INSIGHT IMPAIRMENT AND ASSOCIATED FACTORS AMONG ADULT PATIENTS WITH BIPOLAR DISORDER ATTENDING CLINIC AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

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By

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A Dissertation Submitted in (Partial) Fulfillment of the requirement for the degree award of Master of Medicine (Psychiatry) of

Muhimbili University of Health and Allied Sciences
October, 2021

CERTIFICATION

The Undersigned certify that he has read and Hereby recommended for examination by Muhimbili University of Health and Allied Science dissertation entitled **"Insight impairment and associated factors among adult patients with bipolar disorder attending clinic at Muhimbili National Hospital,** in partial fulfillment of the requirements for the degree of Master of Medicine (Psychiatry) of Muhimbili University of Health and Allied Sciences.

Dr. Samuel Likindikoki MD, MMed

(Supervisor)

Date

DECLARATION AND COPYRIGHT

I, Fridah Tobias Mtui, declare that this dissertation is my own original work and that it has not been presented and it will not be presented to any other University for similar or any other degree award.

Signature…… Date……

ACKNOWLEDGEMENTS

I am so gratefully to The Almighty God for his blessings, keeping me healthy and making this work possible. I am also thankfully to my supervisor Dr. Samuel Likindikoki for his guidance throughout this research work.

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Finally, yet importantly, I am sincerely thankful to all patients who volunteered their time and patience to participate in this study, of which without them, it would not be possible to have the data for completion of this research.

THANK YOU, GOD BLESS YOU ALL!

DEDICATION

I would like to dedicate this work to my beloved parents Tobias Mtui and Emmeline Mtui for inspiring me and believing in me throughout my life.

ABSTRACT

Background: Insight impairment has been found in most patients with bipolar disorders (BD) during both acute and remission phases. Insight impairment significantly differs depending on the clinical characteristics of BD. Neurocognitive deficits, denial of illness as psychological defensive mechanism and misconception in social-cultural context are among the theories which try to explain the impairment of insight among patients with BD but the actual cause is still unknown. Insight impairment is reported to be associated with non-adherence to medications and hence adverse clinical outcome like relapses, frequent hospitalization, suicidality as well as violence behaviors in patients with BD. Studies with interest on insight have developed reports of insight impairment among patients with BD however, little is known about insight among patients with BD.

Aim of the study: The main purpose of this study was to determine prevalence of insight impairment and associated factors among outpatients with BD attending psychiatric clinic at Muhimbili National Hospital (MNH).

Materials and Methods: This was a hospital based cross-sectional analytical study using quantitative approach. Consecutive sampling procedure was used to recruit 154 adult patients with BD attending psychiatric outpatient clinic at MNH in Dar es Salaam. The data on socio-demographic factors, clinical characteristics and insight were collected using a face to face survey from December 2020 to January 2021. Data were analyzed using SPSS version 23. Descriptive statistics was used to summarize socio-demographic information and clinical characteristics. Mean and standard deviation were used to summarize continuous data such as insight score. Bivariate and multivariate linear regression analyses were done to find the association between the insight score and predictors of interest. All the variables associated with insight impairment, with the *p value* of < 0.2 in bivariate regression were further analyzed using multivariate linear regression analysis and variables with a *p value* of < 0.05 were considered to be independently associated with insight impairment.

Results: Among 154 patients with BD who participated in the study, majority of the patients had preserved insight and only 28.6% had insight impairment. Linear regression results revealed that un- employment (β= 0.302, p= 0.003) self-employed (β= 0.302, p= 0.004), illness duration of ≤3 years (β= 0.306, p= 0.001) and manic phase (β= 0.286, p= 0.000) predicted insight impairment among patients with BD. The results did not support association of other social- demographic and clinical factors such as age, sex, marital status, education level, age at onset, substance use, type of BD, psychotherapy interventions given, number of admissions, medication use and type of medication.

Conclusion: About a third of patients had insight impairment and un- employment, self-employment, illness duration of three years or less, manic phase of bipolar disorder were found to be predictors of insight impairment. Assessment of insight using a simple insight assessment tool and treatment of manic phase should be routinized for better insight among patients with BD.

