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Characteristics of clients presenting for substance abuse treatment at cosup centresin the City of Tshwane

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CHARACTERISTICS OF CLIENTS PRESENTING FOR SUBSTANCE ABUSE TREATMENT AT COSUP CENTRES IN THE CITY OF TSHWANE

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A research report submitted in partial fulfilment of the requirements of the degree of Master of Medicine (Public Health Medicine) in the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg

Johannesburg

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DECLARATION

I, Tabea Thama Manyane, declare that this research report is my original unaided work except where I have explicitly indicated otherwise. It is being submitted for the degree of Masters in Medicine (Public Health Medicine) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.



Tabea Thama Manyane

18/11/2020

Date

DEDICATION

Had it not been for the love of God this work would not have been possible. His grace has been sufficient for me and his power my source of strength throughout this journey and on his wings only have I soared.

It is with a grateful heart that I dedicate this work wholly to my children, Katlego, Keabetswe and Thabang who have been affected in every way possible by this quest. Paseka and Mohau, whose encouragement has made sure that I give it all it takes to finish that which I have started. Thank you, my kids. My love for you all can never be quantified.

ABSTRACT

Background: Substance abuse is a growing public health challenge in South Africa. It contributes significantly to the burden of disease. Integrated treatment approaches are required to address the substance abuse problem. The aim of this study was to determine the of risk of harm associated with substance use in subjects enrolled in the community-oriented substance use program (COSUP) in the City of Tshwane, South Africa, using the World Health Organization's Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) tool and determine the demographic characteristics that might be associated with the changes in the ASSIST risk scores and the levels of risk of harm in those subjects.

Methodology: A cross-sectional study design was used to retrospectively analyze secondary data collected from subjects enrolled into COSUP at time of enrolment and three-months follow-up from time of enrolment. Descriptive statistics were used to analyze the demographic characteristics. Univariate and multivariate logistic regression analyses of moderate- to high-risk opioid use in relation to demographic characteristics were done.

Results: Most subjects were males (91.2%), single (79.8%), black (85.6%) and they were relatively young (median age 31$\pm$6.4 years). The high level of risk was found with the use of opioids (74.5%, 607/805), cannabis (28.8%, 232/805), and tobacco (16.1%, 130/805). Moderate levels of risk were found with tobacco (63,9%, 514/805), cannabis (25.6%, 206/805) and opioids (5.1%, 41/805). Moderate and high level of risk was found to be more in males (p=0.03) and in the black race (p=0.02). Multivariate analysis found moderate- to high-risk of opioid use to be positively associated with being married (adjusted odds ratio (aOR) 11.90, 95% confidence interval (CI) 1.30 – 108.20).

Conclusion: Hazardous and harmful use of substances was found among users of opioids, cannabis and tobacco. Screening and harm reduction treatment interventions for substance use should be integrated within primary health care. Further research on the perceptions of substance users about harm reduction treatment interventions is required.

Key words: COSUP**,** Harm reduction, Opioid substitution therapy, Substance abuse

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LIST OF ABBREVIATIONS

ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
COPC	Community Oriented Primary Care
COSUP	Community Oriented Substance Use Program
NDMP	National Drug Master Plan
OST	Opioid Substitution Therapy
PWUD	People who use drugs
SA	South Africa
SUD	Substance Use Disorders
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

DEFINITIONS OF KEY TERMS

Dependence: - the “physiological, behavioral and cognitive phenomena arising from the use of a substance, including a strong desire to use the substance, difficulties in controlling its use, persistence in the use of a substance despite the harmful consequences, such as increased tolerance, and sometimes a physical withdrawal state” (1)

Harmful use of substances: - pattern of use that causes damage to physical or mental health (2).

Illicit substances: - A psychoactive substance which its origin, the production, sale or use is illegal or prohibited (3).

Licit substances: - Drugs that are legally available through a medical prescription or, a drug legally available without medical prescription (3).

Harm reduction: - refers to “policies, programs and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption” (4).

Nyaope: - A local name for heroin of varying quality (combination of heroin and cannabis) (5)

Opioids: - refers to alkaloids like opiates, their synthetic analogues and the compounds synthesized in the body (6)

Opioid Substitution Therapy: - Medical therapeutic procedure of replacing an illegal opioid substance such as heroin with a longer acting opioid such as methadone or buprenorphine, which has less euphoric effects (7).

Psychoactive substances: - Substances that when ingested or taken changes the mental process, perception, thinking or emotion, behavior or motor function of the user (3)

Substance abuse: - the harmful or hazardous use of illicit and psychoactive substances (1).

Substance use: - the unspecified use of controlled psychoactive substances for non- medical and non-scientific purposes.

Substance use disorders: - patterns of symptoms resulting from the use of a substance (8)

CHAPTER 1: INTRODUCTION

This chapter provides the context and background to my research study and the critical review of the literature on the prevalence of substance use, factors associated with substance abuse, the associated health consequences and the approaches to treatment and screening of substance use in the primary health care settings.

1.1 Background and context

Substance abuse refers to the excessive, harmful and hazardous use of alcohol and other licit or illicit drugs such as nicotine, cannabis, opioids and over-the-counter prescription medications (1). The persistent and excessive use of these substances often leads to various clinical states such as acute intoxication, dependence, withdrawal state, and multiple psychotic disorders (9). These clinical states collectively are referred to as substance use disorders (10) and result in users presenting with different kinds of symptoms. The symptoms could be physical (red eyes, sleepy eyes, weight loss), psychological (lack of interest in activities/work or family) and behavioral (irritability, feeling of tiredness or being hyperactive, violent and restlessness) (1,11). Apart from the negative health impact of substance use, people who use drugs also have social needs. It is, therefore, important to ensure that there are services available and accessible to PWUD and their families to help support them in dealing with the problem of substance use and dependence. Dependence means the substance user find it difficult or impossible to stop using the substance unless they are assisted to do so (9). A survey done in South Africa (SA) showed that 60% of the participants did not know that there were services available to assist with substance abuse problems (12).

South Africa faces a major challenge with the growing problem of substance abuse (9). Substance abuse was found to play a role in the increasing rates of crime, violence and other social ills (13). According to the 2018 annual report of South African Police Services, there is an increasing number of cases of drug-related crimes (14). It is

more prevalent in certain provinces in South Africa, such as Gauteng Province as evident from the reports on the demand of substance use treatment. (15) as well as press reports (16,17) highlighting the challenges faced by various communities in Gauteng with regards to the increasing substance use. A customer satisfaction survey by the City of Tshwane indicated that households identified substance use as one of their critical challenge and that it leads to other problems in their communities such as increasing levels of crime (18).

South Africa has implemented several policies and legislations to guide the control of substance use. The Prevention of and Treatment for Substance Abuse Act of 2008, stated that the fight against substance abuse would require a comprehensive response which included having mechanisms that are directed towards demand and harm reduction (19). It further provided that primary prevention and community-centered early treatment interventions are needed. The National Drug Master Plan (NDMP) defined South Africa's drug problem as a substance abuse problem because it encompasses the demand for all types of dependence-forming substances (9). The NDMP which was formulated in terms of the Prevention and Treatment of Drug Dependency Act of 1992 guides the government on how to reduce the demand and supply of drugs and how to ensure the reduction of harm associated with substance use and abuse (9). Harm reduction has been identified as one of the best interventions to control substance abuse, therefore, strengthening the approaches of harm reduction is a priority in the field of substance abuse in SA. Harm reduction benefits people who use drugs, their families and the community. (4) Access to substance abuse related treatment, especially at a primary health care level, remains a challenge for most PWUD and their families, and needs to be addressed. In some instances, it is an issue of affordability while in some it's an issue of availability.

To contribute to the fight and control of the substance abuse problem in the City of Tshwane, South Africa, a municipal drug management plan was adopted. It included plans to implement a community-based treatment intervention. The intervention was envisioned to provide services needed to prevent, treat, rehabilitate and reintegrate into the communities, people who use substances. (18) This intervention, the

Community Oriented Substance Use Program (COSUP) was established through the community oriented primary care (COPC) model (20) and aimed to address the reduction of harm caused by substance dependence in the communities of Tshwane.

The COSUP in the City of Tshwane was established in 2016. It offered support in the prevention and treatment of substance abuse in the city through services that addresses substance related risks and harms to all PWUD. (21) The users and recipients of the services were identified from the communities by community healthcare workers during routine household visits. On identification, they would be referred to nearby centers for further assistance and management. The program has done a lot in expanding substance use services available to the communities of Tshwane. It offered various services that included opioid substitution therapy (OST) with methadone and the needle and syringe exchange program.

