ASSOCIATION BETWEEN ATTITUDE TOWARDS MEDICATION, PERCEIVED MEDICATION INFLUENCES AND LEVELS NON-ADHERENCE AMONG PATIENTS WITH CHRONIC PSYCHOTIC DISORDERS ATTENDING PSYCHIATRY DEPARTMENT AT MUHIMBILI

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Department of Psychiatry and Mental Health

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By

Catherine Daniel Magwiza

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Psychiatry and Mental Health) of

Muhimbili University of Health and Allied Sciences
October, 2021

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Science a dissertation entitled; **"Association between attitude towards medication, perceived medication influences and levels of non-adherence among patients with chronic psychotic disorders attending psychiatric department at Muhimbili",** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Psychiatry and Mental Health) of Muhimbili University of Health and Allied Sciences

_____

Dr. Samuel Likindikoki

(Supervisor)

_____

Date

DECLARATION AND COPYRIGHT

I, **Catherine Daniel Magwiza,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented at any other university for a similar or any other degree award.

Signature …… **Date** ……

ACKNOWLEDGEMENT

First, I would like to thank my supervisor Dr Samuel Likindikoki for his advice and support throughout – from the development of the proposal to completion of this dissertation. I am also grateful for the opportunities you provided me to work with you in your research projects and develop my research skills.

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And finally to my family and friends, I am extremely grateful for their love, prayers and sacrifice. I thank them for providing me with their unfailing support and continuous encouragement throughout my years of study.

DEDICATION

This work is lovingly dedicated to my late father, Mr Daniel Magwiza. Your blessings and prayers have carried me throughout. I miss you every day.

ABSTRACT

Background: Medication non-adherence is a significant global problem in psychiatric practice. Global rates for non-adherence are reported to range from 47% to 95% (Sendt et al., 2015). Attitude towards antipsychotic medication has been one of the most consistently reported and potentially modifiable risk factor for non-adherence (Kim et al., 2019). Individual patient attitudes and perceived benefit from medication can influence adherence behavior and hence the outcome in patients with chronic psychotic disorders. Despite their significant influence on adherence, little is known about the subject in lower income countries.

Aim of the study: The aim of the study is to examine the association between levels of non-adherence and attitude toward medications and perceived medication influences among patients with chronic psychotic disorders.

Materials and methods; This was a secondary analysis of phase 1 quantitative data from a 3-phase uncontrolled prospective intervention trial that focused on refinement and preliminary testing of a customized adherence enhancement program combined with long-acting injectable antipsychotic medication for poorly adherent patients with chronic psychotic disorders. One hundred patients with chronic psychotic disorders were recruited during the phase 1 of the project. Participants were assessed for their levels of non-adherence, attitudes towards antipsychotic medication and perceived medication influences. Other potential predictors of non-adherent behavior were measured including clinical and demographic factors.

Data was analyzed using SPSS version 23.0 and logistic regression was applied to explain the relationships between the variables. Bivariate association was calculated by using the chi-square test and variables with $p<0.2$ were taken through multivariate analysis to determine if the said variables were predictive of non-adherent behavior for patients with chronic psychotic disorders. Variables with $p<0.05$ were considered to be statistically significant.

Results: The mean age of the patients was 35.7 years (SD, 8.80). There were 61 (61%) males and 39 (39%) males. The mean self-reported non-adherence level for the past one week was 89.87% and for the past one month was 64.44%. Attitudes towards antipsychotic medication in this sample were rather negative with 51 participants (51%) falling in the more negative attitudes category. Half of the sample (50%) also had more negative perceived medication influences. Gender was significantly associated with levels of non-adherence for past one week and past month (p=0.015, p=0.002) and male participants were three times more likely to be non-adherent as compared to females in past one week (p=0.022; AOR=3.751; 95% CI 1.21 – 11.63) and four times more likely to be non-adherent in the past month (p=0.002; AOR= 4.809; 95% CI 1.74 – 13.29). Perceived medication influences was significantly associated with levels of non-adherence in the past one month (p=0.027) in the bivariate analysis and marginally associated with non-adherence in the multivariate analysis. Attitude towards antipsychotic medication however showed no significant association with levels of non-adherence for both the past one week and past one month.

Conclusion: Non-adherence to antipsychotic medication has been shown to be an important barrier to the successful treatment of persons with chronic psychotic disorders and is a frequent cause of exacerbations in psychopathology, psychotic relapse and re-hospitalization. It is recommended that further research using larger samples are conducted in our settings to understand modifiable risk factors for non-adherence in patients with chronic psychotic disorders and design appropriate interventions to address these modifiable factors.

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LIST OF ABBREVIATIONS

AMQ	Attitude toward Medication Questionnaire
AMSQ	Attitude toward Mood Stabilizers Questionnaire
CAE-L	Customized Adherence Enhancement with Long acting injectable antipsychotic
CPD	Chronic Psychotic Disorders
DAI	Drug Attitude Inventory
FGA	First Generation Antipsychotics
HBM	Health Belief Model
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
ROMI	Rating of Medication Influences
SGA	Second Generation Antipsychotics
SSA	Sub-Saharan Africa
TRQ	Tablet Routine Questionnaire
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Adherence – The extent to which a person's behavior-taking medication, following a diet and/or executing lifestyle changes corresponds with jointly agreed recommendations from a healthcare provider. (WHO,2003). It includes the initiation of treatment, implementation of the prescribed regime, and discontinuation of the pharmacotherapy.

Attitude towards antipsychotic medication is the subjective feelings, beliefs, experiences, and opinions of patients with schizophrenia towards the prescribed antipsychotic drugs. (Karthik et al., 2014).

Compliance – the extent to which the patient's behavior in terms of taking medications, following diets, or executing other lifestyle changes coincides with medical recommendations. The main difference between adherence and compliance is that adherence requires the patient's agreement to the recommendations. Compliance to medication is often used interchangeably with adherence in research and clinical practice.

Chronic psychotic disorders – this refers to severe mental disorders particularly Schizophrenia and/or Schizoaffective disorders

Medication influence simply refers to the capacity of a drug to have an effect on a person in an indirect but important way

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Adherence is defined as "the extent to which a person's medication taking behavior, following a diet, and/or executing lifestyle changes, corresponds with jointly agreed recommendations from a healthcare provider" (WHO, 2003). Adherence is used both in the context of psychological as well as medication treatment.

Non-adherence is a well-recognized universal problem seen in all fields of medicine and poses a major obstacle to the effective delivery of health care. It has been shown to be associated with poorer treatment outcomes, particularly in the management of chronic diseases, increased hospitalization rates, and even death – and increased costs for health care systems.

There are many reasons for patients' non-adherence. Some patients unintentionally forget to take their medications and some knowingly refuse to take their medications. Adherence problems in patients with chronic psychotic disorders are complex and multi-determined and involve multiple patient, environmental, provider, and medication-related factors. Patient-related factors include severity of symptoms, duration of illness, hostility, level of education, occupation, attitude toward illness, insight and substance abuse. Treatment-related factors for adherence include for example type of antipsychotic, side effects and environment-related factors like social support and living situation.

Among the factors associated with non-adherence, attitude toward antipsychotic medications and subjective experiences of antipsychotic treatment have been increasingly acknowledged as being critical to adherence and the eventual outcome of antipsychotic treatment.(Kuroda & Sun, 2008), (Rocca et al., 2008). Most of the previous work done on adherence behavior in patients with chronic psychotic disorders has not looked at the processes preceding medication intake behavior. Recent research on adherence however, has shifted focus from objective to more subjective factors associated with adherence like attitude towards medication, subjective responses towards medication, perceived daily benefits of medication, and perceived social

support. Attitude toward medication seems to be a key reason for intentional non-adherence and a mediator of effects of other critical variables, such as insight and therapeutic alliance. In patients with chronic psychotic disorders, improved attitude toward medication and insight into illness have been shown to contribute to medication adherence behavior.

A person's attitude to treatment can be influenced by a number of different factors such as demographic factors, insight into illness, severity of symptoms and side effects, health beliefs, attitudes of family members and the doctor-patient relationship.

1.2 Problem statement

Adherence to treatment is an important aspect of health care. Non-adherence to antipsychotic medications has been highlighted as a key challenge to psychiatric care. Among risk factors associated with adherence behavior, attitude towards antipsychotic medication has been one of the most consistently reported risk factor (Kim et al., 2019). High prevalence of negative attitude towards antipsychotic medication has been reported in various settings, ranging from 7.5% to 46.7% (Kuroda & Sun, 2008), (Sajatovic, DiBiasi, & Legacy, 2017), (Effiong & Umoh, 2015), (Okinda, 2014). Despite its impact on adherence and future treatment outcomes, little is known about it in lower income countries like Tanzania. Most of the available data regarding patients' attitude towards antipsychotic medications is from studies that have been done in higher income countries. Findings from this study may be different from other settings because patients with chronic psychotic disorders in Tanzania face many barriers in meeting their medication needs and making non-adherence have serious implications.

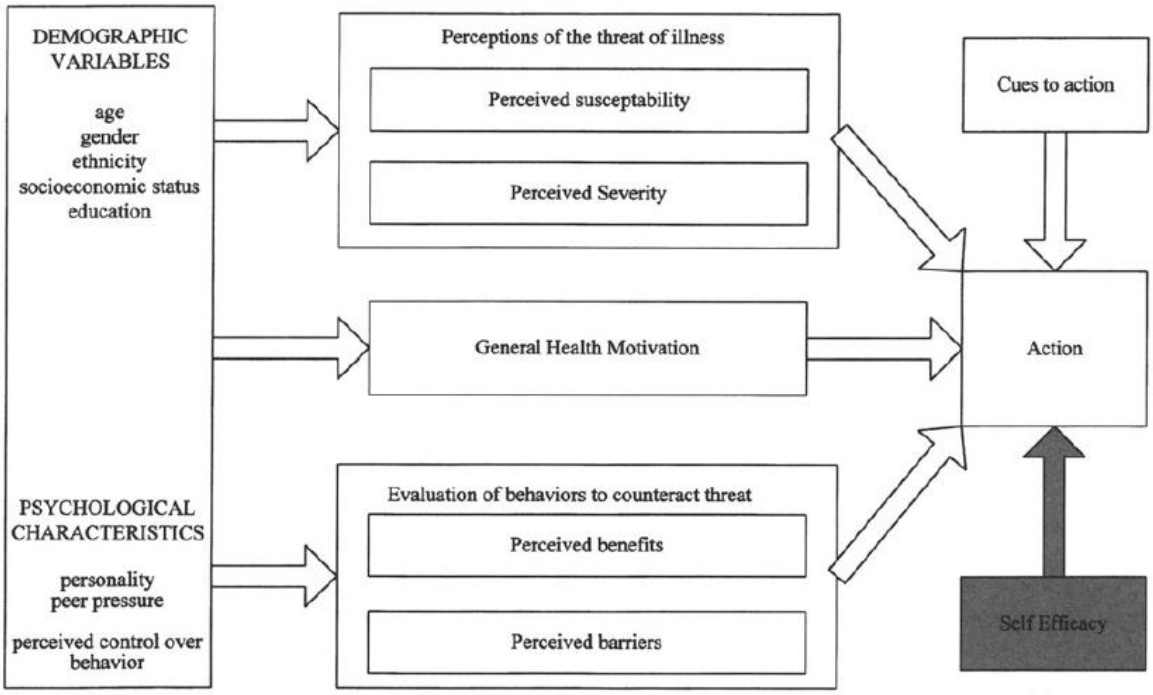
Attitude towards medication is potentially modifiable and therefore can be addressed with targeted interventions.