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LIST OF ABBREVIATIONS

APA	American Psychological Association
BD	Bipolar Disorder
ICC	Intra-class correlation coefficient
ISAD	Insight Scale for Affective Disorder
M.I.N.I	Mini International Neuropsychiatric Interview
MDIS	Mood Disorder Insight Scale
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
SD	Standard Deviation
SMS	Scale for Manic States
SPSS	Statistical Package for Social Sciences
SUMD	Scale for Unawareness of Mental Disorders

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DEFINITION OF TERMS

Bipolar disorder	Is a mood disorder with periods of mania and depression.(James, Sadock and Pedro Ruiz, 2015)
Bipolar I	Mood disorder that describes having a clinical cause of one or more manic episodes and sometimes major depressive episodes (James, Sadock and Pedro Ruiz, 2015)
Euthymia	This describe a stable mood in those affected with bipolar disorder that is neither manic nor depressive and associated with adaptive behavior and enhanced functioning but yet distinguishable from health controls. (Merriam Webster medical Dictionary)
Insight	This refers to the people's understanding of their illness and how the illness affects individuals' interactions with the world. (Marková and Berrios, 1995)
Insight impairment	This refers to decreased or lack of awareness of one's own mental illness, symptoms, need of treatment and social consequences of having mental disorder. (Amador *et al.*, 1993)
Psychotherapy	Psychological services provided by health professions in a form of communication and interaction in management of BD (APA Dictionary of psychology)
Age at first episode of BD	This is the age at which symptoms of BD first appeared in an individual. (APA Dictionary of psychology)

1.0 INTRODUCTION

1.1 Background

Insight towards mental illness started to have clinical importance in 19th century when the patient's awareness of illness had crucial role in management of their illness. It has been a single categorical construct describing the presence or absence of awareness of illness until recently when the definition started to embrace the multidimensional concept which is a continuous phenomenon and varies with time. Amador et al. defined insight using four elements which are; awareness of having a mental illness, understanding the need for treatment, awareness of the social consequences of mental disorder, awareness of the symptoms and attribution of symptoms to a mental disorder (Amador *et al.*, 1993) while previously David conceptualized insight simply into recognition that one has a mental illness, compliance with treatment, and ability to relabel symptoms as pathological (David, 1990). Therefore, definition and measurement of insight towards mental illness is complex due to the multiple concepts it carries.

Different school of thoughts have been put forward in trying to explain about insight impairment among people with mental illnesses since the true cause is not known. Neuropsychology of insight involve functional deficit in the frontal lobe of the brain resulting into neurocognitive deficit characterized by impaired memory and executive functioning and consequently impair awareness of illness and relabeling of symptoms as psychopathology related to the illness.(David, 1990; Lysaker *et al.*, 1998; Dias *et al.*, 2008) Psychologically, impaired insight can be explained as defensive mechanism against realization of own illness helping the patient to cope with the situation.(Moore *et al.*, 1999) To support this, there are number of studies which have found correlation between insight and depression where by patients who are insightful tend to have depression. (Carroll et al 1999, Weiler et al 2000, Smith et al 2004) Furthermore, awareness of mental illness, attributions and treatment depend on patients' social cultural constructs therefore insight of the patient depends on how mental illness is understood in one own social-cultural settings. (Saravanan *et al.*, 2004)

Insight impairment is one among the cardinal features in patients with mental disorders and it is more pronounced during acute phase than in remission phase.(Varga *et al.*, 2006). Patients with Bipolar disorder experience insight impairment which varies depending on type and phase of illness. Bipolar mania and mixed type suffer more insight impairment compared to patients with depression and euthymia. (de Assis da Silva *et al.*, 2015). Furthermore, each component of insight is impaired differently in each mood state in BD. In mania, insight regarding symptoms is more impaired than insight regarding having illness and consequences, self-esteem and impairment in social relationship. (Silva *et al.*, 2016)

Insight on treatment need in patients with BD is found to be an independent predictor of adverse clinical outcome like hospitalization, emergency room visits and violent or suicidal behaviors. (Yen *et al.*, 2008). But also, impaired insight on illness and benefits of treatment tend to have substantial effect on the pattern of adherence of a patient to medications. (Amador *et al.*, 1993) Insight, therapeutic alliance with treating psychiatrist and medication adherence has shown high association during the course illness. These factors co-vary and improvement of one leads to improvement of the others. (Novick *et al.*, 2015) For the best outcome, strategies to improve insight should be emphasized during management. Different psychotherapies have been added to pharmacological treatments to give the best outcome such as group psychoeducation (Colom *et al.*, 2003), compliance therapy, cognitive- behavioral therapy, interpersonal and social rhythm therapy (Miklowitz and Johnson, 2006) and cognitive rehabilitation to patients with neurocognitive deficits (Harvey *et al.*, 2010).

