. During consultation it is important to discuss that a dosage can be missed and it is understandable and if TB patients are treated with respect it will be easier for them to report missed doses and the reasons therefore (Chetty, 2016:20; Krueger *et al.* 2006:4-7). Chetty (2016:16) estimate that 50% of patients do not drink their chronic medication daily in South Africa.

The TBMAS was developed to assist TB PNs not only to identify pulmonary sputum positive TB patients with poor adherence but also to identify potential reasons for non-adherence. If this was a successful survey together with identification of missed doses it could assist TB PNs to design and implement targeted interventions to improve TB adherence. To identify missed doses the TB register and blue TB file of patient are valuable as pharmacy refill records. The TBMAS survey is internationally validated and is an excellent way to determine factors that influence TB non-adherence in the South African context. However the use of the TB register and TB blue file to determine missed doses are not valid. The researcher is of opinion that the current non-adherent status within the South African context is **totally under-estimated** as it is much higher as the current statistics indicates. The researcher is of opinion that the missed doses data is under-reported and is the contributory reason why so many contradictory findings were revealed.

4.5. SUMMARY

This chapter analysed and described data starting with validity and reliability, the Cronbach alpha coefficients were summarised and explained, the demographic data was summarised and illustrated in pie graphs, Pearson's correlation analysis were done between all the constructs of the TBMAS, the Cohen's effect size (d-value) comparisons was summarised and interpreted as well as the means and standard deviations. These all assisted in eventually answering the research question in Chapter 5.

CHAPTER 5:

EVALUATION OF THE STUDY, LIMITATIONS AND RECOMMENDATIONS FOR PRACTICE, RESEARCH, EDUCATION AND POLICY

5.1. INTODUCTION

In the previous chapter data analysis and results were discussed. This chapter evaluates to which extent the research question is answered and whether the objectives have been achieved. The limitations of the study will be outlined. A summary of findings will be written suggestions and will be made available for nursing practice, education and further research.

5.2 EVALUATION OF RESEARCH

The **research aim** was to derive meaningful suggestions from the TBMAS survey to address the unique factors that contribute most to non-adherence to TB treatment that can be considered for implementation in the Tlokwe sub-district in order to improve the TB cure rate.

Thus the following **objective** was set: to determine the unique factors that contribute most to non-adherence to TB treatment among pulmonary sputum positive TB patients according to the TBMAS survey in the Tlokwe sub-district.

The research question:

Which factors contribute most to non-adherence to TB treatment among pulmonary sputum positive TB patients according to the TBMAS survey in the Tlokwe sub-district?

The research question as such was not answered in this study due to contradictory findings in data results. However, as explained in Chapter 4, section 4.4.1 the under reported non-adherence ratio and the high underestimation thereof leads to contradicted results. It does not mean that no suggestions could be made but this was done according to scientific literature and not according to study findings. Thus the aim and objective was also not reached with this study. The researcher is obliged to report these contradictory findings to enhance scientific integrity and honesty. No reports were falsified for the purpose of this study.

5.3. SUGGESTIONS HOW TBMAS CAN BE USED TO ADDRESS NON-ADHERENCE

The following suggestions are made on grounds of the literature review. The TBMAS identified factors that contributed to non-adherence internationally. These factors were not established with the current study but the researcher can make the following suggestions based on literature. Each factor is discussed separately and suggestions are formulated.