Methadone is a full opioid receptor agonist with a much longer half-life than heroin. It is the most widely used and researched form of OST used for opioid dependence worldwide (22,23). The main objectives of using methadone therapy are to assist the patient with alleviating severe withdrawal symptoms, preventing relapse and maintenance of abstinence or reduction in the use of illicit opioids thus decreasing the harms associated with illicit substance use (22). Because of its long half-life (120 hours) and consequently the risk of overdose especially in the first two weeks, most guidelines recommend the induction dose of methadone to be 20 – 30 mg, with increases in five to ten milligrams every three to five days (24,25). The COSUP was following the same guidelines (21).

1.2 Literature review

1.2.1 Prevalence and pattern of substance use

Globally, the increasing number of people were found to be suffering from a substance use disorders (6). The prevalence of substance use among the youth and adult population (15-64 years) was estimated at 5.6% in 2016 (26) and 5.5% in 2017 (6), Around tenth of the substance-users develop clinical disorders (27,28). Illicit substance use such as use of cannabis, opioids, amphetamines and cocaine, poses major challenges for the majority of countries. These ranges from public health challenges to international organized crimes, terrorism, human trafficking, money laundering and illicit arms trade (3,29).

The most commonly used illicit substance globally is cannabis with an estimated prevalence of 3.8%. Opioids, amphetamines and cocaine had estimated prevalence of 1.1% ,0.6% and 0.4% respectively (6). Countries in the North America, Oceania, the West and Central Africa region recorded the highest prevalence for cannabis use at 13.8%, 10.9% and 10.0%, respectively (27,30). Cannabis is also a dominant illicit substance of use in South Africa, followed by alcohol (5). Other illicit substances commonly used in SA are crack, cocaine, heroin, opioids, methamphetamines, inhalants and various substance mixes such as a mixture of heroin and cannabis known in South Africa as “Nyaope” (5,6).

Substance use contributes significantly to the burden of diseases (31,32). In 2017, the global burden of disease attributed to alcohol and illicit substance use was 1.5%, measured in disability-adjusted life-years (DALYs) (27,33). The highest attributable DALYs were for tobacco smoking (170.9 million). Alcohol followed at 85.0 million DALYs and the illicit substances at 27.8 million DALYs (27,34). The major contributor to deaths attributed to substance use was opioid use disorders (6,32,33). The United States of America and Canada have seen an increasing number of opioid overdoses in recent years. (28,35)

South Africa and the global community continue to deal with the burdens of alcohol use (5,36,37). Alcohol abuse is found to be associated to burden of road traffic accidents, domestic violence, homicides (38) and disruption of families (39). The South African Police Services annual crime report indicated an increase of 14.8% for

driving under the influence of alcohol and/or drugs (14). Alcohol also contributes indirectly to the burden of communicable diseases such as elevated risk of HIV (40).

It is difficult to understand the true prevalence of substance use in SA, because of paucity of data on substance use. Several studies done estimates the latest prevalence of substance use in SA at 4.4% (41) The previous estimate was 2.17% in 2016 (36,42,43)

1.2.2 Factors correlated with substance use

Multiple factors have been reported as predictors of substance use disorders. Most studies done around the prevalence and predictors of substance use disorders have found SUD to be more prevalent in males and people of a young age (44,45). A South African population-based survey found that demographic characteristics such as male sex, young age and certain ethnic groups (41,46-47), were associated with substance use. In the USA, reports on substance use has shown that the use and abuse of substances begins during the adolescent years (48). Various factors play a role that leads adolescents or young people to start experimenting with substances. Young people constantly struggle with affirming their identity and to define their sense of belonging they may succumb to peer pressure of using substances, at times it might also be to deal with the emotions surrounding the need to define who they are.

The odds of substance use disorders were greater in males than in females, in previously married participants than in currently or never married participants (49). According to the South African demographic and health survey, males are more likely than females to use tobacco and alcohol and females are more likely to use codeine-containing medications (50). This shows that the pattern of use differs not only by environmental context but also by sociodemographic (51). Men suffers from substance dependence more than women. In 2016, 2.4% of men were dependent, versus 1.2% in women (27). Traditionally, males will use the illicit substances while female are more

likely to use substances that are considered to be more socially acceptable such as prescription drugs or alcohol.

There are also social and environmental factors that are associated with substance abuse. Factors such as no or low education levels, unemployment and also instabilities in the family structures, which could lead to some individuals being homeless. Race or ethnicity also has a correlation with substance abuse. The majority of users who were treated for substance abuse in SA were of black race, below the age of 35 years and of male sex. (5) The risk of harm associated with substance abuse was found to be high in males, young age, low educational status, unemployment and in the urban areas. (15,42,43,46,52,53) Other countries, such as, Nigeria are also experience a similar pattern of substance use correlation with demographic characteristics. (54–57)

1.2.3 Associated health consequences of substances use

The negative impact of substance uses include mental health disorders, bloodborne viral infections such as HIV (58) and hepatitis C (59), liver cirrhosis, liver cancer as well as over-dose and premature death. The greatest harms are those associated with parenteral mode of use because of unsafe injecting practices and sharing of contaminated needles and syringes (60,61)

In Africa, the mortality and morbidity attributed to substance abuse, were more related to HIV/AIDS and less with liver cirrhosis or cancer (62). The high prevalence of HIV/AIDS in this population is due to users injecting substances and not ensuring good hygiene practice when injecting and even sharing needles. Data on injecting of substances by PWUD in Africa is limited. Countries in the North Africa have a low prevalence of people who inject substances. Hepatitis C is also highly prevalent among people who inject drugs (PWID), and results in major negative health impacts in PWID (27,60).

1.2.4 Treatment approaches for substances abuse

Access to treatment by people who use, and abuse substance remains low. Traditionally, services for prevention and treatment of substance abuse are offered separately from the existing health care services. In cases, where services are available, they are often limited. Most of the available treatment services in SA and in most countries are private and specialized, which further makes them unaffordable for most of the people who would require them. In addition, they are often offered outside the reach of people who need them, which further increase the challenge of access. This phenomenon existed and persisted because substance use was not seen as a health problem but rather a criminal and social problem.

It has been widely accepted that there is no single strategy that can solve substance abuse problems. Therefore, there is a need for an integrated approach that includes prevention, treatment, rehabilitation and reintegration of users into the communities and systems they were in before the harmful effects of substance dependence. At a primary level of prevention, interventions must be put in place to prevent the initiation of substance abuse or to delay the initiation age. Studies have shown that the early the age of initiation of substance abuse the more likely the user is to encounter problems related to substance use. Therefore, more efforts should be made in ensuring that more awareness about the dangers of substance use, targeted mostly at the youth is created. This can be done at schools and in various platforms where it can reach majority of the young people.

At a secondary level of prevention, programs, such as harm reduction interventions programs, like the COSUP, which target the individuals who have already started using substances, are necessary. There are currently not a lot of these programs and where they exist not everyone who needs them can access them. These program aims at reducing the degree of harm to the individual.

Supply reduction has been the predominant strategy in dealing with substance use problems (26) The World Health Organization (WHO) and the United Nations Office on Drugs and Crime (UNODC) recommended a transition to harm reduction as an approach to address the risks of substance use. There is, therefore, a need for effective integration of substance use services in the health care system. Such integration in SA falls in line with what the National Health Insurance seeks to achieve which is universal access to health care services for all of its citizens (63). The integration would ensure that PWUD are better served and it will also reduce the disparities in the health outcomes for the population of substance users (60).

Treatment interventions must be evidence-based, and it must be voluntary, unlike what has been seen in the past with some Asian countries, where they implemented compulsory substances detention centers under the pretext of treatment or rehabilitation but PWUD gets confined without their consent or any clinical evaluation (6). In order for the treatment interventions to be effective, services must meet the requirements of the users taking into consideration the levels of severity of the substance use disorders and harm from the use of substances (64). Effective treatment incorporates many components such as community outreach services, screening and brief interventions, primary health care outpatient and hospital inpatient treatment, evidence-based pharmacological treatment, psychosocial interventions and rehabilitation services (65). The preventative measures to be taken should ensure that the people at risk of harm secondary to substance abuse are identified early and the relevant counseling interventions are provided. Primary prevention

1.2.5 Screening tests for Alcohol, Smoking and Substance Involvement

Incorporated in the effective management of substance use is screening and interventions that are linked to the measured risk. Screening is a public health intervention that aims to reduce the harm caused by a disease or its complications.

Harmful and hazardous use of substances often leads to the development of substance use disorders. Studies have shown the benefits of screening, brief intervention and referral to treatment (SBIRT) for substance use disorders for individuals at risk of developing the disorder as well as those who have already developed the disorder (66). In addition, SBIRT can be adapted for use in various clinical care settings, such as hospital emergency, community and primary care clinics (67).