1.2 Problem statement

Insight impairment is a common occurrence among patients with BD. A study done by Varga et al on insight, symptoms and neurocognition among patients with bipolar I showed that 70% of the patients were classified as having impaired insight with prevalence of 47% and 94% in remitted and symptomatic patients, respectively (Varga et al., 2006). During mania, patients with BD show greater impairment of insight than during depression or euthymia in awareness of having BD, awareness of the effectiveness of treatment for the actual symptoms or to prevent a reoccurrence of the illness and awareness of the consequences of the disorder (Silva et al., 2015)

Researchers have revealed that insight impairment is associated with poorer clinical outcomes in patients with BD. A study done by Ghaemi et al, showed that improvement in the level of insight correlated with good outcome, particularly in BD type I ($r = 0.56$ to 0.67 and p-value<0.0005) (Ghaemi, Boiman and Goodwin, 2000). Furthermore, from Yen et al study awareness of treatment need was found to be an independent predictor of adverse clinical outcomes (Yen et al., 2008). However, studies have shown that, treatment of impaired insight is promising potential target that can result in better clinical outcome. (Novick et al., 2015)

Rates of low adherence have been reported to be as high as 69% in patients with BD (Montes et al., 2013) and better insight has shown to be associated with higher adherence to medications with spearman correlation coefficient ranging from 0.39 to 0.49 for the three SUMD general items (p-value<0.0001). (Novick et al., 2015). Many studies on insight has been on schizophrenia but more interest on BD has developed after reports of insight impairment among bipolar patients (de Assis da Silva et al., 2015) however still little is known about insight among patients with BD.

Therefore, this proposed study aimed to assess insight impairment among patients with BD using a multidimensional concept together with contributing knowledge on the association between insight impairment and socio-demographic as well as clinical characteristics in our settings for strengthening insight related interventions. Furthermore, it is the first study to our knowledge that assessed insight impairment among patients with mental illness in East Africa.

1.3 Theoretical framework

In 1977 Dr. George Engel developed biopsychosocial model which tries to understand person's illness and health as they are influenced by biological, psychological and social factors. (Engel, 1977)

The biological component of the biopsychosocial model seeks to understand how person's genetic and biochemical attributes determine the occurrence of an illness while psychological deals with mood, personality and behavior factors. Whereas, the social factors include elements such as values and believes of the society, religion, socioeconomic and familial relationship are involved. Furthermore, these biopsychosocial factors show their influence at different levels such as predisposing, precipitating, maintaining or protecting.