- **Communication with health provider**: this study revealed that there is no difference between the non-adherent and adherent groups as both groups reported that they communicate well with the TB PNs. This was contradictory as Chetty (2016) indicated that the non-adherence rate is much higher than the health professional reported, due to the fact that in this study not enough time was spend with TB patients to prepare them for the demands that 6 months of TB treatment will place on them and to inform them that it is "normal" to miss dosses. The importance of being honest when discussing this real amount of dosses missed must be stressed, to ensure that the treatment can be adapted accordingly. Furthermore the TB PN should take more time to explain the side effects of TB drugs and when to report to the PHC facility. The patient also needs to be advised to establish a proper support system of family and friends for support during the treatment. Some patients do not understand the actual impact of pulmonary sputum positive TB and tend to be reluctant in taking their treatment. Addressing these factors can approve non-adherence of pulmonary sputum positive smear TB adherence.
- Patients with negative **personal traits** (patients who are not neat and clean, are not strict to follow their treatment plan, do not often seek the most effective way in doing things, do not set clear targets or is not organised and systematic to reach goals) contribute to a higher number of missed dosses and non-adherence. If the TB PNs can identify negative personal traits early in treatments, they could focus on the support systems and other strategies to ensure that TB patients do swallow their tablets every morning under supervision e.g. with the re-engineering system currently in the out rolling phase, the CHW can visit the patient in the morning to ensure that TB medications are taken and problems experienced are addressed and if not, take the TB patient to the TB PN.
- Patients with **confidence in curing TB** tend to be more adherent and do not miss dosses and the other way round. The role of the TB PNs communication with TB patients should not be neglected as discussed above.
- The patient with a **good support system** tends to be more adherent than the patient without one. During consultation with TB patients it is important to identify who the TB patient stays with, how many inhabitants there are in the household, what (are) each one's role is and how the TB patient experiences the relationship with them. These factors can only be addressed if TB PNs do not rush off the consultation and pay attention to this important aspect. TB PNs need to take in consideration those patients with weak support systems and implement strategies to enhance this, e.g. request the CHW to meet the patient at a nearby point each date and just have a discussion on how they feel and ensure that they take their tablets during that time.

- Patients with **mood disorders** (patients who sometimes feel depressed, feel frustrated, feel like giving up when they have done something wrong, who sometimes feel helpless and have a weak support system) tend to be non- adherent. The TB patients moods can be enhanced by getting them out of their own environment, letting them visit community members with more severe problems than TB, e.g. a patient who need to cope on a daily base with a wheelchair but do value life, or prescribing anti-depressants for the TB patient if necessary. A walk early in the morning in sunshine enhances the excretion of endorphins and persons walking with these patients when they are strong enough can result in secretion of endorphins. This makes the patient feel better.
- Good **living habits** enhance adherence, but not all TB patients have it. The TBMAS only include two items which indicate that a routine sensitive patient tends to adhere to TB treatment and vice versa. It is thus important for the TB PNs to identify negative living habits as early as possible to reduce non-adherence.
- **Active coping behaviour** mechanisms are essential for adherence and poor coping behaviour mechanisms need to be identified early in the treatment of TB patients to implement supportive systems as necessary.
- **Forgetfulness** enhances non-adherence and needs to be addressed by the necessary strategies. Patients are unique and the TB PNs need to take time to talk to pulmonary sputum positive smear TB patients to establish which suggested strategies will work the best for them.
- **Access to health care** reveals contradictory results in this study as explained in chapter 4. However, the TB PNs need to make sure that they treat pulmonary sputum positive smear TB patients with sensitivity, make them feel at ease and spend enough time with them to minimise non-adherence. The PHC facility is the first level of heath care entry and the majority of the burden of the TB disease is dealt with at PHC level. A caring attitude from TB PNs can reduce non-adherence.

5.4. LIMITATIONS OF THE STUDY

The study did not identify the factors contributing to non-adherence to TB treatment in patients with pulmonary sputum positive TB in the Tlokwe sub-district. The data analysed had many inconclusive results.

Although there is such a high defaulter rate it seems that the TBMAS did not identify enough reason for defaulting, maybe some items should be rephrased or added specifically for the South African context such as:

- Cultural, traditional and belief aspects influencing adherence as there are many different cultures and traditions in South Africa and this should be measured in a survey to make the application more suitable. Further research in this regard is suggested and based on these findings, policy changes could also be done to include all cultural beliefs in addressing pulmonary sputum positive TB;
- Stigma is not measured and plays a big role in patients that do not want to be seen in a PHC facility, thus they do not attend their appointments and refill treatment;
- Health staff availability and waiting time in PHC facilities as well as satisfaction with time management is not effectively measured by the TBMAS although most respondents were satisfied with the PHC facilities service. These patients might not be accustomed to better service and therefore agreed with the service being satisfactory. A measurement of waiting time is in order and the nurse to patient ratio needs to be measured to identify whether these standards are equal to the general standard of health care services;
- Socio economic poverty related questioning. There should be measurement regarding patient income or employment and where they get their daily food and transport money from;
- Behaviour like drinking alcohol, smoking and drug usage also influence adherence and should be questioned and compared to adherence levels;
- Diagnosis of any other chronic illness making a patient prone to default, such as Hypertension, Diabetes and HIV/AIDS increases the pill burden. It should be asked whether they had chosen one medication above another due to side-effects or because of too many tablets;
- One should also consider information on whether close contacts were screened properly and whether they were put on preventative treatment or not.