1.3 Theoretical framework

The Health Belief Model (HBM) was developed to explain and predict health-related behaviors, particularly with regard to the uptake of health services. It focuses on the attitudes and beliefs of an individual in respect to the behavior in question (Rosenstock, 1974). The model has been applied with considerable success to a range of health behaviors and populations, particularly preventive behaviors, such as diet, exercise, smoking cessation, vaccination, contraception and sick role behaviors such as adherence to recommended medical treatments.

The key elements of the HBM focus on individual beliefs about health conditions which predict individual health-related behaviors. The model proposes that the patients must perceive themselves as vulnerable to a condition and anticipate benefits that outweigh risks associated with a treatment if they were to remain adherent to a treatment. With regards to health beliefs on individual behavior, patients consider two determinants; the condition and related treatment. The patient's beliefs and perceptions together will determine whether there is value in changing the behavior in question in favor of suggested behaviors and/or treatments.

Adherence is a dynamic process in the HBM, influenced by cost-benefit analyses and a number of factors play part in a patient's decision to take medication and adhere to treatment. Patients are more likely to adhere to a prescribed medication treatment when they believe that their need for treatment and the benefits of treatment outweigh the negative aspects of it. Attitudes and beliefs about health and illness and medication have consistently been identified as the major factors in such decisions. Attitudes reflect the person's overall evaluation of the behavior and are based on beliefs concerning the likely consequences and evaluation of those consequences of performing the said behavior in question. The role of attitudes towards medication as a predictor for adherence emphasizes the importance of evaluative processes that happen before medication intake behavior. This study aims to determine the association between attitudes towards medication, perceived medication influences and non-adherence to treatment.



The Health Belief Model as suggested by Rosen stock et al

1.4 Rationale of the study

The findings from this study will help in the process of designing sustainable patient centered interventions that explore and improve patients' attitudes towards their antipsychotic medication and ultimately improving adherence behaviors. Available literature has shown that more positive patient attitudes towards medication are associated with better adherence. (Bressington, Mui, & Gray, 2012), (Mohamed & Rosenheck, 2014), (Richardson, Mccabe, & Priebe, 2013). Understanding patients' attitudes toward medication use and perceived medication influences can better inform interventions that have the potential to improve medication adherence.

The study is also in partial fulfillment of the requirements for the Masters of Medicine Psychiatry and Mental Health program of the Muhimbili University of Health and Allied Sciences (MUHAS).

1.5 Research question

What is the relationship between attitude towards medication, perceived medication influences and non-adherence to antipsychotic medication among patients with chronic psychotic disorders attending psychiatry department at Muhimbili National Hospital in Dar Es Salaam, Tanzania?

1.6 Objectives

1.6.1 Broad objective

To examine the association between attitude towards medication and perceived medication influences and levels of non-adherence among patients with chronic psychotic disorders attending Psychiatry department at Muhimbili National Hospital, Dar es Salaam.

1.6.2 Specific objectives

1. To examine the association between demographic and clinical variables and levels of non-adherence in patients with chronic psychotic disorders attending psychiatry department at Muhimbili National Hospital
2. To examine the association between attitude towards medication and levels of non-adherence among patients with chronic psychotic disorders attending psychiatry department at Muhimbili National Hospital, Dar Es Salaam
3. To examine the association between perceived medication influences and levels of non-adherence among patients with chronic psychotic disorders attending psychiatry department at Muhimbili National Hospital, Dar Es Salaam

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Magnitude of non-adherence

Antipsychotic medication treatment is important for the successful treatment of chronic psychotic disorders together with psychosocial approaches. However, medication non-adherence is common and remains a significant global problem in psychiatric practice. Over 50% of patients with chronic psychotic disorders globally do not adhere to their antipsychotic medication. (Sendt et al., 2015). Rates of non-adherence differ worldwide and this may be explained in part, by the differences in populations studied, different methods employed in the studies, criterion used to define non-adherence and the observation period. In Sub-Saharan Africa (SSA), poor adherence is seen in about half of the individuals with chronic psychotic disorders and is attributed to be the major cause of relapse in most patients (Adewuya et al., 2006; Tareke et al., 2018)

Non-adherence to medications negatively impacts the course of illness and the quality of life of individuals suffering from chronic psychotic disorders (Lasebikan & Owoaje, 2015) due to higher risks of relapse and frequent hospitalizations. It also negatively affects the society and the healthcare systems in general with increased health service utilization.

Factors contributing to poor medication adherence are many and of multifactorial causes. The WHO classifies these factors into five categories: socioeconomic factors, factors associated with the health care team and system in place, disease-related factors, therapy-related factors therapy-related factors, and patient-related factors. In broader terms, these factors fall into the categories of patient-, illness-, treatment-, and environment-related factors (Abdel-baki et al., 2012; Higashi et al., 2013)

Risk factors that have been consistently associated with psychiatric non-adherence in several studies include negative attitude toward medications, shorter illness duration, poor therapeutic alliance, less outpatient contact and "poor aftercare environment". The risk factors whose associations with non-adherence show mixed findings include substance abuse, symptom severity, higher antipsychotic dose, use of typical versus atypical agents, family involvement and living stability. A more positive attitude to medication and insight into illness have been found to be the only factors consistently associated with better adherence.

2.2 Attitude towards antipsychotic medications

Attitude toward medications is a complex and multi-faceted construct with many potential determinants. It has been shown to be an important predictor for health-related behaviors including adherence to medications.

The prevalence of negative attitude towards antipsychotic medication is estimated to range from 7.5% to 46.7% (Effiong & Umoh, 2015; Kuroda et al., 2008; Okinda, 2014; Sajatovic et al., 2017). Individual patient attitudes can influence adherence to the use of medications (Rossi et al., 2009) and predict future treatment outcomes in schizophrenia. Unfortunately, most of the available data regarding patients' attitude towards antipsychotic medications is from studies that have been done in developed countries. Despite attitude towards medication being an important factor in contributing to adherence to antipsychotic medications, fewer studies have been done in the developing world and Africa in particular (Adewuya et al., 2006; Eticha et al., 2015) In Tanzania, there is somewhat extensive literature showing barriers and predictors of adherence behaviors in persons with psychotic disorders but few of these studies have specifically assessed patients' attitudes towards medications.

A person's attitude toward medications can be influenced by a number of different factors/variables. Demographic characteristics of individuals appear to have little impact on attitudes (Sood et al., 2018). Some studies have not have found any significant correlations between sociodemographic variables and attitudes towards medications (Haq et al., 2009; Sood et al., 2018). Psychopathology, level of insight, side effects of antipsychotic medications and the therapeutic relationship however, have been more consistently linked with attitudes in different studies (Adewuya et al., 2006; Haq et al., 2009; Kuroda et al., 2008; Lambert et al., 2004; Rocca et al., 2008; Rossi et al., 2009; Vassileva & Milanova, 2012; Sood et al.,2018). Other factors such as employment, seem to have a mixed effect (Ao et al., 2006).

Positive attitudes toward medications has been consistently linked to good adherence and several studies have reported on the importance of positive attitude to medications in improving adherence(Adewuya et al., 2006; Chandra et al., 2014; Mohamed et al., 2014; Vassileva & Milanova, 2012; Sood et al.,2018). An Ethiopian study found that negative attitude toward medication was significantly associated with non-adherence in patients with schizophrenia (Eticha et al., 2015) With such available evidence that more positive attitudes towards medication are associated with better adherence behaviors among patients with chronic psychotic disorders then patients' attitudes may provide a potentially important target for intervention as they are potentially modifiable.

Negative attitude toward medication is a known risk factor for non-adherence (Sendt et al., 2015; Velligan et al., 2017; Yang et al., 2012) as well as for medication discontinuation. There are studies however, that have reported no association between attitude towards medication and adherence behavior. In a study to determine the prevalence and predictors of antipsychotic medication non-adherence among clients with psychotic disorders in Malawi, the author(s) reported that drug attitude did not predict antipsychotic adherence (Doeff et al., 2008)

2.3 Perceived benefit from medications

The perceived benefits of medication have been shown to be crucial for the attitudes toward medication treatment and to adherence behavior in general (Hui et al., 2006; Vassileva & Milanova, 2012). A higher level of perceived beneficial effect of medication was significantly associated with reduced likelihood of early treatment discontinuation (Liu-Seifert et al., 2012). Wiesjahn et al reported fewer perceived side effects, a higher attribution of the symptoms to a mental disorder, a greater sense of needing treatment, more endorsement of biological causes of the disorder, and less approval to psychological causes were associated with more positive attitudes toward medication, which in turn partly predicted better adherence (Wiesjahn, Jung, Lamster, Rief, & Lincoln, 2014). Little is known in our settings about patients' subjective perception of benefits from their antipsychotic medications

2.4 Consequences of non-adherence

Antipsychotic medications are the mainstay therapy in the treatment of chronic psychotic disorders. Non-adherence to antipsychotic medications in patients with serious mental illnesses has been linked to poorer outcomes including worsening of symptoms (Haddad et al., 2014), increased risk of suicide (Novick et al., 2010), increased likelihood of relapse (Novick et al., 2010; Sariah et al., 2014) and the "revolving door" phenomenon of frequent re-hospitalizations (Novick et al., 2010). Repeated episodes of psychosis can lead to the development of chronic psychosis, longer time to symptomatic improvement/response and possible resistance to antipsychotic medications(Remington et al., 2007). Research has shown that poor adherence to medications generally makes treatment ineffective and results in reduced health-related quality of life for patients with schizophrenia (Adelufosi et al., 2012). A study by Lasebikan and Owoaje done in Nigeria to assess the sociodemographic and clinical profile as well as quality of life among patients with psychotic disorders found a significant association between medication adherence and quality of life in people with schizophrenia (Lasebikan & Owoaje, 2015).

Repeated re-hospitalizations are the most important clinical consequence of non-adherence and are disruptive to both the individuals and families, and lead to increased healthcare costs(Joe & Lee, 2016; Karve et al., 2014; Offord et al., 2013; Sun et al., 2007). Previous studies have reported that patients who discontinue antipsychotic medication may be two to five times more likely to relapse as compared to patients who adhere to their antipsychotic medications.