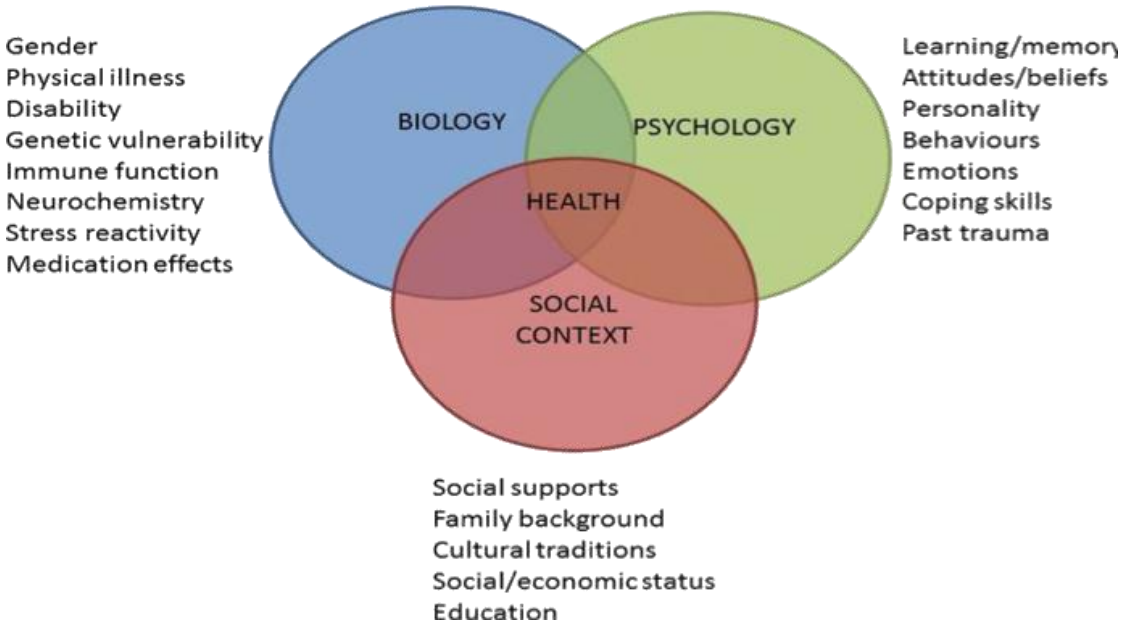

Figure 1: Biopsychosocial model
(JNANAMYOTHERAPY (2020) *Biopsychosocial Model*. Available at: https://jnanamyotherapy.com/biopsychosocial-model/ (Accessed: 28 July 2020)

In biological factors such as age, sex, BD type, BD phase, age at first episode of BD, number of admissions, substance use and medication use have shown to have influence on predicting Insight impairment among patients with BD. However psychological services given to a patient can predict insight impairment as they deal with stress caused by the fact that one has BD, which subject an individual into denial state helping the person to cope with state of illness. Socially, low education level subject an individual in a position of not being able to understand one's condition while culture of the patient with BD gives its own meaning and believes on BD which influences one's insight. The interaction between different biological, psychological and social factors results into differences in insight impairment among patients with BD.

This study used a biopsychosocial conceptual framework as summarized in Figure 2 to determine associations between insight impairment and age, sex, BD type, BD phase, age at first episode of BD, number of admissions, substance use, medication use, psychotherapy services, level of education, employment and marital status of a patient.

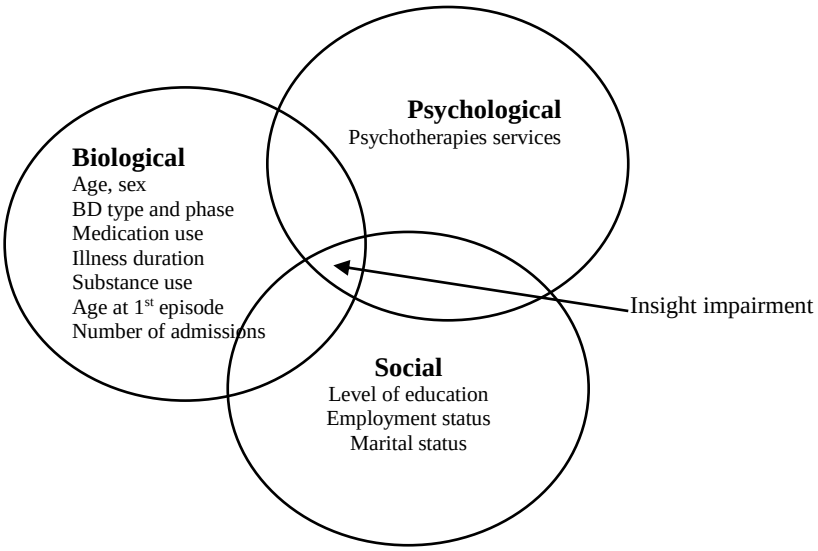

Figure 2: Biopsychosocial model adapted from Biopsychosocial model by Dr. G. Engel

1.4 Rationale for the study

This study was done to inform on insight impairment among patients with BD through a scale for affective disorder which capture the idea of insight as multidimensional concept and also factors associated with it. The data on insight impairment and modifiable associated factors will be used to offer idea of proper biopsychosocial intervention strategies to improve insight and consequently improve on clinical outcome among patients with BD. Furthermore, this study was done as part of requirements to fulfill Masters Degree in Psychiatry.

1.5 Research questions

1. What is the prevalence of insight impairment among patients with BD aged 18 years and older, attending adult outpatient psychiatric clinic at Muhimbili National Hospital?
2. What are the socio-demographic factors associated with insight impairment among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital?
3. What are the clinical characteristics associated with insight impairment among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital?

1.6 Broad objective

To determine prevalence of insight impairment and associated factors, among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital?

1.6.1 Specific objectives

i. To determine prevalence of insight impairment among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital.
ii. To determine socio-demographic factors associated with insight impairment among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital.
iii. To determine clinical characteristics associated with insight impairment among patients with BD aged 18 years and older attending adult outpatient psychiatric clinic at Muhimbili National Hospital.