5.5. RECOMMENDATIONS FOR PRACTICE

Staff should be made aware of the problem of under reporting of non-adherence. Accurate recording of missed doses should be encouraged.

Interventions should be developed to assist patients to set targets for taking TB treatment e.g. to link TB treatment with a daily morning activity TB patients should take their tablets just after the morning meal. This intervention can assist TB patients not to forget to drink their tablets. However, this is the least effective way in measuring adherence. Patients will need to know the importance of reporting missed doses. Rather let them tick off their dosage taken every day on a calendar that they place on the fridge where they cannot miss it.

If patients have mood disorders they should immediately be referred to a medical doctor for evaluation as depression can influence the course of treatment as discussed in Chapter 2. Mood disorders should therefore be identified early in TB treatment and be addressed immediately.

If a patient tends to forget things then the TB PN should assign a CHW to check on the patient daily if there is no family member to do this task. If the patient is unemployed and in walking distance of the PHC facility, he/she should drink their treatment at the PHC facility daily.

5.6. RECOMMENDATIONS FOR EDUCATION

Including the importance of adherence in curriculums of nursing schools is essential as health care professionals are not necessarily aware of the effect that they could have on adherence. Teaching health care professionals in workshops the holistic measures for preventing non-adherence should be done proactively and not only when the problem already exists.

5.7. RECOMMENDATIONS FOR POLICY

Policies should include DOT supporters for every patient that tends to forget. Policies can include psychological evaluations at initial visits for every pulmonary sputum positive TB to identify and address any mood disorders that can influence adherence.

5.8. RECOMMENDATIONS FOR RESEARCH

The researcher suggests that this study should be done in two phases. Phase one should focus on the best way to determine missed doses. Statistics about missed doses should be done for a period of six months. This may help to deal with the under reported “missed dose” statistics. The second phase research should be conducted by using the TBMAS. Both these data sets should be analysed together and this could possibly illicit the factors that contribute most to the non-adherence to TB treatment.

5.9. SUMMARY

In this chapter the contribution of this study, the limitations of the study, suggestions how TBMAS can be used to address non-adherence and recommendations for practice, education, policy and research was evaluated.

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ADDENDUMS

A, B. C, D E AND F

ADDENDUM A: INFORMED CONSENT FORM

Addendum A: Informed consent form

PHC facility number	
Date	
Participant number	

HREC Stamp

INFORMED CONSENT FORM FOR SPUTUM POSITIVE TUBERCULOSIS PATIENTS

Factors influencing non-adherence to tuberculosis treatment in a sub-district, North West Province

REFERENCE NUMBERS: NWU-00347-16-S1

PRINCIPAL INVESTIGATOR: Dr CE Muller (supervisor)

Researcher C van der Zee

ADDRESS: Potchefstroom Campus
11 Hoffman Street
Potchefstroom
2520

Addendum A: Informed consent form

CONTACT NUMBER OF RESEARCHER C VAN DER ZEE: 082 469 5361

You are being invited to take part in a research study about TB in the lungs. The research study wants to know more about why TB patients battle to take TB treatment. The study is part of the researcher's higher degree in nursing (a sister learning further about TB and research). Please take some time to read the information. This letter explains the study to you. Please ask the TB Sister or counsellor in your clinic to explain or translate the advertisement and this letter if you do not understand or cannot read English very well. It is very important that you understand how the study works and why the researcher would like to hear your answers. This letter and advertisement explains to you what the research study is about so that you can decide if you would like to participate. This information is not given to you because you are forced to participate, only for you to understand and to be able to make a choice. Please do not feel forced to participate, no one will know what your decision is. Even if you decide to participate and you feel unsure and want to remove yourself from the research study you are free to do that without any problems.