Effective implementation of SBIRT would require toolkits. After the success of implementing the use of the Alcohol Use Disorders Identification Test (AUDIT) in all health care settings, which includes identification and referral for interventions people with harmful and hazardous use of alcohol, the WHO saw the need to have a similar screening tool that can be used in all settings for licit and illicit substances. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (68) was developed in response to the major global challenge of illicit substance use. It is designed for use in all settings but preferably in the primary health care setting, where substance use can be missed. (69) The tool is used to screen for the following category of substances: (Table 1.1)

Table 1. 1 Category of substances used in the ASSIST score

Tobacco
Alcohol
Cannabis
Cocaine
Amphetamine-type stimulants (ATS)
Sedatives and sleeping pills (benzodiazepines)
Hallucinogens
Inhalants
Opioids

A set of questions relating to the: a) lifetime use of substances, and b) current use of substances over the last 3 months are posed to the substance user (69) The

responses to the questions are used to formulate a risk score that determines the level of harm associated with use of a specific substance.

Table 1. 2: Response and the scores (69)

Past three months (ASSIST questions 2 to 5)		Score
Never	not used in the last 3 months	0
Once or twice	1 to 2 times in the last 3 months	2
Monthly	average of 1 to 3 times per month over the last 3 months	3
Weekly	1 to 4 times per week	4
Daily or almost daily	5 to 7 days per week	6
Lifetime (ASSIST questions 6 to 8)		
No	never.	0
Yes	but not in the past 3 months.	3
Yes	in the past 3 months.	6

The calculated score is used to identify problems that could be associated with substance use. (69) The risk categorization further assists in determining the appropriate interventions as shown in Figure 1.1.

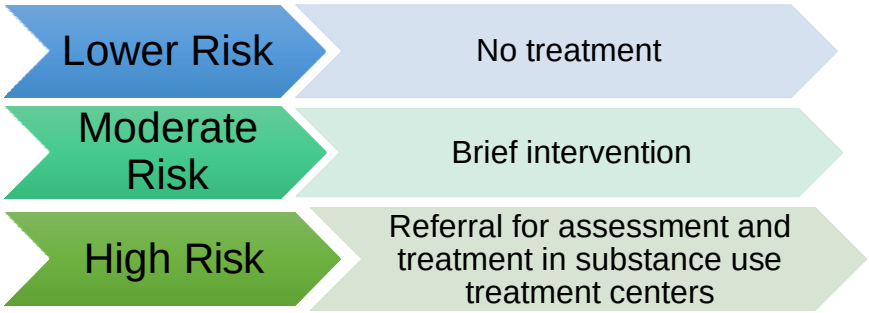


Figure 1. 1: ASSIST risk categories

Few studies have been done to show the efficacy of the ASSIST-linked interventions (70). Findings from a randomized controlled trial in Australia, Brazil, India and the

United States revealed that users across all four countries, significantly reduced the ASSIST total illicit substance involvement scores after receiving the brief intervention. The findings provided the evidence for the effectiveness of an ASSIST-linked brief intervention in reducing the substance-related risks of harm (71). This study is planned to explore this in a South African setting.

1.3 Problem statement

There is a growing public health challenge related to the substance use problem in SA. Despite the growing body of research in the field of substance use, more data is still needed about the prevalence and predictors or correlates of substance use disorders. There is an increasing burden of SUD but access to treatment and prevention services remains a huge challenge. Treatment for substance use in SA is still largely specialized, costly and geographically inaccessible for most people who need it. The legislative control for substance use provides for the adoption and implementation of harm reduction as an approach to combat the negative impacts of SUD across all settings. Despite these provisions, implementation of harm reduction and the integration of substance use treatment services within the existing health care system remains a challenge.

The evidence from the available data showed that there are differences in the patterns, extend and consequences of substance abuse in different areas and communities across the country led to the question of how different the dynamics of substance use among the communities of the City of Tshwane are, with respect to the sociodemographic and prevention and treatment services available to them.

1.4 Significance of the study

This study was planned to document the demographic characteristics of the subjects enrolled for treatment at the COSUP treatment centers in the City of Tshwane during the study period. It further explored the association between demographic

characteristics of the subjects and the harm related to substance abuse. Lastly it sought to address the efficacy of the intervention by assessing the change in the risk scores using the ASSIST questionnaire. The change in the ASSIST risk scores from having high scores to moderate or low scores following the harm reduction intervention, opioid substitution therapy, could mean that there has been a reduction in the harm associated with substance abuse in those subjects.

It is envisaged that this study will contribute data that would fill the information gap on the dynamics of the substance abuse problem in the City of Tshwane through the addition of data on the demographic characteristics of PWUD within the communities of Tshwane. Currently there is scarcity of data that describes the demographics of people who use drugs and providing the description of the subjects that visited COSUP for treatment will assist in closing the information gap. It will also seek to demonstrate the efficacy of a community-based harm reduction intervention mainly opioid substitution therapy (OST) with the use of methadone. This outcome will assist in motivating for the use of methadone in the primary care level settings. A number of PWUD cannot afford going to rehabilitation centers and by using methadone as an opioid substitution may assist in alleviating the harm associated with the abuse of opioids and also assist those who desire to quit using drugs to be able to do so without suffering the withdrawal symptoms.

The study will add knowledge on what the City of Tshwane has done in addressing the substance abuse problem and may present recommendations for policy change relating to the implementation and integration of the COSUP model within the existing district health system's platforms for service delivery.

1.5 Aim and Objectives

The aim of the study was to determine the levels of risk of harm associated with substance use, using the ASSIST scores for subjects enrolled in COSUP, in the City of Tshwane, during the period of December 2016 to September 2018, and determine

the demographic characteristics that might be associated with the levels of risk and changes in the ASSIST risk scores. The specific objectives of the study were:

1. To describe the demographic characteristics of subjects enrolled in COSUP during the study period
2. To determine the level of risk of harm associated with substance use by these subjects using the WHO ASSIST risk scores
3. To assess the association between the demographic characteristics of subjects and the level of risk as determined by the ASSIST risk score at the time of enrolment.
4. To describe the pattern of substance use among subjects at the time of enrolment.
5. To compare the ASSIST risk scores of these subjects at enrolment and follow-up visit post-intervention.

1.6 Structure of the research report

The background to the research has been outlined and discussed in this chapter, followed by the literature review, problem statement and objectives. Chapter two outlines the study methodology. It describes the research methodology which includes the study design, setting and the techniques used for data management. Chapter three presents the results from the analysis of data collected in relation to the aim and objectives of the study. Chapter four provides the discussion of the findings in line with the study objectives and findings from the review of the literature. The last part of the report, chapter five presents the conclusions from the findings of the study related to the objectives of this study, recommendations and also highlights areas for further research in the field of substance abuse.

CHAPTER 2: RESEARCH METHODOLOGY

The methodology for this study was selected on the basis of its aims and objectives. In this chapter the following were discussed: setting, scope, and study design data sources and statistical analysis approach.

2.1 Study setting and scope

This study is a secondary data analysis of the Community Oriented Substance Use Program (COSUP) data set of subjects who were enrolled in the program for harm reduction services. The COSUP was offering substance use harm reduction and opioid substitution therapy (OST) to people who use drugs (PWUD). OST is the medical intervention of replacing an illicit opioid substance such as heroin or nyaope with a longer acting but less euphoric opioid, such as methadone (21)

The COSUP pilot project took place in the City of Tshwane Metropolitan Municipality, which is situated in Gauteng Province of South Africa. Tshwane has a population of 3 275 152, 69% of which are between the ages of 15 – 64 years and a male to 100 female ratio of 98.5. The City of Tshwane's population is predominantly black African population that represents 2,2 million people, followed by a White population at approximately 600000 people, then the Colored and Asian populations at 59166 and 51547 people, respectively. About 37% of the population of Tshwane is classified as youth. (27,72).

The COSUP was embedded in the existing Tshwane Health District platforms such as clinics and hospitals, also in collaboration with social development services. Tshwane Health District comprises of seven health sub-districts, health sub-district one to sub-district seven according to the seven regions of the City of Tshwane Metropolitan Municipality. (Figure 1.1) The COSUP established a 17 treatment centers in four of these sub-districts, sub-district one, three, four and six.