1.7 Research hypothesis

1.7.1 Null Hypothesis

There is no association between insight impairment and socio-demographic factors and clinical characteristics among patients with BD.

1.7.2 Alternative Hypothesis

There is association between insight impairment and socio-demographic factors and clinical characteristics among patients with BD.

2.0 LITERATURE REVIEW

The purpose of this literature is to give the overview of the magnitude of insight impairment among patients with BD and associated factors.

2.1 Magnitude of insight impairment among patients with BD.

Globally, researches have shown that some patients with BD have insight impairment. A few studies that particularly looked at insight impairment among patients with BD were mainly done in South and North America, Europe, Asia and none came from Africa. In Norway, a study was done among 37 patients with BD I to determine the levels of insight using a Scale to assess Unawareness of Mental Disorder (SUMD). This tool is a semi-structured interview designed to evaluate present and past awareness of mental illness. Patients were categorized as having generally preserved or impaired insight based on their SUMD total score and a threshold score of ≤ 3.0 were categorized as preserved while >3 was categorized as impaired insight. Among other things, they found that almost seventy percent (70.2%) met the criteria for impaired insight (Varga *et al.,* 2006). In another study done by Dias et al. among bipolar patients, patients were divided into two groups based on their overall illness awareness (SUMD total score); 25 (35.7%) patients (6 men and 19 women) were considered to have 'preserved' insight (score ≤3), whereas 45 (64.3%) patients (20 men and 25 women) failed to recognize one or more aspects of their mental disorder (score >3), and were considered to have 'impaired' insight. In this study shortened version of SUMD was used.

Insight level differs depending on the phase of the illness. Studies found that patients with BD in acute phase have more insight impairment than patients in remission. A study done in Norway found that, prevalence of impaired insight was 47% and 94% in remitted and symptomatic patients respectively (Varga *et al.*, 2006). Another study done in North Carolina showed similar results among seventeen in patients evaluated during mixed and pure manic episodes and then reevaluated during remission.

They found the mean score lack of insight to be higher (2.176, SD 1.912) during the acute episodes than during remission (0.412, SD 0.795, P=0.001) The study used a different tool called Scale for Manic States (SMS) which has 20 items observer-rated scale for BD and insight impairment was evaluated using item 13 which measures denial of illness and rejection of treatment (Cassidy, 2010).

Studies have shown difficulties in defining insight as it carries multidimensional concepts. Different studies have used different tools among patients with BD making it challenging to be consistent in measuring insight impairment. Furthermore, there are a few studies which have explored insight impairment among patients with BD and none of the reviewed studies was done in Africa. This study defined insight using a multidimensional concept. Therefore, the use of ISAD was a better fit for this study because it is specific for patients with BD and it has the multidimensionality elements.

2.2 Factors associated with impaired insight among patients with BD

2.2.1 Age, gender and race

Age, gender and race are among the factors which have some controversy since some literatures found that there were associations between them and insight impairment among patients with BD while other studies did not find the association. In a study done in 2010 on insight relationship to episode subtypes and symptom dimensions in BD it was found that, race, sex and current age was not significantly correlated with insight impairment. (Cassidy, 2010) This was quite different from results of a study done in Portugal where by age of patients with BD correlated positively with overall illness awareness ($r=0.243$, $P<0.05$) and awareness of the medication effects ($r=0.281$, $P<0.05$), indicating that older patients have significantly less insight in those dimensions.(Dias *et al.*, 2008) Moreover, age and gender were significant predictors of level of insight among BD with depression, thus older age and the female gender were associated with poor insight. Among patients with BD mania only age was a predictor.(de Assis da Silva *et al.*, 2015)

2.2.2 Education level

A few studies looked into the association between insight impairment and level of education. Study done by Dais et al looked at the correlation between the level of insight and education level among patients with BD. They found that, educational level of patients with BD correlated negatively with the awareness of medication effects ($r=-0.270$; $P<0.05$), indicating that patients with high level of education showed significant better insight towards awareness of medication. (Dias *et al.*, 2008).