Additional consequences of medication non-adherence in patients with schizophrenia include greater risk of comorbid substance use disorder; poorer cognitive functioning, reduced quality of life, increased risk of suicide(Lasebikan & Owoaje, 2015; Masand et al., 2009); violence/aggression or victimization (Witt et al., 2013)and increased rates of arrests. All these factors contribute to an even higher risk of non-adherence.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

This was an analytical observational mixed methods design (quantitative and qualitative) that assessed reasons for poor adherence to antipsychotic medication treatment among individuals with chronic psychotic disorders.

This study involved secondary analysis of phase 1 data from a 24 month project funded by the USA's National Institute of Mental Health. The study was a 3-phase uncontrolled prospective intervention trial that focused on refinement and preliminary testing of a customized adherence enhancement program combined with long-acting injectable antipsychotic medication for poorly adherent patients with chronic psychotic disorders. One hundred patients with chronic psychotic disorders were recruited during the phase 1 of the project and I was involved in data collection during this study.

3.2 Study area and setting

The study was conducted at the Department of Psychiatry and Mental Health of the Muhimbili National Hospital (MNH), located in Ilala district, in Dar es Salaam. MNH is the national referral hospital and university teaching hospital. It is a facility with 1,500 beds attending 1,000 to 1,200 outpatients weekly. The Psychiatry Department provides services for patients from all over the country. It provides services to referral cases from the three districts in the region i.e. Ilala, Kinondoni and Temeke. The department is divided into several units including Occupational Therapy, Social Work and Clinical Psychology. The services that are offered by the department include inpatient and outpatient services, child and adolescent services, community services and Methadone Assisted Therapy (MAT) services. The department has a total of 61 beds with 80 staff members; 16 psychiatrists, 50 nurses, 5 social workers, 1 community nurse, 6 occupational therapists and 4 clinical psychologists.

The department's service structure includes five firms or mental health care teams, four that serve patients living in four law enforcement and administrative catchment areas in Dar Es

Salaam region; Ilala, Kinondoni, Magomeni and Temeke while one serves patients with predominantly heroin dependence and also runs a HIV treatment service. Each firm has a specific day for follow up clinic and the attendance for these outpatients follow up clinics per week is about 40 to 50 patients per day.

3.3 Sample and Sampling process

The sample in the primary study (phase 1 quantitative survey) consisted of 100 poorly adherent patients with chronic psychotic disorders who fit the inclusion criteria. These participants were enrolled from the outpatient clinics and inpatient section of the Psyhciatry department of Muhimbili National Hospital. Participants were randomly picked and screened based on the inclusion criteria and those who fit were included in the study.

3.4 Study population

The study population comprised of adult patients (18 years old and older) with chronic psychotic disorders attending the Psychiatry Department at Muhimbili National Hospital, Dar es Salaam.

3.5 Target population

Poorly adherent patients with chronic psychotic disorders attending the Psychiatry Department at Muhimbili National Hospital, Dar es Salaam.

3.6 Selection criteria

Each patient completed a screening form regardless of whether the patient was enrolled or not. Only participants who fit the inclusion criteria were enrolled.

3.6.1 Inclusion criteria

- Individuals age 18 and older with schizophrenia or schizoaffective disorder
- Those who are known to have oral medication treatment adherence problems as identified by the Tablet Routine Questionnaire (TRQ) (20% or more missed medications in past week or month)
- Able to provide written, informed consent to study participation

3.6.2 Exclusion criteria

- Participants with immediate risk of harm to self or others were excluded for Phase 1 quantitative and qualitative surveys

The following were exclusion criteria for Phase 3 intervention

- Individuals on long-acting injectable antipsychotic medication immediately prior to study enrollment
- Medical condition or illness, which in the opinion of the research psychiatrist would interfere with the patient's ability to participate in the study
- Physical dependence on substances (alcohol or illicit drugs) likely to lead to withdrawal reaction during the course of the study
- Immediate risk of harm to self or others
- Female who is currently pregnant or breastfeeding

3.7 Tools and measures

3.7.1 Measure of non-adherence

Levels of non-adherence was assessed using the Tablet Routine Questionnaire (TRQ). The TRQ is a self-report measure which identifies partial and full adherence, identified as failure to take 20% or more of the prescribed antipsychotic medication. It was developed to evaluate treatment adherence in populations with bipolar disorder. The TRQ determines proportion of prescribed medication taken for the past 7 and past 30 days and is not dependent upon timing of medication provided that the medication is taken within the required 24 hour period or day. It consists of 2 general questions regarding any difficulties taking or coping with medications followed by 4 questions regarding approximate number of missed doses in the past week and past month. The TRQ has not been validated in African settings but has been used in western countries to assess adherence behavior in patients with bipolar disorder(Sajatovic et al., 2015, 2014)

3.7.2 Measure of attitude toward antipsychotic medication

Attitude toward antipsychotic medication was assessed using the Modified Attitude toward Medication Questionnaire (AMQ). This is a modification of the Attitudes towards Mood Stabilizers Questionnaire (AMSQ) which evaluates an individual's attitudes towards mood stabilizing medications. The AMQ is a self-report questionnaire with a yes-no format composed of 19 items grouped into 7 subscales: general opposition to prophylaxis (4 items), denial of therapeutic effectiveness (2 items), fear of side effects (2 items), difficulty with medication routines (4 items), denial of illness severity (3 items), negative attitudes toward drugs in general (3 items), and lack of information about psychiatric medication (1 item). Higher scores on each subscale represent more negative attitudes toward medication. The AMSQ has not been used in any study in Africa but has been validated for use in western countries to assess for correlates of attitudes towards mood stabilizers in patients with bipolar disorder (Sajatovic et al., 2017, 2011).

3.7.3 Measure of perceived medication influences

Perceived medication influences were assessed using the Rating of Medication Influences (ROMI). The ROMI tool is a measure of attitudes toward medication treatment that was originally developed for populations with schizophrenia (Weiden et al., 1994).It assesses a broad range of factors influencing a patient's personal decisions on adherence. The tool contains a total of 20 items, separated into two sub-scales or parts: patient reported compliance and patient-reported noncompliance. Part II of the ROMI was used, which contains 10 items that directly inquire about influences leading to non-adherence. Each item is answered on a 4-point scale; strongly disagree, disagree, agree and strongly agree. The ROMI has been found to be a valid and reliable instrument that can be used to assess the patient's subjective reasons for medication compliance and non-compliance.

The 20 interviewer-rated items have good interrater agreement (kappa > .60) with kappa coefficients ranging from .75 to 1.0 for reasons for compliance items, and .63 to 1.0 for reasons for noncompliance items. The ROMI has a literature base of over 20 years showing its relationship to adherence behavior, medication levels, and treatment outcomes and it has been used to assess adherence attitudes in psychiatric patients, particularly those with schizophrenia in various settings (Ascher-Svanum et al., 2014; Baby et al., 2008b; Sajatovic et al., 2010)

3.8 Data collection, management and analysis

In this study, the dependent variable was levels of antipsychotic medication non-adherence. Non-adherence was defined as missing at least 20% of the prescribed antipsychotic medication for either past week or past month and was assessed using the self-reported Tablet Routine Questionnaire (TRQ). The sample was dichotomized into less non-adherent and more non-adherent individuals based on the mean non-adherence level.

Independent variables were age, gender, marital status, place of birth, level of education, employment status, primary residence, duration of illness, attitudes towards medication and perception of medication influences.

Less non-adherent vs. more non-adherent patients were compared on attitudes towards antipsychotic medication and perceived benefit from antipsychotic medication at past one week and past one month. Paired samples t-test were conducted to determine the difference between the mean levels of non-adherence as it was repeatedly assessed in this sample at one week and one month duration.

Attitude towards medication were assessed by the Attitude toward Medication Questionnaire (AMQ) which has seven sub-scales evaluating an individual’s attitude towards taking antipsychotic medication. Higher scores on each subscale represent more negative attitudes towards medication. The mean total scores were used for the analysis and the sample was dichotomized into those with less negative attitudes and those with more negative attitudes towards antipsychotic medications.

Perceived benefit from antipsychotic medication was assessed using the Rating of Medication Influences scale (ROMI). Part II of the ROMI was used, which looks at attitudes or reasons influencing non-adherence. Higher scores reflect stronger beliefs regarding benefits from medications. Mean total scores were calculated and the sample categorized into those with less negative perceived benefit from antipsychotic medication and those with more negative perceived benefit from antipsychotic medications.

This study examined the relationship between attitudes toward medication, perceived medication influences and non-adherence. A hundred poorly adherent individuals with chronic psychotic disorders were recruited from both the outpatient and inpatient units of the Psychiatry department at Muhimbili National Hospital (MNH). Data were collected through structured interviews by trained interviewers.

Trained research staff were responsible for data collection. I was also involved in the data collection process. Collected data was maintained in hard copy subject files and stored by the principal investigator of the parent study. It was also de-identified to maintain anonymity and ensure confidentiality. For baseline information such as previous psychiatric hospitalizations and medication history that participants could not recall, a reference was made to their clinical case files/notes.

Data was entered using the statistical package for Social Sciences 23.0 (SPSS for windows version 23). The analysis included reviewing and cleaning the data, and preparing variables for analysis. Most of the variables were grouped for ease of analysis. Descriptive statistics were used to summarize the data. The analyses were conducted as follows; Bi-variate analyses were done to determine the presence of association between clinical and demographic variables and levels of non-adherence for past one week and past one month. The chi-squared and Fisher's exact test were summarized from the analyses with relevant p-values reported. The variables that were found to have p-value < 0.2 were included in a logistic regression model.

Multiple regression analyses were performed to determine if demographic and/or clinical variables were predictive of non-adherent behavior for the patients with chronic psychotic disorders. Adjusted odds ratio (AOR) and 95% confidence interval (95% CI) were calculated. All the analyses were two-tailed and the significance level was set at 0.05.

3.9 Ethical issues and research clearance

Research clearance was requested from the MUHAS Senate Research and Publications Committee. The parent study also obtained approval from the Institutional Review Board of Muhimbili University of Health and Allied Sciences (MUHAS) and the National Institute for Medical Research (NIMR).

All participants were required to provide informed consent form prior to study participation. They were informed about study objectives, risks and benefits of study participation verbally and voluntarily asked to participate. Participants with limited literacy had the consent form read aloud to them and family members were encouraged to participate in the consent process to allow for opportunity to ask questions and completely understand the study. Voluntary participation was encouraged and it was also clearly communicated to the participants that refusal to participate in the study will not bear any consequences to them and that they were free to agree or refuse. Consent form was put in the participants' files and to each a copy was given. Participants were also assured of confidentiality of information obtained from them and assessments were done in a private space.