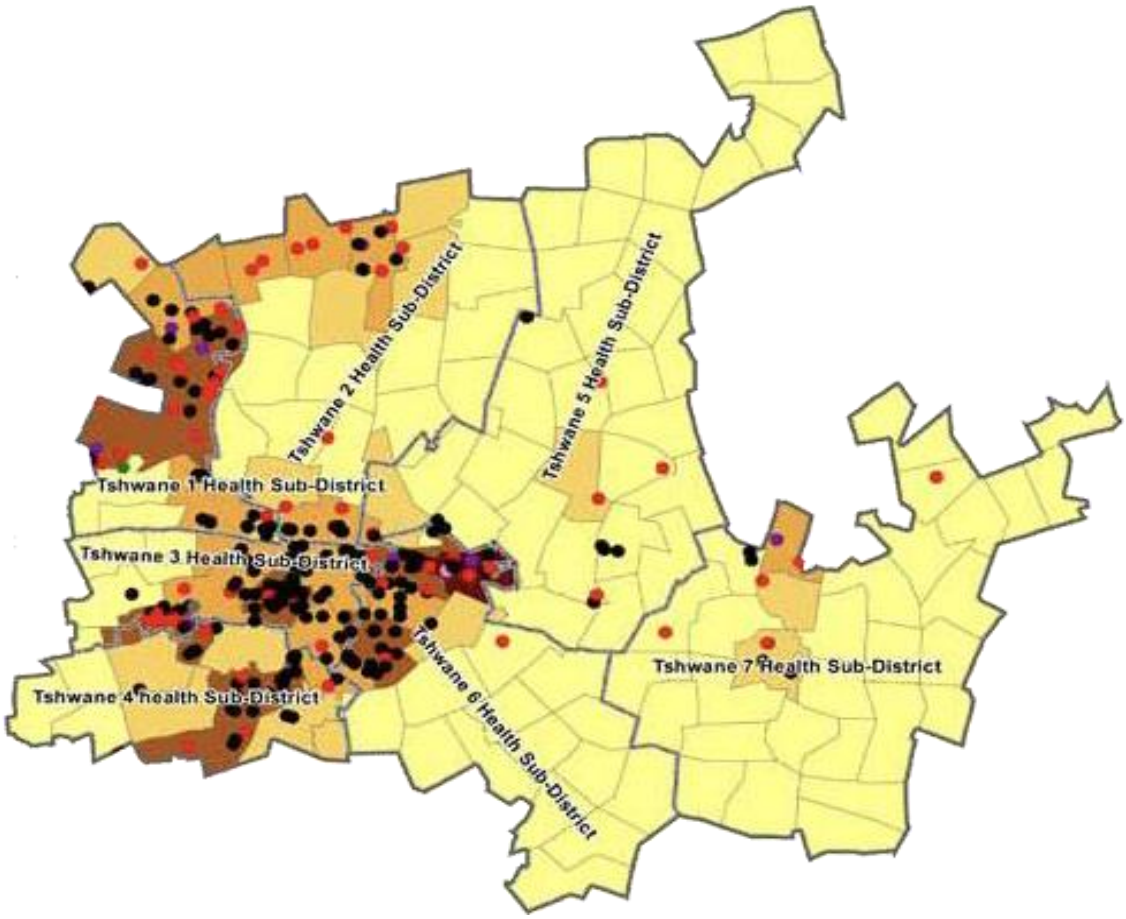


Figure 1. 2: Map of the Tshwane with health sub-districts

These centers offer comprehensive services for people who use drugs (PWUD). Services includes harm reduction through opioid substitution therapy for people using opioids, heroin or nyaope and the needle syringe exchange services. The objective of COSUP was to prevent, treat, rehabilitate and reintegrate people affected by the use of alcohol and other illicit substances such as opioids and heroin.

2.2 Study design

In this study the data used were from a secondary source, the COSUP electronic health information database. The study assessed data collected at the time of enrolment into COSUP and at three-months follow-up time from enrolment. In addition,

assessment of the changes in ASSIST risk scores collected at enrolment and at three months to demonstrate changes in the level of risk of harm.

The study has two components:

- The section one of the study focused on the first four objectives of the study. A cross-sectional study design was used to retrospectively analyze data collected from the subjects at the time of enrolment.
- The following section focused on the fifth objective of the study using data collected at the time of follow-up visits of these subjects which were analyzed and compared with the data obtained from these subjects at the time of enrolment.

2.3 Study population and sample

The study population comprised of all subjects that were enrolled for opioid substitution therapy in the period December 2016 to September 2018, therefore there was no sampling done. In the time period of the study, a total of 805 subjects had enrolled for opioid substitution therapy in the COSUP. Therefore, the sample size for objectives one to four was 805.

The objective five focuses on the comparison of the ASSIST risk scores of the subjects at enrolment and at follow-up visit post-intervention. Two hundred and fifty subjects (31%) returned for follow-up visit at three months from the time of enrolment.

The inclusion criteria for COSUP was any person who use substances (PWUD) and seeking services to reduce the substance-related risk of harm. For this study, the exclusion criteria were any COSUP subjects not enrolled for opioid substitution therapy.

2.4 Procedure

Subjects who presented at the COSUP treatment centers were evaluated by the clinical associates. Clinical Associates are mid-level health care providers who plays a role in the provision of primary health care. They were trained by the COSUP team leaders on harm reduction and how to support subjects who were on opioid substitution therapy (OST). The evaluation included history taking, recording of the demographic data, substance use history and a physical assessment on all subjects to elicit eligibility for OST. The demographic, clinical and substance use history were recorded in the medical files and subsequently captured on the electronic data system, Synaxon. Synaxon captures all the health records data of subjects enrolled in COSUP across all the treatment centers. Synaxon is a clinical care knowledge management system that enables seamless integration between health management organizations and provider partners (21).

The WHO Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) questionnaire version 3.0 (69) was used to measure the specific substance involvement risk scores and determine the level of risk of harm for each substance the subjects used. Based on the level of risk of harm, low, moderate or high risk, the subjects would receive a brief intervention or referred for further assessment and initiation of OST by a medical doctor.

a. Intervention

Subjects enrolled for opioid substitution therapy (OST) received methadone treatment at a standard initial dose of 20 mg daily taken orally. Direct observation of treatment and review of symptom was done daily for two weeks. The dosage would be adjusted accordingly in the DOT period until a maintenance dose was reached which was between 50 and 120 mg. When stable on the prescribed dose, follow up assessment would then be done at three months and the ASSIST risk score assessment repeated to measure the level of risk of harm. The subjects were also offered psycho-social support given by the social workers on the first consultation and as necessary while in the program.

b. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)

The ASSIST is a score-based screening tool used to determine and classify the substance user's risk of harm associated with the use of a particular substance. The tool was administered at the time of enrolment and at the three-months follow-up visit. The WHO ASSIST version 3.0 questionnaire was used, and the following question asked:

Table 2. 1 ASSIST v 3.0 Questions

Question 1	In your life which of the following substances have you ever used?
Question 2	In the past 3 months how often have you used the substances you mentioned?
Question 3	During the past 3 months how often have you had a strong desire or urge to use (drug)?
Question 4	During the past 3 months how often has your use of (drug) led to health, social, legal or financial problems?
Question 5	During the past 3 months how often have you failed to do what was normally expected of you because of your use of (drug)?
Question 6	Has a friend or relative or anyone else ever expressed concern about your use of (drug)?
Question 7	Have you ever tried to cut down or stop using (drug) but? failed?
Question 8	Have you ever used any drug by injection?

Each question is allocated a numerical score based on the response. The scores for questions two to seven are then added together to make a specific substance involvement score (referred to in this study as the 'substance ASSIST risk score'). This was done for any substance of use. (tobacco, alcohol, cannabis, cocaine,

amphetamine-type stimulants, inhalants, sedatives/sleeping pills, hallucinogens, opioids and 'other' substances) Once a substance ASSIST risk score was determined, the scores were categorized into three levels of risk as follows:

Table 2. 2 ASSIST Risk categories and scores

Risk categories	Scores	
	Alcohol	All other substances
Lower risk	0-10	0-3
Moderate risk	11-26	4-26
High risk	27+	27+

Responses to question eight determines the risk of harm associated with injecting of substances.

2.5 Data Management

2.5.1 Data collection

All the data of subjects, demographic data, the ASSIST risk scores, dose of methadone was captured into the electronic information system, Synaxon. A data extraction tool was designed using MS Excel (Appendix 1) for the extraction of the data from Synaxon ®. Data was extracted using the subject's COSUP study number. All available demographic variables were extracted, age, sex, marital status, ethnicity as well as data on the mode of substances use, dose of the methadone treatment and the ASSIST risk scores captured at enrolment and at the three-months follow-up visit. Data extracted into the MS excel spreadsheet was then exported into StataIC 15.1 ® (73) for merging, cleaning, and analysis.

2.5.2 Data analysis

In this study some variables were recoded to facilitate analysis and to make interpretation meaningful.

2.5.2.1 Description of Variables

i. Independent Variables

The independent variables comprise the demographic characteristics of the subjects, which are essentially the background variables that predict risk of harm of substance use. It is expected in this study that these variables, as defined in Table 2.1, are associated with the outcome under study.

Table 2. 2 The variable list

Variable description	Type
Age	Categorical groups of ten years each from 15 - 24 years up to 45 - 54 years then 55+ years
Sex	Categorical - male or female
Marital status	Categorical - married, single and separated. 'Separated', was made up by all who were separated, divorced and widowed.
Ethnicity	Categorical - Black, Colored, White, and Indian.
Dose	Continuous

ii. Outcome Variables

The primary outcome variable was the change in the opioid ASSIST risk score from the time of enrolment to the three-months follow-up.