The researcher has received permission to do the research as assessed and decided by all the important persons that protect all participants and the community from harm. The important people that have given permission are the Department of Health, clinic managers and the Ethics committee of the University of PUKKE. The permission number is: NWU-00347-16-A1. The researcher has strict rules to follow that helps protect you from harm and that provides you with a token of appreciation (see later in this letter). The Ethics committee of PUKKE might want to see the information of this research study to make sure you are not harmed by the study.

What is this research study about?

This study would like to find the reasons that make it difficult for TB patients to take their TB treatment or to complete their treatment up to the end. The reason for this is that the researcher has read about patients that battle with this because of many reasons for example the clinic does not always have the treatment, or the patient needs to go to work and cannot go the clinic in time and sometimes the side-effects of TB treatment is very bad and makes patients feel even worse. The researcher would like to find the information about this situation for the people living in Potchefstroom so that help can be found. If you are not good with reading and writing English you do not have to worry at all. The researcher is arranging translators to help and the researcher will help you to complete you questionnaire. The answers will not need you to write anything but just to choose the facial expression that you feel about a question. The researcher is very good with explaining and will have the

translator to help explain to you in Setswana if you want to. The researcher used to be a Sister in Potchefstroom in one of the clinics and has experience with the cultural background of the Setswana community.

The researcher will need 80 participants to complete questionnaires.

The researcher would like to find the reasons that make it difficult for TB patients to drink their treatment so that this information can help to improve the situation. If one knows the patient's problems one can develop improvements. The researcher will also give the Department of Health a letter after the research and explain what the problems in the community are because curing TB is very important to them.

Why have you been invited to participate?

You have been invited to participate because you have TB in your lungs and this kind of TB can make others ill too. This participation will not ask you about HIV/AIDS, so you do not have to be afraid of answering a question about HIV/AIDS. If you are not sure if you are allowed to participate you can just ask your TB sister to help you. The TB sister will have the information and will be able to show you how you are part of the patients that can participate.

The rest of the important things to be able to participate are listed below:

- *You have TB in the lungs that was proven by a sputum test that was positive;*
- *You are a clinic TB patient;*
- *Only allowed to participate if you would like to;*
- *It does not matter if you drink your treatment or not as long as you have TB of the lungs;*
- *It does not matter for how long you have been on TB treatment;*
- *It does not matter how many times you have had TB;*
- *It does not matter if you are drinking treatment for anything else;*
- *You have to be 18 years or older;*

You will not be able to participate if you do not have TB in the lungs for example TB of the spine. It is important that you ask the TB sister to help you if you are not sure if you may participate.

What will the researchers need from you?

Addendum A: Informed consent form

The researcher will only need you to send a SMS or Please Call Me to the number provided on top of this letter and on the advertisement if you are interested to participate. If you want the researcher to contact you on a different number you can provide it in the SMS or Please Call Me. The researcher will phone you back and make arrangements with you. The researcher will ask for your name and surname, a contact number for future phone calls, your preferred language (English or Setswana), the name of the clinic and when is your date and time for consultation with the TB PN for your appointment in September. The day of your appointment the researcher will have the translator available if needed and will need you to bring your two informed consent letters (this letter) back and you will have to be willing to sign them with two witnesses (these letters are given to you to sign at home where you are comfortable and can ask family members to sign with you). You will receive two letters but they are exactly the same, you do not need to read both but you need to sign both. You will receive one for yourself and the researcher will need the other one in case PUKKE thinks that the researcher has forced or harmed you to participate. This letter will then be proof that you agreed to participate without force. These letters basically just say that you understand what the research is about and what is needed of you and that you are participating without anyone forcing you. These forms will not be traced to your questionnaire because the researcher is protecting your answers from everyone. There is no catch or small print that you need to be worried about.

On the day of your consultation appointment, you will be taken to the researcher after your consultation for completing the questionnaire the researcher and translator will be there to help you to understand the questions and how to answer them correctly if you are not good with English. This questionnaire has 30 short questions that ask about you and your TB treatment. The questionnaire takes about 20 minutes of your time and if you feel emotional after answering some sensitive questions the researcher has arranged a person for you to talk to after to make sure that you are OK. You will only need to complete one questionnaire and you are never asked about your HIV/AIDS status.

Benefits of the study for you:

There are no direct benefits for you. The researcher is providing free refreshments and your taxi fee to get to the clinic on your appointment date. The researcher will also leave you an educational leaflet with the TB sister after the research is done and remind you to collect it by sending you a SMS.