CHAPTER FOUR

4.0 RESULTS

4.1 Descriptive statistics

4.1.1 Description of demographic and clinical characteristics of the sample

Data for 100 poorly adherent patients with chronic psychotic disorders were analyzed. There were 61 (61%) males and 39 (39%) males. The mean age of the patients was 35.7 years (SD, 8.80; range 19 to 62) and 47 (47%) of them were in the age group between 30 and 39 years. Twenty nine patients (29%) were in the 40+ years group and twenty four (24%) fell in the group under 29 years of age. Seventy two patients (72%) had no partner, that is, they were either single, divorced or separated and/or widowed. Fifty four patients (54%) had post-primary education and52 (52%) were employed. Majority of the patients 89 (89%) lived with family or a relative. Regarding diagnoses, 80 (80%) patients had the DSM-5 diagnosis of Schizophrenia and 53 (53%) had positive family history of mental illness. The mean age of onset (sd) of chronic psychotic disorders for this sample was 22.38 years (7.64) with the range of 1 to 49. The average years of having had chronic psychotic disorders was 12.39 (SD=7.99; range, 1-36 years). Fifty eight (58%) reported to have had chronic psychotic disorders for more than 10 years. Antipsychotic medication prescribed to patients in this sample included Haloperidol 72 (72%), Olanzapine 11(11%), chlorpromazine 8 (8%) and Risperidone 8(8%). Of the participants, 83 (83%) among those recruited were in-patients. In addition, 57 (57%) of the patients reported to be using alcohol. The summary for the clinical and demographic characteristics of poorly adherent patients with chronic psychotic disorders is provided in Table 1.

Table 1: Distribution of demographic and clinical characteristics of poorly adherent patients with chronic psychotic disorders attending Psychiatry department at MNH (N=100)

Characteristic	n (%)
Age in years Mean (SD)	35.7(sd=8.80) range 19 to 62
Age in years	
<29	24 (24%)
30-39	47 (47%)
40+	29 (29%)
Gender	
Male	69 (69%)
Female	31 (31%)
Marital status	
Married	28 (28%)
Single (Never married/divorced/separated/widowed)	72 (72%)
Education level	
Primary	46 (46%)
Secondary	46 (46%)
University/college	8 (8%)
Employment status	
Employed	52 (52%)
Unemployed	48 (48%)
Primary residence	
Lives alone	11 (11%)
Lives with family/other	89 (89%)
DSM-5 diagnosis	
Schizophrenia	80 (80%)
Schizoaffective	20 (20%)

Age of CPD onset Mean (SD)	22.38 (7.64) range 1 to 49
Family history of mental illness	
Yes	53 (53%)
No	47 (47%)
Illness duration (years) mean	12.39 7.99) range 1 to 36
Illness duration (years)	
10 years and below	42 (42%)
More than 10 years	58 (58%)
Treatment status at assessment	
Inpatient	83 (83%)
Outpatient	17 (17%)
Antipsychotic medication used	
Chlorpromazine	8 (8%)
Haloperidol	72 (72%)
Olanzapine	11 (11%)
Risperidone	8 (8%)
Alcohol use	
Yes	43 (43%)
No	57 (57%)

4.2 Distribution of levels of non-adherence

4.2.1 Levels of non-adherence

Less non-adherent vs. more non-adherent patients were compared on attitudes and perceived benefit from medications at past one week and past one month. Paired samples t-test were conducted to determine the difference between the mean levels of non-adherence as it was repeatedly assessed in this sample for past one week and past month. On average, the self-reported non-adherence level for the past one week (M=89.87, SE=2.1.8) was higher than that assessed for the past one month (M=64.44, SE=3.77).

This difference 25.43, 95% CI (19.23-31.63), was statistically significant t (99)=8.134, p=0.000, and represented a medium-sized effect, Cohen's d=0.67. Table 2a below shows t-test results comparing mean levels of non-adherence at one week and one month duration.

Table 2a: t-test Results comparing levels of non-adherence for one week and one month duration for poorly adherent patients with chronic psychotic disorders (N=100)

Level of non-adherence	Mean	Std dev	SE mean	95% CI	Paired t-test		
					t-value	df	Sig (2-tailed)
For 1 week	89.87	21.77	2.18	19.23-31.63	8.134	99	0.000
For 1 month	64.44	37.65	3.77				

4.2.2 Attitudes toward antipsychotic medication and perceived medication influences

The total mean score on the AMSQ was 11.45 with a standard deviation of 0.502. Attitudes towards antipsychotic medication in this sample hereby, were rather negative with 51 participants (51%) falling in the more negative attitudes towards antipsychotic medication category.

The total mean score on the ROMI was 13.62 with a standard deviation of 0.503. Perceived antipsychotic medication influences based on the total mean score showed equal distribution of the sample in the two categories, 50 participants (50%) in the more negative perceived benefit category and 50 participants (50%) in the less negative perceived benefit category.

4.2.3 Association between demographic and clinical characteristics with levels of non-adherence

In the bivariate analyses, gender is the only characteristic that showed significant association with levels of non-adherence for both past one week ($p<0.05$) and past one month ($p<0.05$).Level of education was shown to be associated with levels of non-adherence for the past one month ($p<0.05$) in the bivariate analysis. No association was observed between the levels of non-adherence and age of the patient, marital status, primary residence of the patient, employment status and duration of illness for both past one week and past one month. The results of the multivariate analysis revealed gender as the only demographic factors to be significantly associated with levels of non-adherence in the past one week (AOR=3.751; 95% CI 1.21 – 11.63; $p<0.05$) and past one month (AOR=4.809; 95% CI 1.74 – 13.29; $p<0.05$).Illness duration in years was marginally associated with levels of non-adherence for the past one month (AOR=3.01; 95% CI 0.93 – 9.76;$p=0.066$). The results of the bivariate analysis are shown in Table 2b.

Table 2b: Bivariate analysis - Association between demographic and clinical variables and levels of non-adherence for past one week and past one month for poorly adherent patients with chronic psychotic disorders attending psychiatry department at MNH (N=100)

Variable	Past one week				Past one month			
	Less non-adherent	More non-adherent	Chi-square	p-value	Less non-adherent	More non-adherent	Chi-square	p-value
Gender								
Male	8(13.1%)	53(86.9%)	5.86	**0.015***	20(32.8%)	41(67.2%)	9.43	**0.002***
Female	13(33.3%)	6 (66.7%)			25(64.1%)	14(35.9%)		
Age in years								
<29	7(29.2%)	17(70.8%)			9(37.5%)	15(62.5%)	1.08	0.584
30-39	6(12.8%)	41(87.2%)	3.64	0.162	11(44.7%)	26(55.3%)		
40+	8(27.6%)	21(72.4%)			25(51.7%)	14(48.3%)		
Marital status								
Married	9(32.1%)	19(67.9%)	2.91	0.088	13(46.4%)	15(53.6%)	0.03	0.858
Single	12(16.7%)	60(83.3%)			32(44.4%)	40(55.6%)		
Primary residence								
Lives alone	2(18.2%)	9(81.8%)	0.06	0.808	6(54.5%)	5(45.5%)	0.46	0.50
Lives with family/other	19(21.3%)	70(78.7%)			39(43.8%)	50(56.2%0		
Level of education								
Primary	8(17.4%)	38(82.6%)			27(58.7%)	19(41.3%)		
Secondary	11(23.9%)	35(76.1%)	0.67	0.714	15(32.6%)	31(67.4%)	6.52	**0.038***
University	2(25.0%)	6(75.0%)			3(37.5%)	5(62.5%)		
Employment status								
Employed	1(19.2%)	42(80.8%)	0.20	0.651	23(44.2%)	29(55.8%)	0.03	0.872
Unemployed	11(22.9%)	37(77.1%)			22(45.8%)	26(54.2%)		
Illness duration in years								
10 and below	9(21.4%)	33(78.6%)	0.008	0.929	16(38.1%)	26(61.9%)	1.395	0.238
More than 10 years	12 (20.7%)	46(79.3%)			29(50.0%)	29(50.0%)		
Attitude towards AP medication								
Less negative	9(18.4%)	40(81.6%)	0.40	0.526	20(40.8%)	29(56.2%)	0.679	0.410
More negative	12(23.5%)	39(76.5%)			25(49.0%)	26(51.0%)		
Perceived benefit from AP medications								
Less negative perceived benefit	12(24.0%)	38(76.0%)	0.542	0.461	28(56.0%)	22(44.0%)	4.89	**0.027***
More negative perceived benefit	9(18.0%)	41(82.0%)			17(34.0%)	33(66.0%)		

4.2.4 Association between attitude toward antipsychotic medications and perceived benefits of antipsychotic medication with levels of non-adherence

Attitude towards antipsychotic medication was not significantly associated with levels of non-adherence in both the bivariate analysis and multivariate analysis. Perceived medication influences was significantly associated with levels of non-adherence for past one month only ($p<0.05$) in the bivariate analysis and had marginal association with levels of non-adherence in the multivariate analysis (AOR=3.01; 95% CI 0.93-9.76;p=0.066). These results are summarized in table 3.

Table 3: Multivariate regression analysis – Association between demographic and clinical variables and levels of non-adherence for past one week and past one month duration for poorly adherent patients with chronic psychotic disorders attending psychiatry department at MNH

Variable	Levels of non-adherence at one week		Levels of non-adherence at one month	
	AOR (95%CI)	P-value	AOR(95% CI)	P-value
Gender				
Female	Ref		Ref	
Male	3.751(1.21-11.63)	**0.022***	4.809 (1.74-13.29)	**0.002***
Marital status				
Married	Ref		Ref	
Single	3.320(0.96-11.51)	0.058	0.838 (0.29-2.43)	0.745
Employment status				
Employed	Ref		Ref	
Unemployed	0.584 (0.19-1.84)	0.358	0.883 (0.35-2.25)	0.794
Level of education				
University/College	Ref		Ref	
Primary	1.579(0.19-13.31)	0.675	0.304 (0.05-1.83)	0.193
Secondary	0.810 (0.10-6.34)	0.841	1.157 (0.20-6.64)	0.870
Age in years				
40+	Ref		Ref	
<29	0.712 (0.13-3.83)	0.692	0.802 (0.18-3.55)	0.771
30-39	2.756(0.71-10.64)	0.141	1.267 (0.42-3.79)	0.673
Illness duration in years				
More than 10	Ref		Ref	
10 and below	1.480 (0.36-6.11)	0.588	3.013 (0.93-9.76)	**0.066***
Attitude toward AP medications				
Less negative attitudes	Ref		Ref	
More negative attitudes	0.738 (0.24-2.27)	0.596	1.031 (0.41-2.62)	0.949
Perceived benefit from AP medications				
Less negative perceived benefit	Ref		Ref	
More negative perceived benefit	1.398 (0.45-4.33)	0.562	3.013 (0.93-9.76)	**0.066***

CHAPTER FIVE

5.0 DISCUSSION

This study explores the association between attitude towards medication and perceived medication influences and levels of non-adherence. The mean self-reported non-adherence levels for this sample were 89.87 and 77 for past one week and past one month respectively. These rates are similar to earlier reported global rates ranging from 47% to 95% (Sendt et al., 2015) but comparably higher to rates found in some Sub-Saharan countries (Adelufosi et al., 2012; Ao et al., 2006; Effiong & Umoh, 2015; Eticha et al., 2015; Gebeyehu et al., 2019; Girma et al., 2017; Ibrahim et al., 2015; Tesfay et al., 2013)

5.1 Association between demographic and clinical variables and levels of non-adherence

In this study, gender was shown to be significantly associated with levels of non-adherence for both the past one week and past one month ($p=0.015$ and $p=0.002$) respectively. Multivariate regression analysis findings also showed significant difference in non-adherence levels among male and female participants. Men were shown to be three times more likely to be non-adherent as compared women for past one week and four times more likely to be non-adherent for past month. The association between male gender and non-adherence was also reported by Fleischhacker et al (Fleischhacker et al., 2003). While literature on the relationship between gender and adherence has been inconsistent, some authors have reported women to be more adherent (Diaz et al., 2004;Ngui et al., 2015; Sellwood & Tarrier, 1994) and some have shown men to be more adherent as compared to women(Castberg et al., 2009; Chen et al., 2014)There are previous studies that have not found gender differences with regards to non-adherence (Acosta, 2012; Beebe et al., 2016; Chandra et al., 2014; Hui et al., 2016; Yang et al., 2012).