A descriptive analysis was done on the total population at enrolment. The continuous variable (such as age) was described using the mean and standard deviation, when

normally distributed; in other cases, median and inter-quartile range were used. Categorical variables were described using proportions and percentages. Descriptive analysis was used to demonstrate the extent of harmful and hazardous use of substances in the subjects that were enrolled in COSUP and to describe the population under study.

A univariate and multivariate analysis was used to assess the association between the demographic variables, the dose of methadone and the change in the opioids ASSIST risk score. Pearson residuals would be calculated which are defined as the standardized difference between the observed frequency and the predicted frequency (73). They measure the relative deviations between the observed and fitted values.

To identify the demographic characteristics that might be associated with the change in opioid ASSIST risk score between the time of enrolment and the three-months follow-up visit, a univariate and multivariate logistic regression models were used, and the association quantified using crude and adjusted odds ratios with associated confidence intervals.

2.6 Ethical Considerations

Ethical approval for the study (M190747) was granted by the University of the Witwatersrand Human Research Ethics Committee (WHREC). Permission for data utilization was given by the chairperson of the COSUP-COPC Research Unit, University of Pretoria.

To maintain confidentiality, data were extracted from the COSUP database without any details that could reveal the identity of the subjects. Only study numbers were used. The study data were kept in a secure, password-protected computer and all excel spreadsheets were password-protected. Only the aggregate data are presented,

and no subjects' names or other identifying information was used in any publication coming out of the study.

2.7 Study limitations

The analysis of data to answer the research question was restricted to characteristics identified in the literature that are available in the data set. The other limitation with this study was that no diagnosis was assigned to the substance user, which makes it difficult to determine the effect of the intervention on any specific diagnostic category. The quality of data such as inconsistencies in recording some variables may affect the results of the study.

2.8 Study strengths

The study contributed data to the information gap on the nature and extend of substance use in communities of the city of Tshwane. It also adds information on the use of the screening tool, ASSIST in the primary care settings. To my knowledge this study is one of the few in South Africa to evaluate the efficacy of a community-based harm reduction intervention using the ASSIST risk scores, and it could provide useful information that can help guide the implementation of harm reduction interventions for substance use in the primary care settings as well as promote the screening of substance use with the WHO ASSIST tool.

CHAPTER 3: RESULTS

The results obtained from the data analysis are described in this chapter.

3.1 Introduction

Section 3.2 presents a summary of demographic characteristics of the subjects at enrolment. The research addressed the following key variables namely: demographic characteristics including age, sex, marital status, and ethnicity. In sections 3.3 and 3.4 respectively, the pattern of substance use by the subjects and the ASSIST risk scores for all types of substances used by subjects at enrolment are presented. Furthermore, the results from models assessing associations between the demographic characteristics and the ASSIST risk scores as well as the comparison of the opioid ASSIST risk scores at baseline and follow up are presented in sections 3.5 and 3.6 respectively.

I. First visit

3.2 Demographic characteristics of subjects at enrolment

Table 3.1 presents the demographic characteristics of the COSUP subjects (n= 805) at time of enrolment. Age of the subjects is normally distributed (Figure 3.1); the mean age of the subjects at time of enrolment was 31$\pm$ 6.4 years, Males were 91,2% (n=734) with majority of the total number of subjects, 79.8% (n=647) single and 85,6% (n=689) of the subjects being black.

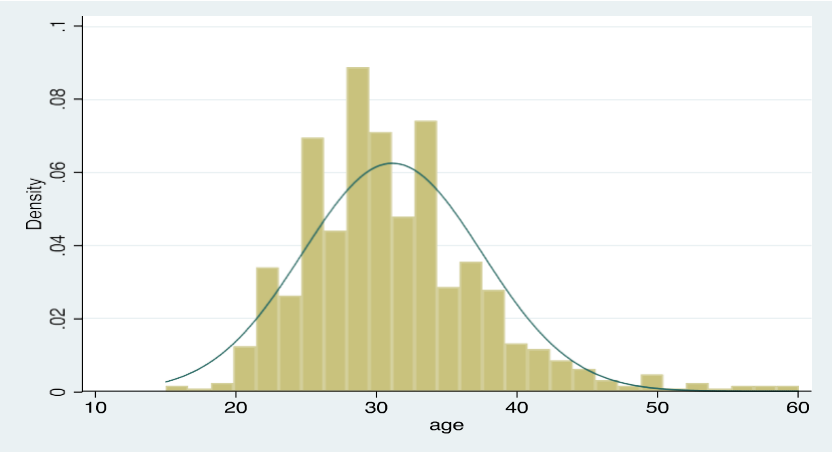


Figure 3. 1: Age distribution of the subjects (n= 805)

Table 3. 1: Baseline characteristics

Variables	N (805)	%
Sex		
Male	734	91.2
Females	71	8.8
Age (years)		
15-24	100	12.4
25-34	512	63.6
35-44	168	20.9
45-54	18	2.2
>55	7	0.9
Marital status		
Married	21	2.6
Single	647	79.8
Separated	7	0.86
Ethnicity		
Black	689	85.6
White	57	7.1
Colored	42	5.2
Indian	14	1.7
Others	3	0.4

3.3 Determining the level of risk of harm associated with substance use using the ASSIST scores

The total sample (n=805) was used in this analysis and the lower risk scores included the score of zero which means that subjects didn't use the substance in the last three months before the screening or they were not using the substance at all. The proportion of subjects who used opioids (74.5%, n=607) were at high risk of harm with 5.1% (n=41) at moderate risk. The remaining proportion of opioid users, 19.5% (n=157) had lower risk of harm. For tobacco users, 16.1% (n=130) were at high risk with the majority of users (63,9%, n=514) at moderate risk of harm while 19.9% (n=161) were at lower risk. Subjects who used cannabis, 25.6% (n=206) and 28.8% (n=232) had high and moderate risk of harm, respectively, with 45,6% (n=367) having lower risk of harm. The majority of subjects, who used cocaine (82.7%, n=666), amphetamine (96,5%, n=777), inhalants (99.0%, n=797), sedatives (98%, n=789) and hallucinogen (99.6%, n=802), had lower risk of harm associated with the use of each of the substances. Table 3.2 presents the risk categories based on the ASSIST scores for all substances used by subjects at the time of enrolment.

Table 3. 2 ASSIST scores risk categories at time of enrolment

Substance assessed	Risk categories (ASSIST scores)	n= 805	%
Tobacco	Lower risk (0-3)	161	19.9
	Moderate risk (4-26)	514	63.9
	High risk (27+)	130	16.1
Alcohol	Lower risk (0-10)	724	89.9
	Moderate risk (11-26)	56	7.0
	High risk (27+)	25	3.1
Cannabis	Lower risk (0-3)	367	45.6
	Moderate risk (4-26)	232	28.8
	High risk (27+)	206	25.6
Cocaine	Lower risk (0-3)	666	82.7
	Moderate risk (4-26)	80	9.9
	High risk (27+)	59	7.3

Substance assessed	Risk categories (ASSIST scores)	n= 805	%
Amphetamines	Lower risk (0-3)	777	96.5
	Moderate risk (4-26)	16	2.0
	High risk (27+)	12	1.5
Inhalants	Lower risk (0-3)	797	99.0
	Moderate risk (4-26)	7	0.9
	High risk (27+)	1	0.1
Sedatives	Lower risk (0-3)	789	98.0
	Moderate risk (4-26)	12	1.5
	High risk (27+)	4	0.5
Hallucinogens	Lower risk (0-3)	802	99.6
	Moderate risk (4-26)	1	0.1
	High risk (27+)	2	0.3
Opioids	Lower risk (0-3)	157	19.5
	Moderate risk (4-26)	41	5.1
	High risk (27+)	607	75.4

3.4 The association between demographic characteristics of subjects and the level of risk of harm of substance use at the time of enrolment.

Moderate and high levels of risk of harm was found to be more in males ($p<0.05$) and in the black race ($p<0.05$) (Table 3.3).