The risks of participating in this study:

The only risk is that you might feel emotional after answering personal and sensitive questions about your treatment. The researcher will comfort you if you might feel sad and will then refer you to the professional person to talk to after to make sure that you are OK before going home.

How will the researcher protect your name and identity (confidentiality) and who will see the answers?

Your questionnaires and informed consent letters will not have your name on. The researcher is the only one that will know your name and have your name on a list with your participating number that you will use for your identity in this research. This is to protect your name from anyone seeing it. The list with names and the participant numbers will be locked in a safe and the list will be on a computer for back-up but this file will be protected with a password. No personal or private information of you will be seen by anyone.

The researcher will also make sure that the translator and the researcher signs a form that legally says none of the information discussed may be spoken about with your name.

When you are finished completing the questionnaire the researcher will keep it in a file and take it to the supervisor's office on the same day and lock it in a cupboard where no one can access it.

Remuneration

This study is funded by the researcher alone and is aimed to improve public health, which is why the researcher cannot afford to pay the participants with money but will prevent you from losing any money while taking part. For example your travel fee and a refreshment for the day will be given to you. The researcher also makes the appointment after your consultation with the TB sister to suit you because the researcher would not want to prevent you from a working shift or anything else important.

If you have any questions

- You can contact the researcher Van der Zee at **082 469 5361**; if you have any questions. Please save this number if you are going to participate so that you can identify the researcher's call in the future.

- You can contact PUKKE: Mrs Carolien van Zyl at 018 299 1206; carolien.vanzyl@nwu.ac.za if you have any worries or complaints about the research study or researcher.
- You will also receive a copy of this information and consent form for yourself.

How will you know about the findings?

The findings of the research will be shared with you on a leaflet with the educational leaflet when the research is over. The TB Sister will keep it for you in a sealed envelope. The researcher will SMS you to collect it if you would like to see the findings.

Declaration by participant

By signing below, I ……..…… agree to take part in a research study entitled: Factors influencing non-adherence to tuberculosis treatment in a sub-district, North West Province.

I declare that:

- The information was explained to me by the TB Sister (gatekeeper) even if I am able to read it myself and I received a pamphlet about the research study and two consent forms to take home to decide whether I would like to participate or not. The consent form was signed in the presence of the TB Sister after one week and the TB Sister explained the informed consent form to me again.
- I was given enough time to ask questions and all my questions were answered.
- I understand that helping the researcher is my own choice and I was not forced in any way to take part.
- I know that I may ask the researcher to withdraw my answers from the study in case I decide not to participate anymore and no one will be angry with me.

Signed at (place) .....…..…….. on (date) ……..……. 20....

---------- ----------

Signature of participant Signature of witness 1

Signature of witness 2:

Declaration by gatekeeper

I (name) ……..…… declare that:

- I explained the information in this document to ……..

- I encouraged the participant to ask questions and allowed enough time for answering questions.
- I am satisfied that participant thoroughly understands all aspects of the research, as discussed above

Signed at (place) ..... on (date) …….…….. 20….

---------- ----------
Signature of gatekeeper Signature of witness

Declaration of translator

I (name) ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged the participant to ask questions and allowed enough time for answering questions.
- I am satisfied that participant thoroughly understands all aspects of the research, as discussed above

Signed at (place) ..... on (date) …….…….. 20….

---------- ----------
Signature of researcher Signature of witness

Declaration by the researcher

I (name) ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged the participant to ask questions and allowed enough time for answering questions.
- I am satisfied that participant thoroughly understands all aspects of the research, as discussed above

Signed at (place) ..... on (date) …….…….. 20….