Patients' level of education was significantly associated with levels of non-adherence for the past one month in the bivariate analysis. This association was however, not significant on the multivariate analysis. There are similar studies that have reported no association between education and adherence behavior (Acosta, 2012; Beebe et al., 2016; Hui et al., 2016; Siddiqui

et al., 2016; Yang et al., 2012). In contrast, there are studies that have shown education level to be related to non-adherence in patients with psychotic disorders. Eticha et al., 2015 (Eticha et al., 2015) reported lower education level to be significantly correlated with non-adherence. On the other hand, an Indian study reported higher education to be correlated with non-adherence (Baby et al., 2008).

Findings from this study show no significant relationships between variables such as age, marital status, primary residence and employment status with levels of non-adherence. These characteristics have also been shown to have inconsistent associations with non-adherence in patients with mental illness in previous studies. The inconsistencies have been attributed to nature of the populations sampled or smaller sample sizes which have resulted into reduced power of the said studies. Several studies have reported no significant association of adherence to sociodemographic variables (Kishore et al., 2015; Siddiqui et al., 2016; Yang et al., 2012). Another Nigerian study did not find any significant relationship between medication adherence and clinico-demographic factors other than age of participants and age at the onset of illness(Ogunnubi et al., 2017).

In this study, age was not significantly associated with levels of non-adherence for the past one week and past one month. Various other studies have also reported no significant relationship between age of the patient and adherence/non-adherence (Baby et al., 2008; Christy Lai Ming Hui et al., 2016; Yang et al., 2012).There are however, previous findings that have shown age as a significant predictor of non-adherence(Bressington et al., 2012; Chandra et al., 2014; Eticha et al., 2015; Moritz et al., 2013). Poor adherence has been reported specifically for patients with mental illness who are younger (Bressington et al., 2012; García et al., 2016; Novick et al., 2010; Ogunnubi et al., 2017). This relationship could be explained by the fact that younger people may hold beliefs that their illness may not be as severe that they may not need treatment. One Ethiopian study however, has reported older patients (age group 45-64 years) to be less adherent to their treatment as compared to younger patients and attributed this difference to higher prevalence of comorbidity in their sample.

Regarding marital status for example, results from previous studies have been inconsistent in association found with non-adherence. Whereas some have shown marital status to be related to adherence behavior (Eticha et al., 2015)with married individuals reported to be more adherent to medications as compared to their single counterparts some studies have reported no association(Acosta, 2012; Baby et al., 2008; Siddiqui et al., 2016; Yang et al., 2012).

There was no significant association between employment status and levels of non-adherence. Previous studies have reported mixed findings regarding employment and non-adherence. There are some studies that are in support of the association between unemployed status and non-adherence (Agarwal et al., 1998; Barbui et al., 2009) whereas some have reported employed patients being most likely to have non-adherence issues and negative attitudes towards their treatment (Baby et al., 2008). Adelufosi and colleagues (Adelufosi et al., 2012) reported that adherence was significantly better among respondents who were employed as compared to those who were not employed.

In terms of illness duration, no significant association was seen with levels of non-adherence. Some studies have also reported this similar finding between illness duration and non-adherence (Brain et al., 2013; Yang et al., 2012). In contrast to this study, there is however, literature showing patients with shorter illness duration to be poorly adherent to their medications (García et al., 2016).

While primary residence or living arrangement has been linked to non-adherence in previous studies, this study found no association between the two. This finding is also in support of studies by Hui et al.,2016 and Beebe et al.,2016 (Beebe et al., 2016; Christy Lai Ming Hui et al., 2016).

5.2 Association between attitude towards antipsychotic medication and levels of non-adherence

Attitudes towards medication for patients in this sample were rather negative. Half of the sample fell in the more negative attitudes category. Contrary to previous studies, this study did not find any significant association between attitude towards antipsychotic medication and non-adherence levels. Previous evidence has shown attitude towards medication to be associated with adherence behavior in patients with schizophrenia (Higashi et al., 2013; Christy L.M. Hui et al., 2006; Wiesjahn et al., 2014).Studies from various international settings have also reported positive attitudes towards antipsychotic treatment to be associated with better adherence (Ao et al., 2006; Baby et al., 2008; Baloush-Kleinman et al., 2011; Beck et al., 2011; Eticha et al., 2015; Hui et al., 2016; Mohamed et al., 2009; Rossi et al., 2009; Sendt et al., 2015)and negative drug attitudes to be linked with non-adherence (Brain et al., 2013; Velligan et al., 2017; Xiao et al., 2015).

5.3 Association between perceived medication influences and levels of non-adherence

Perceived medication influences were significantly associated with levels of non-adherence in the past one month in the bivariate analysis. This association was however, marginal on the multivariate analysis with a wide confidence interval indicating that this sample was too small and the need to replicate this study with a large sample. There is evidence that patients' perceived benefit from medications may positively influence adherence (Ascher-Svanum et al., 2014; Jónsdóttir et al., 2009; Moritz et al., 2009; Sapra et al., 2014; Teferra et al, 2013). Patients with mental illness have reported perceived medication influences in relation to their illness as a reason for non-adherent behavior. A study of outpatients with schizophrenia by Yamada et al., in Japan reported that patients with strong reasons for non-compliance as determined by the ROMI-J (a translated Japanese version of the ROMI) did actually tend to have non-adherent behavior (Yamada et al., 2006). Some of the specific reasons for non-compliance given by patients have been a feeling that antipsychotic medications were no longer necessary, distressing side effects from medications, fear of dependence, a feeling of recovery or feeling able to manage their lives without medications or because they just did not

want medication generally. Side effects from medication is also one of the commonly cited reasons for non-compliance (Baloush-Kleinman et al., 2011; Jónsdóttir et al., 2009). A qualitative study by Rofail and colleagues(Rofail, Heelis, & Gournay, 2009)reported that although patients with schizophrenia generally found their treatment to be somewhat acceptable, they did not always find their antipsychotic medication to be helpful and reported adverse events and negative impacts on their daily lives. Some of these adverse events and negative impacts that were mentioned included for example medications making them feel tired, look medicated, loss of identity and the resulting inability to work.

CHAPTER SIX

6.0 CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

6.1 Conclusion

Non-adherence remains a serious and complex problem in patients with chronic psychotic disorders. Attitude towards medications and perceived medication influences have are among important predictors for adherence behavior. By examining the association between levels of non-adherence and attitude towards medications and perceived medication influences, this study found the sample to have relatively high non-adherence levels, poor attitudes towards their antipsychotic medication and their perceptions of antipsychotic medication benefit were also rather negative. Furthermore, findings from this sample showed marginal association between perceived medication influences and levels of non-adherence. In contrast to findings from previous researchers, no significant association was found between attitude towards medication and levels of non-adherence. Modification of patients' attitudes towards their medications may help in improving adherence.

6.2 Recommendations

The following recommendations are proposed based on the study findings;

- Further research using a larger sample (and preferably a control sample of adherent patients) is needed to explore the association between attitude towards medication and adherence. Greater understanding of the factors associated with medication non-adherence is needed so that modifiable risk factors can be identified and addressed using appropriate interventions.

- For clinical services/practice, it is recommended that patients are first educated about their condition and treatment to help change medication attitudes. Patients should also be properly screened to determine factors that pose as barriers to adherence and comprehensive intervention strategies used to address these modifiable risk factors.

Interventions designed should have a patient-centered approach that focuses on individual barriers. Regular counselling and follow-up of patients may also help improve adherence for patients with chronic psychotic disorders.

6.3 Limitations

- Small sample size may have decreased the power of the study. As a secondary analysis, it is acknowledged that this is a limitation that could not be mitigated and recommendations have been made for future research on the subject.

- Secondary data analysis did not allow for inclusion of a comparison/control group of patients. The sample itself was also flawed as it was comprised only of patients that were non-adherent to antipsychotic medications.

- The use of self-reports in assessing medication adherence. Self-reported measures of adherence have been known to overestimate actual adherence rates. Participants were encouraged to be honest in their responses. For future research, multi-measure approach is recommended to reduce self-report bias.

- In addition, expressed attitudes towards medication and adherence as evaluated on rating scales may not identify actual attitudes that individuals may be not willing to share. Participants were assured of anonymity and confidentiality, study objectives and procedures were clearly explained and an opportunity to ask questions and for clarification was provided.

- Recall bias; recall may be difficult in patients with schizophrenia due to neurocognitive deficits and thus the reported adherence rates may not be actual. Reference was made to patients' clinical case files for information that the patients could not recall for example number of psychiatric hospitalizations, medication history, etc

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APPENDICES

Appendix I: Informed Consent form for Survey (English)

Introduction/Purpose

You are invited to participate in a research study. You were chosen as a possible participant for this study because you have been diagnosed with a chronic psychotic disorder (CPD) and you have missed some of your psychiatric medication doses in the past month.

Doctors at University Hospitals Cleveland Medical Center (UHCMC) and Case Western Reserve University (CWRU) Department of Psychiatry in the US and The Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania want to find out reasons that people are non-adherent (do not take all of their medications) for CPD (schizophrenia or schizoaffective disorder).

This study is funded by the National Institute of Health in the United States. You will be one of 100 participants enrolled in this research.

Study Procedures

If you agree to be in the study you will be asked to complete a questionnaire about reasons you do not always take your CPD medication.

Risks

The risks to you from participating in this research study include possible discomfort from thinking about your mental and physical health during the survey. You will be allowed to skip any questions that you do not want to answer. The greatest risk is to your privacy. However, your results will be recorded and kept in a confidential manner and will only be available to study staff.