Table 3. 3: Associations between demographic characteristics and the moderate to high levels of risk of harm of substance use

Variables	Moderate and high levels of risk of harm with any substance use	X^2	P-value
Sex			
Male	611 (83.5)	4.4	0.035
Females	53 (73.6)		
Age (years)			
15-24	85 (85.0)	1.5	0.811
25-34	424 (82.8)		

Variables	Moderate and high levels of risk of harm with any substance use	X^2	P-value
35-44	134 (80.2)		
45-54	16 (88.9)		
>55	4 (80.0)		
Marital status			
Married	21 (100)	2.5	0.468
Single	607 (94.0)		
Separated	6 (85.8)		
Ethnicity			
Black	578 (84.0)	11.67	0.02
White	39 (68.4)		
Colored	32 (76.2)		
Indian	13 (92.9)		

3.5 Pattern of substance use among subjects at the time of enrolment.

Opioids, tobacco, cannabis and alcohol were the substances used by most subjects. The proportion of opioid use (opiates, heroin, and nyaope) was 80.8% (n=650) followed by tobacco (80.6%, n=649), cannabis (57.3%, n=461), alcohol (32.6%, n=262), cocaine (20%, n=161), amphetamine-type stimulants (5.0%, n=40), sedatives (2.7%, n=22), inhalants (1.1%, n=9) and ‘hallucinogens (0.8%, n=6) as seen in Table 3.4. For any use of substances, 82.8% (n=424) of subjects were between the ages 25-34 years.

Table 3. 4: Type of substances used (n=805)

Variables	Any use of substances n* (%)	Tobacco n* (%)	Alcohol n* (%)	Cannabis n* (%)	Cocaine n* (%)	Amphetamine n* (%)	Inhalants n* (%)	Sedatives n* (%)	Hallucinogen gens n* (%)	0pioids n* (%)
ALL		649 (80.6)	262 (32.6)	461 (57.3)	161 (20.0)	40 (5.0)	9 (1.1)	22 (2.7)	6 (0.8)	650 (80.8)
Sex										
Male	611 (83.5)	600 (81.9%)	242 (33.0%)	430 (58.7%)	145 (19.8%)	35 (4.7%)	8 (1.1%)	16 (2.2%)	6 (0.8%)	598 (81.6%)
Females	53 (73.6)	49 (68.1%)	20 (27.8%)	31 (43.1%)	16 (22.2%)	5 (6.9%)	1 (1.39)	6 (8.3%)	0 (0%)	52 (72.2%)
Age (years)										
15-24	85 (85.0)	84 (84%)	33 (33%)	54 (54%)	22 (22%)	7 (7%)	1 (1%)	3 (3%)	0 (0%)	84 (84%)
25-34	424 (82.8)	416 (81.3%)	171 (33.4%)	303 (59.2%)	104 (20.3)	26 (5.1%)	6 (1.2%)	10 (2%)	6 (1.2%)	413 (80.7%)
35-44	134 (80.2)	128 (76.7%)	53 (31.6%)	91 (54.2)	28 (16.7%)	6 (3.6%)	1 (.6%)	7 (4.2%)	0 (0%)	134 (79.8%)
45-54	16 (88.9)	16 (88.9%))	3 (16.7)	11 (61.1%)	6 (33.3%)	1 (5.56)	1 (5.6%)	1 (5.56%)	0 (0%)	14 (77.8%)
>55	4 (80.0)	3 (60%)	1 (20%)	1 (20%)	1 (20%)	0 (0%)	0 (0%)	1 (20%)	0 (0%)	4 (80%)
Marital status										
Married	21 (100)	21 (100%)	8 (38.1%)	11 (52.4%)	5 (23.9%)	2 (9.52	0 (0%)	3 (14.3%)	0 (0%)	21 (100%)
Single	607 (94.0)	592 (91.6%)	240 (31.1%)	429 (66.3%)	145 (22.4%)	36 (5.6%)	8 (1.24)	19 (2.9%)	^ (0.9%)	593 (91.7%)
Separated	6 (85.8)	6 (85.7%)	2 (28.6%)	5 (71.4%)	4 (57.1%)	0 (0%)	0 0%)	0 (0%)	0 (0%)	6 (85.7%)
Ethnicity										
Black	578 (84.0)	565 (82.1%)	230 (33.4%)	407 (59.1%)	133 (19.3%)	19 (2.8%)	6 (0.9%)	13 (1.9%)	5 (0.7%)	564 (81.86%)
White	39 (68.4)	37 (64.9%)	16 (28.1%)	21 (36.8%)	8 (14.0%)	7 (12.3%)	1 (1.8%)	6 (10.5%)	0 (0%)	39 (68.4%)
Colored	32 (76.2)	31 (73.8%)	14 (33.3%)	24 (57.1%)	11 (26.2%)	14 (33.3%)	1 (2.4%)	2 (4.8 %)	1 (2.4%)	32 (76.2%)
Indian	13 (92.9)	13 (92.9%)	1 (7.1%)	2 (66.7)	8 (57.1%)	0 (0%)	1 (7.14%)	1 (7.14)	0 (0%)	13 (92.9%)

*multiple responses

More than three-quarters (81.9%) of subjects were polysubstance users. Table 3.5 shows that 35% (n=281) of subjects used three types of substances at once.

Table 3.5: Number of substances used (n = 805)

Number of substances used	n	Percentage
1	146	18.1
2	103	12.8
3	281	35
4	187	23.2
5	68	8.5
6	18	2.2
7	1	0.1
8	1	0.1

At the time of enrolment 44.6% of the total number of subjects used substances by injection while the rest of the subjects (55.4%) used other routes of administration such as smoking, snorting, inhaling or ingestion (see Table 3.6).

Table 3.6: Route of use for the type of substance (n=805)

Type of substances	Total Users	Injection		Others route smoking, snorting, inhalation, ingesting	
	n*	n	%	n	%
Tobacco	649			649	80,6
Alcohol	262			262	32,6
Cannabis	461	169	36,7	292	63,3
Cocaine	161	70	43,5	91	56,5
Amphetamines	40	23	57.5	17	42.5
Inhalants	9	4	44,4	5	55,6
Sedatives	22	14	63,6	8	36,4
Hallucinogens	6	4	66,7	2	33,3
Opioids	650	286	44	364	56
Others	6	4	66,7	2	33,3

II. Follow-up visits

3.6 Comparing opioid use ASSIST risk scores at enrolment and follow up

The COSUP program was giving all subjects using opioids a substitution with methadone treatment. The dosages were between 20 – 30 mg at initiation and could increase up to the maximum of 100 mg for maintenance. This section presents the results of the comparison made between the ASSIST risk scores for opioid use at enrolment and at three-months follow-up. The doses were optimized for each client within the range of 20 – 30 mg at initiation and 60 – 120 mg for maintenance. Two hundred and fifty (31%) subjects came for the follow-up visit at three months from the time of enrolment.

3.6.1 Demographic characteristics of subjects at follow-up visit

The demographic characteristics of these subjects (n=250) are presented in Table 3.7. The demographic characteristics of this cohort were similar to the cohort of subjects enrolled at the start of the program. (See Table 3.7)

Table 3. 7: Demographic characteristics of subjects at follow-up

Variables	N (%)	%
Sex		
Male	224	90
Females	25	10
Age (years)		
15-24	25	10.0
25-34	157	63.1
35-44	56	22.5
45-54	10	4.0
>55	1	0.4
Marital status		
Married	9	3.6
Single	235	94.0

Variables	N (%)	%
Separated	4	1.6
Ethnicity		
Black	209	83.6
White	19	7.6
Colored	16	6.4
Indian	6	2.4

3.6.2 Changes in the ASSIST risk scores for opioid use

Comparison was done for the ASSIST risk scores of the subjects at the time of enrolment and follow-up visits. There was a significant decline in total ASSIST scores for opioid-use from baseline (at enrolment) to follow-up visit (paired t-test, ($p<0.0001$).

Table 3. 8: ASSIST score for opioid use at enrolment and at follow-up

Level of risk	At enrolment (n=250)	At three-months follow-up (n=250)
Lower risk (0-3)	27	44
Moderate risk (4-26)	19	99
High risk (27+)	204	107

* SD – standard deviation

3.6.3 The predictors of change in the ASSIST levels of risk for opioid use

A univariate logistic regression models were used to assess factors that may be significantly associated with the decline in opioids risk scores between the baseline (at enrolment) and follow-up and are reported in the Table 3.7. In univariate models, demographic characteristics factors that were significantly associated with the reduction of the ASSIST scores for opioids were being married and with regards to the intervention, the dose of the opioid substitution treatment, methadone, administered was significantly associated with the reduction. Sex, age, and ethnicity did not explain the reduction in the scores.