---------- ----------
Signature of researcher Signature of witness

CELL PHONE NUMBER OF PARTICIPANT SO THAT THE RESEARCHER CAN CONTACT YOU IF NEEDED_____
THANK YOU FOR TAKING THE TIME TO READ THIS LETTER

KIND REGARDS
VAN DER ZEE, THE RESEARCHER

ADDENDUM B: COVER LETTER AND SURVEY

Addendum B: Cover letter and survey

Research project

Factors influencing non-adherence to tuberculosis treatment in a sub-district, North West Province

by

Researcher: Van der Zee, Student researcher in Magister Curationis in Nursing Science 2016

North-West University, Potchefstroom Campus

Dear Mr/Ms

The correct drinking of TB treatment in Tlokwe sub-district has been difficult according to statistics. You have decided to participate in the research study of the researcher: Ms C Van der Zee, a Master's student at PUKKE (the North-West University). You have been invited to be part of this study because you have lung TB tested with the sputum bottle you handed in at your clinic. You started to drink TB medicine because your sputum test was positive. That is why you can help the researcher to collect important information about the problems with drinking TB treatment. The aim of this research is to understand the problems TB patients have with drinking their TB treatment or for completing the treatment for as long as six months. This information will help the researcher to report to Department of Health how to help new TB patients in the future. You are kindly asked to complete this questionnaire with the help of the researcher and translator as honest as possible.

Thank you for your participation in this research project.

Researcher: Van der Zee

Addendum B: Cover letter and survey

PHC facility number	
Date	
Participant number	

Factors influencing non-adherence to tuberculosis treatment in a sub-district, North West Province

Demographic data

Please answer the following questions by choosing the most applicable answer and placing an X in the corresponding space. Choose only one answer unless specified otherwise.

1. Age

18- 25	1
26-30	2
31-40	3
41-65	4
65+	5

2. Gender

Male	1
Female	2

3. **Duration of TB treatment**

1 month	1

4. How many previous TB treatments?

One	1
Two	2
Three	3
More than 3	4
None (first time on treatment)	5

6. Literacy level

Did not attend school	1

2 months	2
3 months	3
4 months	4
5 months	5
6 months	6
7 months	7
8 months	8

Grade 1 - 4	2
Grade 5-7	3
Grade 8-11	4
Matric	5
Diploma or degree	6

7. Chronic illness

Hypertension (High blood)	1
Diabetes mellitus (Suciri)	2
Asthma	3
COPD (Chronic obstructive pulmonary disease – please ask the researcher to check your health card	4
None	5

8. Living area

Rural	1
Peri-urban	2
Urban	3

Addendum B: Cover letter and survey

Survey: TB Medication Adherence Scale

In the following scale you are asked to choose one option that suits your feeling best towards the statement. Please mark the applicable box with an X according to the number that suits your attitude toward the statement best.
Choose:

1. if you strongly disagree,
2. if you disagree,
3. if you are neutral,
4. if you agree and
5. if you strongly agree.

Please answer the following regarding the communication with the TB health care worker. Table 1: TB medication adherence scale

Items	Strongly disagree 1 	Disagree 2 	Neutral 3 	Agree 4 	Strongly agree 5 
1. I am satisfied with the health care worker's attitude toward me.					
2. The health care worker described TB to me clearly.					
3. The health care worker explained my condition to me clearly.					
4. The health care worker explained the method of taking medicine clearly.					
5. The health care worker explained the side-effects of medicine clearly.					
6. The health care worker led me to believe that my TB can be cured.					

Addendum B: Cover letter and survey

Please answer the following regarding personal traits

Items	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5
7. I often keep my things neat and clean.					
8. I am strict with myself to follow my plan.					
9. I often seek the most effective way in doing things.					
10. I often set clear targets.					
11. I am organised and systematic in approaching my target.					

Please answer the following regarding confidence in curing TB

12. I am very confident to completely cure TB.					
13. My treatment regimen is very simple.					
14. I am very confident in taking TB medicine regularly for 6 months.					
15. I am very confident in tolerating side-effects.					

Addendum B: Cover letter and survey

Please answer the following regarding social support

Items	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5
16. I am satisfied with the support between our family members.					
17. My family members often remind me to take medicine.					
18. My friends often remind me to do things.					
19. People around me often give me necessary help.					

Please answer the following regarding mood disorders

20. I sometimes feel depressed.					
21. When I do something wrong, I feel frustrated and want to give up.					
22. I sometimes feel helpless and want other people's help.					

Addendum B: Cover letter and survey

Please answer the following regarding living habits

Items	Strongly disagree 1 	Disagree 2 	Neutral 3 	Agree 4 	Strongly agree 5 
23. I sleep and wake up regularly every day.					
24. I have meals regularly every day.					