Benefits

There are no direct benefits to you by your participation in this study. Your participation in this study may aid in our understanding of the best treatments for those with CPD disorder that have difficulty sticking with treatment.

Alternatives to Study Participation

You may choose to not take part in this study.

Financial Information

You will receive TSh. 23,000 for completing the questionnaire. There is no cost to you or your insurance for participation in this research study.

Confidentiality

We will do everything we can to keep your personal information confidential. Your name or any other information that could directly identify you is replaced with a "code." A list linking your code to your name is kept by the original researchers. This coding makes it harder for other people to find out who you are.

Your personal information may be disclosed if required by law. No publication of this study will use your name or identify you personally.

People who may review your records include: The Muhimbili University of Health and Allied Sciences (MUHAS) and/or University Hospitals Cleveland Medical Center Institutional Review Board, Ethics Committee, other local regulatory agencies, National Institutes of Health, Office for Human Research Protections, study staff, study monitors, and their designees.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to

participate in it, you will be notified so that you can decide whether or not to continue participating.

If injury occurs as a result of your involvement in this research, medical treatment is available from the Muhimbili National Hospital or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Jessie Mbwambo can also be contacted at +255 754 339 747. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the Directorate of Research and

Publications, at 2152489 or write to: Directorate of Research and Publications, P.O. Box 65001, Dar es Salaam.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

Signature of Participant								Date
x								
Printed Name of Participant								
If participant does not have the capacity to consent and protocol is approved for inclusion								
x								
Signature of Legally Authorized Representative (LAR) or Next of Kin								Date
Printed name of Legally Authorized Representative (LAR) or Next of Kin								
If Next of Kin, please mark ONE relationship from list below (in descending order of priority):								
	Spouse		Adult Child		Custodial Parent		Adult Sibling		Adult relative (related by blood or adoption)

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
Printed name of person obtaining informed consent	

Appendix II: Informed Consent form for Survey (Swahili)

Jina La Mradi: Kupunguza Tatizo la Magonjwa sugu ya Kuchanganyikiwa Tanzania – Survey
Watafiti Wakuu: Dr. Jessie Mbwambo (Tanzania) na Dr. Martha Sajatovic (Marekani)

Utangulizi/ Lengo (Introduction / Purpose)

Unakaribishwa kushiriki katika utafiti. Ulichaguliwa kama mtu unayeweza mshiriki katika utafiti huu kwa sababu Uligundulika kuwa na ugonjwa sugu wa kuchanganyikiwa na umekosa kutumia baadhi ya dawa zako za ugonjwa wa akili katika kipindi cha mwezi mmoja uliopita.

Madaktari katika Chuo Kikuu Kishiriki cha Afya na Sayansi shirikishi Muhimbili (MUHAS) cha Tanzania, Pamoja na madaktari wa Hospitali ya Chuo ya Cleveland Medical Center (UHCMC) na chuo cha Case Western Reserve (CWRU) idara ya afya na magonjwa ya akili vya Marekani wanataka kujua sababu zinazowafanya watu washindwe kuzingatia matummizi ya dawa.(wasitumie dawa zao zote za magonjwa ya kuchanganyikiwa) (skizofrrenia au skizoafective

Utafiti huu umegaramiwa na National Institute of Health ya Marekani. Utakua mmoja kati ya washiriki 100 watakaoshiriki katika utafiti huu.

Taratibu za utafiti (Study Procedures)

Ikiwa utakubali kushiriki katika utafiti huu, utaobwa kujaza dodoso kuhusu sababu zinazopelekea wewe kutotumia dawa zako za ugonjwa wa akili mara zote.

Madhara (Risks)

Madhara kwako yatakayotokana na wewe kushiriki katika utafiti huu ni pamoja na kujisikia vibaya kutokana na kufikiri kuhusu afya yako ya akili na ya kimwili wakati wa mahojiano haya. Utaruhusiwa kuruka au kutojibu swali lolote ambalo usingependa kulijibu.

Madhara makubwa ya kushiriki katika utafiti huu yanahusu usiri wa mambo yako. Hata hivyo, maelezo yaliyorekodiwa yatahifadhiwa katika hali ya usiri na yataweza kufikiwa na watumishi wa utafiti huu pekee.

Faida (Benefits)

Hakuna faida za moja kwa moja kwako kwa kushiriki katika utafiti huu. Ushiriki wako katika utafiti huu utasaidia uelewa mzuri wa matibabu ya watu wenye magonjwa sugu ya kuchanganyikiwa ambao wanapata changamoto katika kufuatilia matibabu yao.

Mbadala katika ushiriki wako katika utafiti (Alternatives to Study Participation)

Unaweza kuamua kutoshiriki katika utafiti huu.

Maelezo ya kifedha (Financial Information)

Utapokea TSh. 23,000 kwa kujaza dodoso hili

Wewe au bima yako hamtopata garama yoyote kwa wewe kushiriki katika utafiti huu.

Usiri (Confidentiality)

Tutafanya kila tunaloliweza kuhakikisha kuwa tunaweka maelezo yako binasfi katika hali ya usiri. Jina lako au taarifa nyingine yoyote ambayo inaweza kukutambua moja kwa moja vitaondolewa na kutumia “namba/kodi”. Orodha itakayooanisha namba na jina lako itahifadhiwa na watafiti wakuu. Namba hii itafanya iwe vigumu kwa watu wengine kujua wewe ni nani.

Maelezo yako binafsi yanaweza kutolewa ikiwa yatahitajika kisheria, na hakuna machapisho yoyote ya mradi huu wa kitafiti yatakayotumia jina au kutoa maelezo yako binafsi.

Watu wanaoweza kuangalia taarifa zako ni pamoja na: Chuo kikuu kishiriki cha afya na sayansi shirikishi Muhimbili (MUHAS) pamoja na/au hospitali ya Chuo ya Cleveland Medical Center (UHCMC),Bodi za uhakiki wa tafiti, Institutional Review Board, bodi ya maadili, (Ethics Committee), pamoja na agenti za kusimamia tafiti, (local regulatory agencies, National

Institutes of Health, Office for Human Research Protections) watumishi wa utafiti, wasimamizi wa utafiti, pamoja na wale waliowachagua .

Ufupisho wa haki zako kama mshiriki wa utafiti (Summary of your rights as a participant in a research study)

Ushiriki wako katika utafiti huu ni wa hiari. Kukataa kwako kushiriki hakuta badili huduma za kawaida unazopatiwa au kupigwa faini or kunyimwa stahihi yako. Ikiwa utaamua kushiriki utafiti huu, unaweza kujitoa muda wowote kwa sababu yoyote bila faini au kunyimwa stahiki yako. Ikiwa tafiti hii itachapishwa au kutangazwa, taarifa zako binafsi hazitaelezwa. Ikiwa kuna taarifa mpya zitapatikana ambazo zitatakua na athari katika haki au madhara kwako yanayotokana na utafiti huu, au utayari wako wa kushiriki, utajulishwa ili uweze kuamua iwapo ungependa kuacha au kuendelea na ushiriki.

Ikiwa kutakua na jeraha/madhara yoyote katika ushiriki wako, matibabu yanapatikana katika hospitali ya Taifa ya Muhimbili au katika vituo vingine vya afya, lakini wewe au bima yako ya afya itagaramia matibabu hayo. Madhara /jeraha la kitafiti ni jeraha linalotokana na ushiriki katika utafiti. Ikiwa umejeruhiwa na matibabu a kipimo ambacho ungepatiwa hata kama hukushiriki katika utafiti hii haichukuliwi kama madhara ya utafiti. Hakuna mipango ya malipo ya garama za matibabu au malipo mengine ikiwemo ujira uliopotea kwa sababu ya utafiti. Ili kusaidia kupunguza matatizo/ madhara, ni muhimu kufuata taratibu za utafiti.

Kutolewa taarifa za taarifa zako (Disclosure of your study records)

Juhudi zitatumika kuweka taarifa zako binasfi katika rekodi yako ya utafiti katika hali ya usiriri; lakini usiri timilifu hauwezi kuahidiwa. Bodi ya kudhibiti na kufuatilia tafiti ya Hospitali ya Chuo ya Cleveland Medical Center (UHCMC) inaweza kupitia taarifa zako. Ikiwa utafiti huu unadhibitiwa na **wadhibiti wa dawa na chakula (FDA**), kuna uwezekano taarifa zako zikakaguliwa na **shirika la udhibiti wa chakula na dawa (FDA**. Vilevile, kwa tafiti za kimatibabu, wadhamini nap bodi za udhibiti za nje (foreign regulatory agencies) zinaweza kupitia taarifa zako. Ikiwa taarifa zako zitapitiwa, unaweza kujulikana nao.

Taarifa za Mawasiliano (Contact information)

_____ Amekuelezea kile kitakachoenda kufanyika, athari, na faida zilizopo. Unaweza pia kuwasiliana na Mtafiti mkuu Dr. Jessie Mbwambo kupitia namba +255 754 339 747. Ikiwa una swali, angalizo au malalamiko kuhusiana na utafiti huu hapo baadae unaweza pia kuwasiliana nao.

Ikiwa umeshindwa kuwapata watafiti, au ikiwa ungependa kuzungumza na mtu mwingine ambaye sio mtafiti kuhusu dukuduku linalohusiana na mradi, haki za washiriki wa utafiti, athari za utafiti, au suala linguine linalohusu watu katika utafiti, tafadhali mpigie Mkurugenzi wa tafiti na machapisho kupitia namba 2152489 au muandikia kupitia anuani ya: Mkurugenzi wa Tafiti na Machapisho, S.L. P 65001, Dar es Salaam.