Adjusting for the selected factors from univariable models (dose of methadone, married) and including sex and ethnicity as a priori variables in a multivariable model, only married and the dose, significantly explained the reduction in ASSIST scores between baseline (at enrolment) and follow-up visit. A reduction in ASSIST scores for subjects, who were married was 11.90 times the odds [95% CI (1.30 – 108.20)] of reporting a reduction in ASSIST scores for those who reported to be single at baseline. This result was statistically significant ($p<0.05$). Furthermore, an increase in treatment dose was associated with reduced odds of reporting a reduction in scores between baseline and follow-up visit [OR=0.98, 95% CI (0.95 – 0.99), p=0.03]

Table 3.9: Factors that might influence changes in opioid-use level of risk at enrolment and follow-up

	Univariate models		**Multivariable models**	
	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	Adjusted p-value
Sex				0.72
Male	1		1	
Female	0.95 (0.40 – 2.21)	0.91	0.84 (0.34 – 2.10)	
Age (years)				
15-24	1		1	
25-34	0.72 (0.29 – 1.77)	0.48	0.70 (0.29 – 1.80)	0.46
35-44	0.67 (0.25 – 1.82)	0.44	0.51 (0.18 – 1.41)	0.19
45-54	0.56 (0.13 – 2.41)	0.44	0.37 (0.07 – 1.83)	0.22
Marital status				
Single	1		1	0.04
Married	9.25 (1.13 – 75.11)	0.03	11.90 (1.30 – 108.20)	
Separated	0.38 (0.04 – 3.75)	0.41	0.55 (0.05 – 5.71)	
Ethnicity				
Black	1		1	0.54
White	0.61 (0.23 – 1.62)	0.32	0.60 (0.21 – 1.70)	
Colored	0.82 (0.29 – 2.27)	0.70	0.84 (0.30 – 2.35)	
Indian	1.04 (0.20 – 5.32)	0.95	0.52 (0.08 – 3.58)	
Methadone Dose (continuous)				
	0.98 (0.96 – 0.99)	0.05	0.98 (0.95 – 0.99)	0.03

Therefore, there are two factors (married and methadone dose) which significantly explained the reduction in ASSIST scores between baseline (at enrolment) and follow-up visit. Subsequently, Pearson residuals were calculated to measure the relative deviations between the observed and fitted values based on the findings from the multivariate analysis. The opioid outcomes are plotted in X axis and residuals in the Y axis (Figure 3.2).

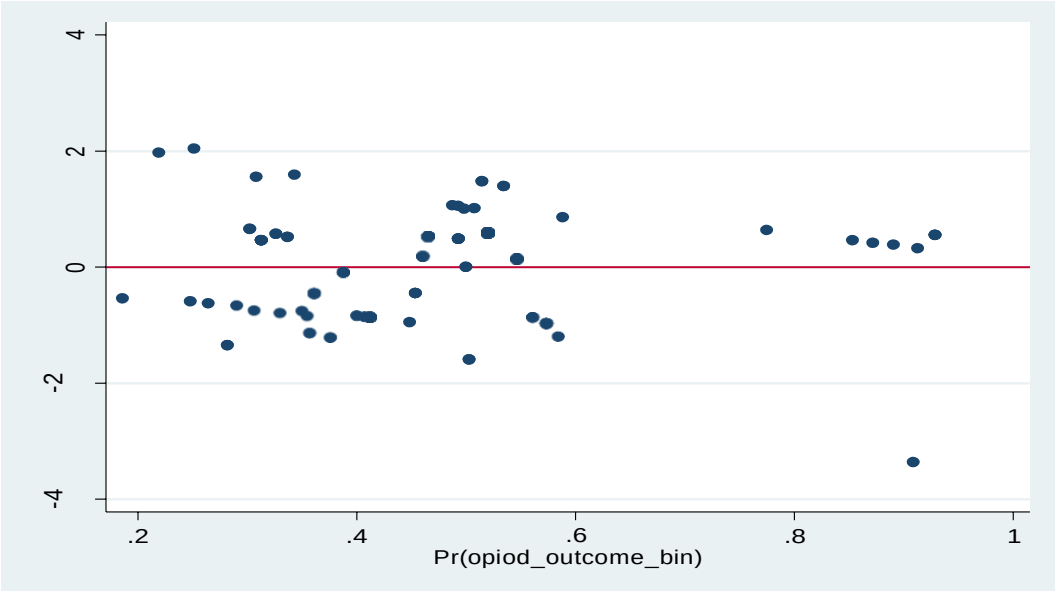


Figure 3.2: Residual plot (n= 805)

The above plot shows how data points are more spread making it easier to see extreme observations as included in the models. The majority of the observations that are close together with most of the other observations with no point requiring particular attention as most of the residuals are small and within an acceptable range. As such the fitted logistic regression model described above is of acceptable fit as assessed using the residual plots.

CHAPTER 4: DISCUSSION

In this chapter, the results obtained from the analysis of the data were discussed and compared with those from other published studies.

4.1 Introduction

This study was conducted in an urban health district with a purpose of determining the levels of risk of harm associated with substance use, and the change in the ASSIST risk score for opioid use by subjects enrolled in COSUP during the study period. In addition, demographic characteristics that might be associated with the levels of risk of harm of substance abuse were analyzed and the changes in the ASSIST scores.

4.2 Demographic characteristics of subjects enrolled in COSUP during the study period

The study found that substance use was associated with male sex, younger age, black race and being identified as single. These findings are in line with those of Peltzer and Ramlagan (43), and reports by the South African community epidemiology network on drug abuse (74), also reported that the demand for substance use treatment in the period between July – December 2017 was by males and the youth. Other studies (57) showed that using substances can be related to social roles where men would be much more likely than women to drink alcohol and use illicit drugs recreationally, while women were more likely to abuse prescribed substances.

A South African study found the use of substance being fairly prevalent among the youth and more frequent in male youths. They also found that their use of substances was taking place in uncontrolled social situations and under social pressures (47). These findings are also consistent with the national population survey study on illicit

substances in SA (53) and the reports on the demand of treatment, (5) both these studies reported that substance use was more prevalent in males and the youth.

Studies on substance use in South Africa showed that youth especially black youth, reported the use of substances and it was related to peer pressure and drinking for enjoyment (47,75). The theory of primary socialization (76) has shown the influence of peers, schools, and parents on youth substance use behavior. The study by Meghdadpour Sian et al, found that the odds of consuming alcohol by male youths increased when they have travelled out of town (77).

4.3 Level of risk associated with substance use by these subjects using the ASSIST risk scores from the WHO ASSIST questionnaire

The finding of the study showed that 75% of the subjects that used opioids were at greatest risk of harm, as evidenced by the high ASSIST risk score for opioid use. This finding supports the importance and the need for harm reduction interventions such as the opioid substitution therapy offered by COSUP. High risk scores for specific substances indicates dependence to that substance by the user while moderate risk indicate harmful or hazardous use (69). Substance dependence leads to substance use disorders which often require long-term treatment and care (7). Opioid dependence is a burdensome health condition that have negative consequences on the health and social wellbeing of users (78) Treatment and care to reduce the mortality and morbidity associated with the harmful and hazardous use of opioid is necessary (7,21) Treatment must be aimed at reducing harm to the health of users, to facilitate reintegration into communities and to improve social functioning. Opioid substitution therapy, methadone therapy, was found to be the most effective treatment option for opioid dependence and to deal with opioids use and intolerable withdrawal symptoms (79)

4.4 Association of demographic characteristics and substance use

The study found that moderate and high levels of risk of harm was more in males and in the black race. Majority of studies on the prevalence and predictors of substance abuse have found that there is a correlation between ethnicity and substance abuse. Studies done is SA has found that being colored and white has a greater likelihood of using licit and illicit substances more than black ethnic groups (51) but most of the studies on substance abuse in SA have been on the black youth (41,47,80). It is also worth noting that the COSUP program was implemented in a community that is predominantly of a black race (72). Studies have also found that men are more likely to have dependence syndrome than women (27).

4.5 Pattern of substance use among subjects at the time of enrolment

The study population was comprised of users who were seeking opioid substitution therapy and it is to this reason that opioids were found to be the dominant substance of use and having the highest risk of harm as measured by the ASSIST risk scores. Majority of the subjects were polysubstance users. A study that explored the pattern of substance use among users, found polysubstance use to be common. (5,51,81,82) Tobacco and cannabis are reported in most studies (5,41,43) as dominant substances of use followed by opioids, but the harmful effects on the health of users are seen with opioids use. A study by Liebenberg et al, on the “fatalities involving illicit drug use in Pretoria for the period 2003 – 2012 found heroin to be the frequently detected substance post-mortem, followed by cocaine as well as a combination of alcohol with an illicit substance” (83).

4.6 Comparison of the ASSIST risk scores of these subjects at enrolment and follow-up visit post-intervention

The major finding of the study was that the ASSIST risk scores for opioid use decreased significantly between time of enrolment and follow-up. The finding

highlights the importance of screening for substance use and implementation of effective interventions in any clinical care setting. This is in agreement with the findings from a study by Humeniuk et al, which found a significant reduction in the ASSIST total illicit substance involvement scores following an intervention that was linked to the ASSIST risk score (71,84). The studies showed that to reduce the risk of harm of substance abuse the interventions to be implemented must be linked to the levels of risk as determined by screening tools such as the ASSIST. The interventions should be able to be implemented in any clinical care service, such as primary health care facilities (85).