Please answer the following regarding active coping behaviour

25. I actively pursued knowledge on TB when I knew I had been infected.					
26. I often ask the health care worker about my condition since I know I have been infected.					

Please answer the following regarding forgetfulness

27. I sometimes forget to do important things I planned to do.					
28. My memory is good					

Addendum B: Cover letter and survey

Please answer the following regarding access to health care

Items	Strongly disagree 1 	Disagree 2 	Neutral 3 	Agree 4 	Strongly agree 5 
29. It's convenient to refill my TB medicine					
30. The TB control institution I visit meets my need.					

(Yin *et al.* 2012:4)

Thank you for completing the questionnaire.

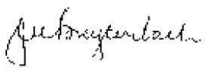
ADDENDUM C: STATISTICAL CONSULATION

Addendum C: Statistical consultation

ADDENDUM C: STATISTICAL CONSULTATION

Declaration of statistical consult

I, Dr C.E. Muller, supervisor of this study solemnly declare that two statistical consultations were attended at the North-West University, Potchefstroom Campus, statistical consultation services for the study regarding **management of non-adherence – the pivot of successful tuberculosis outcomes in Potchefstroom sub-district, North West Province.** The statistical consultations were conducted with Mrs Wilma Breytenbach, a statistical consultant at the North-West University, Potchefstroom Campus. According to the outcomes of the consultation I, Mrs Wilma Breytenbach, declare that this study is eligible to answer the research questions according to statistical calculations, the amount of questionnaires to be filled in are statistically accurate as described in the data collection process and the questionnaire of TBMAS (Yin *et al.* 2012:4) is statistically valid and reliable.



ADDENDUM D: ADVERTISEMENT TO RECRUIT PARTICIPANTS

Do you have TB?

Researcher aiming to determine the unique factors that contribute most to non-adherence to TB treatment among pulmonary sputum positive TB patients in Tlokwe sub-district.

DID YOU KNOW?

TB IS A CURABLE DISEASE

Want to participate? Keep reading...

This study will use a QUESTIONNAIRE called the TB medication adherence scale to collect information from patients

To participate you NEED to be:

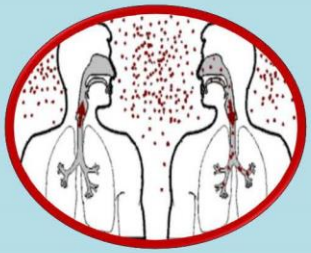
- 18 years and older
- diagnosed with smear sputum positive TB
- on TB treatment at any stage
- willing to participate and sign an informed consent form
- diagnosed with Xpert MTB/RIF sputum test

You will NOT be able to participate if you:

- are diagnosed with TB other than the lungs and if you do not have infectious TB

Interested?

Please SMS or send a Please Call Me with your name and preferred contact number to the researcher @ **082 469 536**.
The researcher will contact you.



ADDENDUM E: PERMISSION FROM NORTH-WEST UNIVERSITY

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Private Bag X6001, Potchefstroom,
South Africa, 2520

Tel: (018) 299-4900
Faks: (018) 299-4910
Web: http://www.nwu.ac.za

Institutional Research Ethics Regulatory Committee
Tel: +27 18 299 4849
Email : Ethics@nwu.ac.za

ETHICS APPROVAL CERTIFICATE OF STUDY

Based on approval by **Health Research Ethics Committee (HREC)** on **01/02/2017** after being reviewed at the meeting held on **20/10/2016**, the North-West University Institutional Research Ethics Regulatory Committee (NWU-IRERC) hereby **conditionally approves** your study as indicated below. This implies that the NWU-IRERC grants its permission that provided the special conditions specified below are met and pending any other authorisation that may be necessary, the study may be initiated, using the ethics number below.

Study title: Factors influencing non-adherence of Tuberculosis treatment in Potchefstroom sub-district, North West Province.

Study Leader/Supervisor: Dr CE Muller
Student: C van der Zee

Ethics number: NWU-00347-16-A1
(Institution - Study Number - Year - Status)
Status: S = Submission; R = Re-Submission; P = Provisional Authorisation; A = Authorisation

Application Type: Single study
Commencement date: 2017-02-01 **Risk:** Medium

Continuation of the study is dependent on receipt of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation up to a maximum period of three years.