Sahihi

Kwa kutia sahihi hapo chini inaonesha kuwa imejulishwa kuhusu utafiti huu ambapo umeridhia kushiriki pasipo kulazimishwa/ kushurutishwa; ya kua umeuliza swali ambalo labda ulikua nalo kuwa taarifa ulizopewa zimekufanya uweze kufanya maamuzi yakinifu nay a huru kuhusu ushiriki wako katika utafiti huu. kwa kutika sahihi fomu hii haujatoa ruhusa ya kuvunjwa haki zako kisheria na watafiti au wadhamini hawajarahisishiwa/ kuondolewa tuhuma watakazo weza kuwa nazo. Utapewa Nakala ya fomu hii ya idhini arifu.

x	
Sahihi ya Mshiriki	Tarehe
x	
Jina la Mshiriki kwa herufi kubwa	
Ikiwa mshiriki hana uwezo wa kutoa ridhaa, na ikiwa amekidhi vigezo vya kushiriki	
x	
Sahihi ya muwakilishi kisheria (LAR) au Mrithi	tarehe
x	

Jina la muwakilishi kisheria kwa herufi kubwa (LAR) au Mrithi									
Ikiwa ni Mrithi, tafadhali weka alama katika moja ya mahusiano katika mfululizo unaoendana na kipaumbele.									
	Mwenza		Mtoto mtu mzima		Mzazi wa kisheria		Ndugu mtu mzima		Ndugu mtu mzima wa kuzaliwa au wa kufikia

Kwa Mtumishi wa Mradi Tu (Ni watu walio kwenye orotha tu ndio wanaweza kuomba ridhaa)

x	
Sahihi ya mtu anayeomba ridhaa arifu.	tarehe
x	
Jina la mtu anayeomba ridhaa arifu kwa herufi kubwa	

Appendix III: Questionnaire (English versions)

Demographic Form

1. Gender Male _____ Female _____
2. Date of Birth _____/_____/_____ Age: _____
   MM DD YY
3. Marital Status (Select One) _____
   1. Single/Never Married
   2. Married
   3. Separated
   4. Divorced
   5. Widowed
   6. Don't know
   7. Refused to talk
4. Do you have any children? _____
   1. Yes
   2. No
   3. Refused

a. If YES, how many? _____

5. What country were you born in? _____
   1. Tanzania
   2. Other
   3. Refused

6. Language: Patient's primary language: _____
   1. English
   2. Swahili
   3. Other

a. If Other, please specify primary language: _____

b. If not English au Swahili, is patient comfortable speaking/reading/writing English or Swahili _____

7. Education (number of years) _____

8. W

hat would you say best reflects your highest level of occupation for atleast the past 12 months? _____

1. Full time gainful employment, or home maker fulfilling all expected duties, or full-time student
2. Part time gainful employment (anything 30 hours or less per week), or homemaker fulfilling some but not all expected duties, or part time student
3. Unemployed but expected to work by self or others
4. Unemployed and not expected to work by self or others (disabled)
5. Other

9. Primary residence (Select One) _____

1. Lives alone
2. Lives with family
3. Other
4. Refused

10. Age of onset of schizophrenia/schizoaffective (first psychotic episode) _____

11. Duration of illness in years (rounded to closest year) _____

12. Have you ever taken any of the following medications:

Chlorpromazine tablets (Thorazine)		Olanzapine tablets (Zyprexa)	
Flupenthixol injection (Fluanxol)		Promethazine tablets	
Fluphenazine injection (Permitil, Prolixin)		Risperidone tablets (Risperdal)	
Haloperidol decnoate (Haldol Decanoate)		Trifluoperazine tablets (Stelazine)	
Halopereidol injection (Haldol)		Zuclopenthixol Accuphase Injection (Clopixol)	
Haloperidol tablets (Haldol)		Zuclopenthixol Depot Injection (Clopixol)	

13. List current psychiatric medications

_____

_____

14. Lifetime number of psychiatric hospitalizations?

_____

15. Lifetime number of substance use disorder hospitalizations

_____

16. In your opinion have you had any history of physical abuse? _____

1. Yes
2. No
3. Refused

17. In your opinion have you had any history of physical abuse?
    1. Yes
    2. No
    3. Refused
18. Is there any family history of mental illness? _____
    1. Yes
    2. No
    3. Refused

19. Is there any family history of substance or alcohol abuse? _____
    1. Yes
    2. No
    3. Refused

20. Who is your Mental Health Provider? _____

21. Has the patient signed a consent form and agreed to adhere to the study protocol including injections? _____

22. Did the participant agree to be called/contacted for follow-up appointment reminders? _____

23. Was I.D. number assigned to participant? _____
    (do not assign ID number until pt has started treatment)

Tablet Routine Questionnaire (TRQ)

Please answer the following questions, which are about your tablet routine.
We would like to know more about your routine ***in the past month.***
Prescribed psychiatric medication:

Medication Name **Dosage (in mg)** **Number of times taken daily**

_____ _____

Check all boxes that apply:

1. Do you have any trouble taking all of your prescribed medication? Yes☐ No ☐

2. Do you ever try to cope on your own without your medicine? Yes☐ No ☐

Check one response only to the following questions:

3. How many days in the past **week** did you miss at least
   One dose of your medication? _____
   (missing a dose qualifies for 1 day)

a) Percentage of dosages missed over the **last week:** _____
   (for example: missed 3 days/7 days = 43%)

b) Equal to or more than 20% of prescribed treatment Yes☐No ☐

4. On average, how many days in the **past month**
   Did you miss your medication?
   _____

(Missing a dose qualifies for a day)

a) Percentage of dosages missed over the **last month:**

_____

(for example: missed 3 days/30 days = 10%)

b) Equal to or more than 20% of prescribed treatment Yes☐ No ☐

RATER CONFIDENCE RATING:

Is the above information significantly distorted by:

Patient's misinterpretation? Yes☐ Possibly☐ No ☐

Patient's inability to understand? Yes☐ Possibly☐ No ☐

Modified Attitude towards Medication Questionnaire (AMQ)

Instructions

The following are concerned with feelings you may have about taking Psychiatric Medication (PM) treatments as they apply to your present situation. Please answer yes or no by circling your answer after each one to indicate whether it applies to you. Do not spend too long on each statement, but please answer each one. Thank you for your cooperation.

1. I would find it perfectly acceptable having to take PM for several years. Yes No
2. I take PM now and then, whatever I feel I need to. Yes No
3. It is definitely worth taking despite its side effects. Yes No
4. Taking PM exactly as prescribed fits in very easily with my daily routine. Yes No
5. Finding relief from personal stress is more important than taking PM In keeping me, well. Yes No
6. I consider that PM is at present necessary for my personal well-being. Yes No

7. I worry about possible side-effects from my PM tablets, even when Yes No
   I am feeling well.
8. Most people I know would probably be in favor of my taking PM. Yes No
9. I sometimes try to forget I have been ill by taking a break from PM tablets. Yes No
10. I rely on my tablets and if they were to be stopped, I could be concerned. Yes No

11. People often have to remind me to take my PM tablets. Yes No
12. PM is just as acceptable to me when I consider the need for repeated blood tests and checkups. Yes No
13. I often think that since PM is an artificial way to keep stable I should be able to do without it Yes No
14. It is very easy to remember to take PM at the right time. Yes No
15. I often doubt that my condition is sufficiently serious to justify the long-term use of PM. Yes No
16. I have an adequate factual knowledge of PM and its effects. Yes No
17. Being weak for several months would make me consider coming off PM. Yes No
18. If my daily routine changes for any reason, I have difficulty in remembering to take my tablets. Yes No
19. I am convinced of the beneficial effects of PM from my own personal experience of taking it. Yes No

Rating of Medication Influences (ROMI)

Please check off the most applicable response below on reasons why you are reluctant to take your medication.

Are you reluctant to take your medications because:

	Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**
1. You don't feel any better after taking the medication.	☐	☐	☐	☐
2. Although you may have needed them in the past, you don't currently need the medication.	☐	☐	☐	☐
3. You don't believe you ever had a mental illness (emotional problem) that needs medication.	☐	☐	☐	☐
4. You feel that medication interferes with achieving certain goals or life aspirations.	☐	☐	☐	☐
5. The side effects of the medicine are too upsetting to you.	☐	☐	☐	☐
6. You feel embarrassed about taking medications.	☐	☐	☐	
7. You look "medicated" to other people.	☐	☐	☐	☐
8. A family member or a friend believes that you should not be taking medicine.	☐	☐	☐	☐
9. You have difficulty getting to your appointments, and/or difficulty getting	☐	☐	☐	☐

medications.

10. You stop your medications before or during the times you drink or get high. ☐ ☐ ☐ ☐

11. Do you sometimes use traditional treatments (herbs or supplements, not including daily vitamins) either with or instead of psychiatric medicines? Yes ☐ No ☐

Screening Form

Instructions: Check "YES" or "NO" for every line

Inclusion:

YES_____ NO_____ 18 years or older

YES_____ NO_____ Clinically diagnosed with schizophrenia or schizoaffective disorder

YES_____ NO_____ Have medication treatment adherence (20% or more missed medications in past week or past month) as identified by the Tablet Routine Questionnaire

YES_____ NO_____ Able to be rated on psychiatric rating scales

YES_____ NO_____ Willing to take long-acting injectable medication

YES_____ NO_____ Able to provide written, informed consent to study participation

Exclusion:

YES_____ NO_____ History of allergy or intolerance to haloperidol or haloperidol decanoate

YES_____ NO_____ On long-acting injectable antipsychotic medication immediately prior to study enrollment

YES_____ NO_____ Medical condition or illness, which in the opinion of the research psychiatrist, would interfere with the patient's ability to participate in the trial

YES_____ NO_____ Physical dependence on substances (alcohol or illicit drugs) likely to lead to withdrawal reaction during the course of the study in the clinical opinion of the treating research psychiatrist

YES_____ NO_____ Immediate risk of harm to self or others

YES_____ NO_____ Female who is currently pregnant or breastfeeding

Must have "Yes" checked for all Inclusion Criteria and "No" checked for all exclusion criteria to be eligible for the study

Appendix IV: Questionnaire (Swahili Versions)

Demographic Form

1. Jinsia Me_____ Ke_____

2. Tarehe ya kuzaliwa _____

3. Hali ya ndoa
    1. Sijaoa/Sijaolewa
    2. Nimeoa/Nimeolewa
    3. Nimetengana na mwenza
    4. Nimetalikiana na mwenza
    5. Nimefiwa na mwenza
    6. Sijui
    7. Sitaki kujibu

4. Je, una watoto?
    1. Ndiyo
    2. Hapana
    3. Sitaki kujibu

    a. Kama ndiyo, una watoto wangapi? _____

5. Je, umezaliwa nchi gani?
    1. Tanzania
    2. Nchi nyingine
    3. Sitaki kujibu

6. Lugha unayozungumza
    1. Kingereza
    2. Kiswahili

3. Lugha nyingine

a. Kama ni lugha nyingine, tafadhali taja _____

b. Kama si Kiswahili au Kingereza, je, unaweza kuzungumza, kusima au kuandika Kiswahili au Kingereza?