The fitted logistic regression model found two factors (married status and methadone dose) which significantly explained the reduction in ASSIST scores between baseline (at enrolment) and follow-up visit. The residual analysis showed that model is of acceptable fit. Being married was found to be a protective factor. This finding is similar to findings of studies that looked at the correlates of alcohol and other substance use, where it was found that being married is protective against high risk of harm associated with substance use (55).

International literature agrees that the ideal maintenance dose of methadone, which will most likely lead to retention in treatment and reduction in the use of illicit opioids, is a dose of 60 mg to 120 mg per day (86,87). The reduction in the use of illicit opioids will result in the reduction in the risk of harm. The OST, methadone therapy intervention in COSUP was done in a community primary care setting. This in agreement with the study that was done to look at the effectiveness of Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)-linked brief intervention on harmful and hazardous use of alcohol in Nigerian semirural communities delivered by community health workers (70) The finding of this study also shows that substance use harm reduction interventions are potentially effective in reducing the risks and harms associated with substance use disorders

4.7 Limitations

This study had potential limitations. One, the lack of a strict active follow-up resulted in substantial attrition, where some subjects were not monitored for the second visit assessment to determine if the program had any impact on their ASSIST scores at the follow-up visit. The other limitation with this study is that no diagnosis was assigned to the substance user which makes it difficult to determine the effect of the intervention on any specific diagnostic category. Lastly the quality of data such as inconsistencies in recording variables.

a. Internal validity

To control for bias, there was no sampling done. The study population included all the client that were enrolled in the program since its inception, no one was excluded. Everyone who has the potential of being part of the study was part of the study. The procedure in the primary study was the same in all participants. On analysis of the data, the findings were found to be similar in interpretation with other similar studies.

In looking at the demographic characteristics associated with the change in the ASSIST risk scores for opioid, the univariate and multivariate logistic regression models use was used to control for confounding.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

In this chapter, appropriate conclusions are drawn from the study results assessed in relation to the aims and objectives of the study. Based on the findings of the study, appropriate recommendations and suggestions for future research are included.

5.1 Conclusions related to the aims of the study

The aim of the study was to determine the level of risk associated with substance use by the subjects enrolled in the COSUP project in the city of Tshwane and to measure the change in ASSIST risk scores following a harm reduction intervention.
It further aimed to assess potential characteristics (demographic) that are associated with the changes in ASSIST risk scores.

5.1.1 Demographic characteristics of subjects enrolled in COSUP during the study period

The study found that substance use was associated with being male, of younger age, black race and being identified as single.

5.1.2 Level of risk associated with substance use by these subjects using the ASSIST risk scores from the WHO ASSIST questionnaire

At the time of enrolment, the high ASSIST risk scores were found in association with the use of opioids, cannabis and alcohol. Majority of subjects with the high-risk scores were those who used opioids, followed by the ones who used cannabis. These high levels of risk lead to increased risk of negative effects on the health of users, such as dependence, which will lead to users seeking medical care and treatment for

substance abuse. Moderate ASSIST risk scores were associated with tobacco use. Other substances involved had low risk scores.

5.1.3 Pattern of substance use among subjects at the time of enrolment

The dominant substance of use with the highest risk of harm to the health of the users was opioids. The risk of harm was further increased in subjects who were using parenteral mode of administration as compared to those who were using other mode of administration such as smoking, snorting or ingesting. Most of the subjects were polysubstance users, using three substances at a time. These patterns of use further increase the severity of the risk of harm associated with substance use.

5.1.4 Comparison of the ASSIST risk scores of these subjects at enrolment and follow-up visit post-intervention

A decline in the level of risk of substance use, measured by decline in the ASSIST risk scores was seen in subjects that reported to be married which suggest that being married is a protective factor. The ASSIST risk scores for opioid use, measured at the three months follow-up visit from the initiation of the opioid substitution therapy, methadone, was found to have declined significantly when compared to the risk scores at the time of enrolment. This finding suggests that OST, methadone, is an effective intervention in reducing the risk of the harmful effects of opioid use.

5.2 Summary and final conclusion

To my knowledge this study is the first in South Africa to evaluate the efficacy of a community-based harm reduction intervention, OST, using the ASSIST risk scores. This study was done using secondary data of subjects enrolled in the community-oriented substance use program, COSUP. Given the findings and limitations of the study, it is concluded that delivering a harm reduction intervention such as methadone

therapy at a primary health care level together with screening for substance use using the ASSIST tool at a primary care level is feasible.

5.3 Recommendations based on the study

The findings suggest that a program such as COSUP, delivering an opioid substitution therapy, may be an efficacious intervention for reducing the risk of harm associated with opioid use. The findings further indicate that it is feasible to implement such an intervention in a primary health care setting. It allows for screening of people who presents at primary health care facilities and also at a household level by community health workers. Findings also suggests that opioid substitution therapy (OST) is a potentially effective intervention for reducing risk for substance use disorders. These findings expand current knowledge on the use of the screening tool, ASSIST, in primary health care settings, the value of implementing harm reduction within the existing primary care service delivery platforms and the potential value of OST being included in the standard treatment guidelines.

It is therefore recommended that a policy that guides the use of methadone is necessary. This policy should also speak to the procurement as well as addition of methadone in the essential drug list used in the primary health care level. Further training of health care practitioners on how to administer and monitor individuals on methadone at a community primary care level as well as at a hospital level should be considered. All individuals visiting health care facilities at all levels of care must be screened for substance use, and if it is found that they are at an increased risk of harm, interventions such as counselling and substitution therapy must be given to all who needs it.

5.4 Further Research

This study was based on secondary analysis of data of subjects enrolled into an intervention program that aimed to reduce the risk of harm associated with the use of substances. It would add value to have more studies that investigate the perceptions of the users about the harm reduction intervention program and what influenced their uptake and retention within the program. The information generated from such research could be used to improve existing substance use services in the primary health care level to be appropriate and client-centered in order to improve uptake by substance users. It is recommended that a qualitative research with an exploratory design could be done as it would enable for a better understanding of the factors that influenced user's uptake of the services through first-hand experience.

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APPENDIX A: DATA EXTRACTION TOOL

Study number	GENDER M/F	Age (yrs)	Marital status S- Single M-Married. D- Divorced/Separated. W-Widowed	Ethnicity 0=black 1=white 2=colored 3 =indian	Route (mode ofuse) Injecting, smoking, snorting 0 =smoker 1 =injector 2 =snorting	Date ofFirst Visit	Date ofFirst Assist Risk Assessment	First ASSIST score - Tobacco	First ASSIST score - Alcohol	First ASSIST score - Cannabis	First ASSIST score - Cocaine	First ASSIST score - Amphetamines	First ASSIST score - Inhalants	First ASSIST score - Sedatives	First ASSIST score - Hallucinogens	First ASSIST score -Opioids	First ASSIST score -Other	Date of Second Assist Risk Assessment	Second ASSIST score - Tobacco	Second ASSIST score - Alcohol	Second ASSIST score - Cannabis	Second ASSIST score - Cocaine	Second ASSIST score - Amphetamines	Second ASSIST score - Inhalants	Second ASSIST score - Sedatives	Second ASSIST score - Hallucinogens	Second ASSIST score - Opioids	Second ASSIST score - Other	Date treatment Initiated	Date treatment Terminated
PID001																														
PID002																														
PID003																														
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APPENDIX B1: CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr T Manyane

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M190747

NAME: (Principal Investigator)	Dr T Manyane
DEPARTMENT:	School of Public Health Department of Community Health Medical School University
PROJECT TITLE:	Characteristics of clients presenting for substance abuse treatment at COSUP centres in City of Tshwane
DATE CONSIDERED:	2019/07/26
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professors S Naidoo and D Basu
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2019/11/04

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **July** and will therefore reports and re-certification will be due early in the month of **July** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

TManyane

Principal Investigator Signature

11/11/2019

Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

APPENDIX B2: LETTER OF PERMISSION

COSUP

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

CITY OF TSHWANE
IGNITING EXCELLENCE

24-06-2019

To the Chairperson of the Health Science's Ethics Committee

RE: Permission for access and use of the Community Orientated Substance Use Program (COSUP) data: Dr. Tabea Manyane

I hereby confirm that we give Dr. Tabea Manyane approval to use the COSUP client data which is an electronic database of clients records, to do secondary data analysis for her research project titled; *Characteristics of clients presenting for substance abuse treatment at COSUP centres in the City of Tshwane*, a sub-study into COSUP, that aims to look into the impact of Opioid Substitution Therapy by determining the changes in the ASSIST risk scores and assessing the factors (socio-demographic) that might be associated with the level of risk of substance abuse and the changes in the ASSIST risk score. She will analyze the demographic data and the ASSIST risk scores.

The COSUP falls under the research protocol "Researching the Development, Application and Implementation of Community Orientated Substance Use Programme (COSUP)". Ethics Protocol No. 83/2017.

Regards



JFM Hugo
Director and Head of Department