Special conditions of the approval (if applicable):

- The applicants will have to provide the HREC with copies of the signed permission letters from the entities and individuals as indicated in the application i.e. from the Department of Health at both provincial and district level, the clinic manager of the primary health care clinics and the tuberculosis primary nurse.

General conditions:

While this ethics approval is subject to all declarations, undertakings and agreements incorporated and signed in the application form, please note the following:

- *The study leader (principle investigator) must report in the prescribed format to the NWU-IRERC via HREC:*
  - *annually (or as otherwise requested) on the monitoring of the study, and upon completion of the study*
  - *without any delay in case of any adverse event or incident (or any matter that interrupts sound ethical principles) during the course of the study.*
- *Annually a number of studies may be randomly selected for an external audit.*
- *The approval applies strictly to the proposal as stipulated in the application form. Would any changes to the proposal be deemed necessary during the course of the study, the study leader must apply for approval of these amendments at the HREC, prior to implementation. Would there be deviated from the study proposal without the necessary approval of such amendments, the ethics approval is immediately and automatically forfeited.*
- *The date of approval indicates the first date that the study may be started.*
- *In the interest of ethical responsibility the NWU-IRERC and HREC retains the right to:*
  - *request access to any information or data at any time during the course or after completion of the study;*
  - *to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process.*
  - *withdraw or postpone approval if:*
    - *any unethical principles or practices of the study are revealed or suspected,*
    - *it becomes apparent that any relevant information was withheld from the HREC or that information has been false or misrepresented,*
    - *the required amendments, annual (or otherwise stipulated) report and reporting of adverse events or incidents was not done in a timely manner and accurately,*
    - *new institutional rules, national legislation or international conventions deem it necessary.*
- *HREC can be contacted for further information or any report templates via Ethics-HREC Apply@nwu.ac.za or 018 299 1206.*

The IRERC would like to remain at your service as scientist and researcher, and wishes you well with your study. Please do not hesitate to contact the IRERC or HREC for any further enquiries or requests for assistance.

Yours sincerely

Prof LA Du Plessis
Digitally signed by Prof LA Du Plessis
Date: 2017.02.27 12:17:36 +02'00'

Prof Linda du Plessis
Chair NWU Institutional Research Ethics Regulatory Committee (IRERC)

ADDENDUM F: POLICY, PLANNING, RESEARCH, MONITORING AND EVALUTATION

health
Department of
Health
North West Province
REPUBLIC OF SOUTH AFRICA

Cnr Sekame & First Street
New Office Park
Mafiheng, 2745
Private Bag X2068
MMABATHO, 2735

Enq: Nthabiseng Mapogo
Tel: 018 391 4504
Fax: 018 388 6202
NMapogo@nwpg.gov.za
www.nwhealth.gov.za

2030 NDP

POLICY, PLANNING, RESEARCH, MONITORING AND EVALUATION

Name of researcher : Ms. Van der Zee
North West University

Physical Address
(Work/ Institution) _____

_____

_____

Subject : **Research Approval Letter – Factors influencing non-adherence of Tuberculosis treatment in Potchefstroom sub-district, North West Province.**

This letter serves to inform the Researcher that permission to undertake the above mentioned study has been granted by the North West Department of Health. The Researcher is expected to arrange in advance with the chosen facilities, and issue this letter as proof that permission has been granted by the Provincial office.

This letter of permission should be signed and a copy returned to the department. By signing, the Researcher agrees, binds him/herself and undertakes to furnish the Department with an electronic copy of the final research report. Alternatively, the Researcher can also provide the Department with electronic summary highlighting recommendations that will assist the department in its planning to improve some of its services where possible. Through this the Researcher will not only contribute to the academic body of knowledge but also contributes towards the bettering of health care services and thus the overall health of citizens in the North West Province.

Kindest regards.

Dr. FRM Reichel
Director: PPRM&E

LEPAPHA LA BOITEKANELO
DEPARTMENT OF HEALTH
Kgetsana Poso /Private Bag X2068
Mmabatho,2735
13 JUN 2017
NORTH WEST PROVINCE
REPUBLIC OF SOUTH AFRICA

12/06/2017
Date

Researcher

20/07/2017
Date