    1. Ndiyo – Kingereza
    2. Ndiyo – Kiswahili
    3. Hapana

7. Elimu yako (Miaka) _____

8. Je, umekuwa ukijishughulisha na nini kwa miezi 12 iliyopita?

1. Nimeajiriwa ajira kamili ya wakati wote/nafanya majukumu yangu yote ya nyumbani/mwanafunzi wa wakati wote
2. Nimejiajiri ajira ya wakati kwa wakati/nafanya baadhi ya majukumu yangu/mwanafunzi wa wakati kwa wakati
3. Sina ajira na nategemewa kuwa na ajira
4. Sina ajira na sitegemewi kuwa na ajira
5. Nyinginezo

9. Unaishi na nani?

1. Naishi mwenyewe
2. Naishi na familia
3. Nyinginezo
4. Sitaki kujibu

10. Ulikua na umri gani ulipougua ugonjwa wa akili kwa mara ya kwanza? _____

11. Umeugua ugonjwa ya akili kwa muda gani sasa? Miaka _____

12. Umeshawahi kutumia dawa zifuatazo? Weka tiki sehemu sahihi

Vidonge Chlorpromazine (Thorazine)		Vidonge Olanzapine (Zyprexa)	
Sindano Flupenthixol (Fluanxol)		Vidonge Promethazine	
Sindano Fluphenazine (Permitil, Prolixin)		Vidonge Risperidone (Risperdal)	
Haloperidol decnoate (Haldol Decanoate)		Vidonge Trifluoperazine (Stelazine)	
Sindano Haloperidol (Haldol)		Sindano Zuclopenthixol Accuphase (Clopixol)	
Vidonge Haloperidol (Haldol)		Sindano Zuclopenthixol Depot (Clopixol)	

13. Taja dawa za magonjwa ya akili unazotumia kwa sasa

_____

_____

_____

14. Umeshalazwa mara ngapi kwa matibabu ya magonjwa ya akili? _____

15. Umeshalazwa mara ngapi kwa matibabu ya matumizi mabaya ya vilevi? _____

16. Umeshawahi kunyanyasika kimwili?

1. Ndiyo
2. Hapana
3. Sitaki kujibu

17. Umeshawahi kunyanyasika kingono?

1. Ndiyo
2. Hapana
3. Sitaki kujibu

18. Je, kuna historia ya magonjwa ya akili kwenye familia yako?
    1. Ndiyo
    2. Hapana
    3. Sitaki kujibu

19. Je, kuna historia ya matumizi mabaya ya vilevi kwenye familia yako?
    1. Ndiyo
    2. Hapana
    3. Sitaki kujibu

20. Nani anahusika kukupatia matibabu ya magonjwa ya akili?_____

21. Je, mshiriki ametia saini katika fomu ya ridhaa arifu na kukubali kufuata taratibu za jaribio ikiwemo kupatiwa sindano?_____

22. Je, mshirirki amekubali kutafutwa na kukumbushwa kuhusu mahudhurio ya kliniki? _____

23. Je, mshiriki amepewa namba ya utambulisho kwenye jaribio? (Mshiriki asipewe namba ya utambulisho hadi atakapoanza matibabu)_____

Utambuzi wa ugonjwa kulingana na DSM-5

Utambuzi wa ugonjwa kulingana na DSM-5 (Weka tiki kwenye moja inayohusika)

1. Schizophrenia
2. Schizoaffective disorder

Chanzo cha taarifa za utambuzi wa ugonjwa (Tiki zote zinazohusika)

1. Rekodi za matibabu
2. Uchunguzi mpya wa kitabibu

Tablet Routine Questionnaire (TRQ)- (Swahili)

Tafadhali jibu maswali yafuatayo yanahusu utaratibu wako wa kunywa dawa.
Tungependa kufahamu zaidi kuhusu utaratibu huo katika **mwezi mmoja uliopita**.

Jina la dawa unayotumia **Dozi (mg)** **Matumizi ya dawa kutwa**

_____ _____ _____

Weka tiki kwa yote yanayohusika:

1. Je, unapata shida yoyote kutumia dawa zako? Ndiyo☐ Hapana ☐

2. Je, huwa unajaribu kukaa bila kutumia dawa? Ndiyo☐ Hapana ☐

Chagua jibu moja kwa maswali yafuatayo:

3. Umekosa dawa zako kwasiku ngapi ndani yawiki iliyopita? _____
   (kukosa dozi moja ni sawa na kukosa siku 1)

c) Asilimia ya dozi uliyokosa **wikiiliyopita:** _____
   (mfano: kukosa siku 3/siku 7 = 43%)

d) Je, ni zaidi ya 20% ya dozi unayotakiwa kupata? Ndiyo☒ Hapana☐

4. Umekosa kutumia dawa kwa sikungapi ndani ya mwezi uliopita? _____

(kukosa dozi moja ni sawa na kukosa siku 1)

c) Asilimia ya dozi uliyokosa **mwezi uliopita:**

_____

(mfano: siku 3 /siku 30 = 10%)

d) Je, ni zaidi ya 20% ya dozi unayotakiwa kupata? Ndiyo ☐ Hapana☐

RATER CONFIDENCE RATING:

Kuhusu taarifa hizo hapo juu, je kuna upotoshaji:

Je, mgonjwa ametafsiri vibaya ? Ndiyo☐ Inawezekana ☐Hapana☐

Je, mgonjwa ameshindwa kuelewa? Ndiyo☐ Inawezekana☐ Hapana☐

Modified Attitude towards Medication Questionnaire (AMQ) - (Swahili)

Yafuatayo yanahusiana na hisia unazoweza kuwa nazo sasa kuhusu utumiaji wa dawa za kutibu magonjwa ya akili. Tafadhali jibu 'Ndiyo' au 'Hapana' kwa kila kauli. Zungushia jibu sahihi.

Asante kwa ushirikiano.

1. Nitakubali kabisa kutumia dawa za magonjwa ya akili kwa miaka kadhaa. Ndiyo Hapana
2. Ninatumia dawa mara tu ninapojisikia kufanya hivyo. Ndiyo Hapana
3. Dawa kwa hakika zina manufaa japokua zina madhara madogo madogo. Ndiyo Hapana
4. Utumiaji wa dawa kama ninanvyoelekezwa na daktari unaemda sawia na ratiba zangu za kila siku. Ndiyo Hapana
5. Kutafuta njia za kutatua dhiki zangu binafsi ni muhimu kuliko kutumia dawa. Ndiyo Hapana
6. Ninatambua kwamba kwa sasa dawa ni muhimu kwa afya yangu. Ndiyo Hapana

7. Huwa ninapata wasiwasi kuhusu uwezekano wa kupata madhara madogo madogo yatokanayo na dawa hata kama ninaendelea vizuri. Ndiyo Hapana
8. Watu wengi ninaowafahamu wanakubaliana na mimi kuhusu kutumia dawa. Ndiyo Hapana
9. Kuna vipindi situmii dawa zangu, kwa kujisahaulisha kuwa sina ugonjwa wa akili. Ndiyo Hapana
10. Ninazitegemea dawa zangu na endapo zitasitishwa itaniletea maswali mengi. Ndiyo Hapana
11. Mara nyingi ninahitaji kukumbushwa kuhusu kutumia dawa zangu. Ndiyo Hapana
12. Ninakubali kutumia sawa nikilinganisha na uhitaji wa vipimo vya mara kwa mara. Ndiyo Hapana
13. Mara nyingi ninafikiria kwamba ninaweza kukaa bila kutumia dawa kwa kuwa dawa hizi ni njia bandia ya kuniweka sawa. Ndiyo Hapana
14. Ni rahisi sana kukumbuka kutumia dawa kwa wakati sahihi. Ndiyo Hapana
15. Mara nyingi ninafikiria hali yangu si mbaya kunifanya nihitaji kutumia dawa hizi kwa muda mrefu. Ndiyo Hapana
16. Nina uelewa wa kutosha kuhusiana na dawa na madhara yake. Ndiyo Hapana
17. Kuwa dhaifu kwa miezi kadhaa huenda kukanipelekea kuacha kutumia dawa. Ndiyo Hapana
18. Ninapata ugumu kukumbuka kutumia dawa endapo ratiba yangu ikibadilika, Ndiyo Hapana
19. Ninakubali kuwa dawa zina manufaa kutokana na uzoefu wangu katika kuzitumia. Ndiyo Hapana

Rating of Medication Influences (ROMI) – (Swahili)

Tafadhali chagua chaguo sahihi zaidi hapa chini kuhusiana na sababu zinazosababisha uzembee kutumia dawa:

1. Hujisikii nafuu yoyote baada ya kupata dawa
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

2. Unajisikia kuwa japokua ulizihitaji mwanzo, huzihitaji kwa sasa
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

3. Huamini ulishawahi kuwa na magonjwa ya akili (matatizo ya kihisia) yanayohitaji matibabu
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

4. Unajisikia kuwa dawa zinaathiri mipangilio yako au kuzuia kufanikisha malengo yako kimaisha
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

5. Madhara madogo madogo ya dawa yanakuudhi sana
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

6. Unajisikia aibu kuwa unatumia dawa
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

7. Huwa unaonekana umetumia dawa kwa watu wengine
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

8. Mwanafamilia au rafiki anaamini kuwa hupaswi kutumia dawa
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

9. Unapata changamoto kuonana na daktari na kuhudhuria kliniki hospitali kama ulivyopangiwa
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

10. Unaacha kutumia dawa zako kabla ya kutumia pombe au vilevi vingine
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

11. Huwa ukitumia tiba za asili wakati mwingine pamoja na dawa zako au kama mbadala wa dawa zako
    a. Sikubali kabisa
    b. Sikubali
    c. Nakubali
    d. Nakubali kabisa

Appendix V: Approval of ethical clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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Ref. No.DA.282/298/01.C/ Date: 07/10/2020

MUHAS-REC-10-2020-381
Catherine Daniel Magwiza
MMed in Psychiatry and Mental Health, School of Medicine
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: Association Between Attitude Towards Medication, Perceived Medication Influences and Non-Adherence Among Patients With Chronic Psychotic Disorders Attending Psychiatry Department at Muhimbili

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

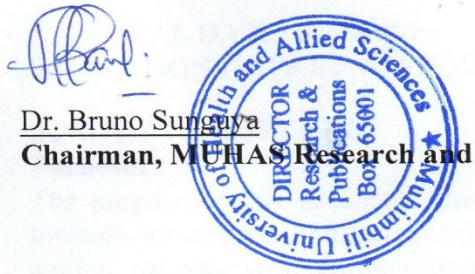
APPROVAL DATE: 07/10/2020
EXPIRATION DATE OF APPROVAL: 09/10/2021

STUDY DESCRIPTION:
Purpose:
The purpose of this secondary analysis is to examine the association between attitude towards medication and perceived medication influences and levels of non-adherence among patients with chronic psychotic disorders attending Psychiatry department at Muhimbili National Hospital, Dar Es Salaam

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20144.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
8. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.



Dr. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

Appendix VI: Introduction Letter

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES

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Ref. No. HD/MUH/T.202//2017

03rd November, 2020

The Executive Director,
Muhimbili National Hospital,
P.O. Box 65000,
DAR ES SALAAM

Re: INTRODUCTION LETTER

The bearer of this letter is Catherine Daniel Magwiza, a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing MMed. Psychiatry and Mental Health.

As part of her studies she intends to do a study titled: "**Association Between Attitude Towards Medication, Perceived Medication Influences and Non-Adherence Among Patients with Chronic Psychotic Disorders Attending Psychiatry Department at Muhimbili.**"

The research has been approved by the Chairman of University Senate.

Kindly provide her the necessary assistance to facilitate the conduct of her research.

We thank you for your cooperation.

Ms. Sharifa Kamby
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Medicine, **MUHAS**
cc: Catherine Daniel Magwiza