2.2.3 Frequency of admissions, illness duration and age at first diagnosis

Some researchers were interested to know the association between insight among patients with BD with age at first diagnosis, illness duration and number of admissions the patient had ever had since diagnosis of bipolar. Among other things Cassidy found that lack of insight was not significantly correlated with lifetime number of psychiatric hospitalization ($r = -0.044$), age of first psychiatric hospitalizations ($r = 0.013$), or years of illness since first psychiatric hospitalization ($r = 0.054$). (Cassidy, 2010) but Silva found that shorter duration of illness was related to poor insight in both mixed and manic type (da Silva *et al.*, 2018)

2.2.4 Mood state, manic, depressive and psychotic symptoms

Studies indicate that the level of insight in patients with BD is predicted by mood state (manic, depressive or euthymic) of the patient at the time of assessment. A study done in Rio de Janeiro on insight levels among ninety-five patients with BD at different mood state (depression, mania and euthymia), found that patients in mania had poorer insight about condition compared to patients in depression or euthymia ($p < 0.006$), with no significant differences between depression and euthymia ($p > 0.05$) (Silva *et al.*, 2015) but also Cassidy in his study done in 2010 North Carolina found that mean score for lack of insight among the pure manic group (2.395, SD 1.625) was significantly greater than the mean score of the mixed manic group (1.345, SD 1.495, $P = 0.012$), bipolar depressed group (0.571, SD 0.852, $P= 0.001$), and the euthymic group (0.444, SD 0.934, $P= 0.001$) (Cassidy, 2010)

There is association between levels of insight and clinical symptoms among patients with BD. Particularly in patient with BD mania, severe symptoms of mania are associated with worse insight both total and specific insight concepts. In a study of 165 patients with BD mania, found that the worse global insight correlated with more severe symptoms such as elevated mood (ρ=0.44, $p<0.01$), speech (ρ=0.50, $p<0.01$) and language/ thought (ρ=0.37 $p<0.01$). For the case of insight about symptoms the worse insight was associated with same changes (elevated mood (ρ= 0.42 $p<0.01$, speech (ρ= 0.53 $p<0.01$, language/ thought (ρ= 0.42 $p<0.01$) and agitation/ energy (ρ=0.40, $p<0.01$). Furthermore, the lower insight on having BD correlated with more severe alterations in thought content (ρ= 0.44 $p<0.01$) and appearance (ρ= 0.48 $p<0.01$) which can indicate that patients with untidy appearance have worse insight because their self-perception and self-care skills are not preserved. (Silva *et al.*, 2016) Cassidy in his study after regression analysis of symptoms and prediction of impaired insight concluded that psychomotor pressure (β= 0.208 p= 0.029) , and irritable-aggression (β= 0.423 $p<0.001$)were positively related and significantly predicted insight impairment (Cassidy, 2010).

Depressive symptoms are associated with better insight among patients with BD mania. This was found among patients with BD mania in a study done by Silva et al where by higher levels of depressive symptoms (β= -0.13 p= 0.034) were predictive of better insight.(Silva *et al.*, 2016).Though there some depressive symptoms correlate with lower insight when compared among patients with BD depression. A study on clinical correlates of loss of insight in BD depression revealed there was association between insight and depressive and manic symptoms. There were significant moderate correlations between ISAD total scores (ρ = 0.30, p = 0.028) and suicidal ideation/attempt, which means the worse insight correlated with higher rates of suicide ideation/attempt. Fewer sub-syndromal manic symptoms such as mood elevation, increased energy and sexual interest had correlation with worse insight as ISAD total scores showed moderate negative correlations with elevated mood (ρ = -0.33, p = 0.045), increased energy (ρ = -0.40, p = 0.045) and sexual interest (ρ = -0.36, p = 0.045).(Silva *et al.*, 2017)

Presence of psychotic symptoms among patients with BD is associated with insight impairment but show better insight on symptoms attribution compared with patients without psychotic symptoms. Findings from a study done in Netherlands showed that among 85 patients with BD, patients who had lifetime psychotic features (LPF) showed significantly less awareness of their illness (LPF mean score 3.4 SD 1.0, Without LPF mean score 3.9 SD 0.5 $p < 0.004$), but better symptom attribution (LPF mean score 3.3 SD 0.8 without LPF mean score 2.6 SD 1.0 $p < 0.001$) than patients without LPF. The higher scores on the subscale symptom attribution in patients was explained by the presence of psychotic symptoms, which were more salient in the sense of being abnormal than manic or depressive symptoms making it more likely that patients recognize these symptoms as abnormal once they are in a remitted phase. (Van Der Werf-Eldering *et al.*, 2011) Insight on having BD mania both correlated with thought content ($\rho= 0.41$ $p<0.01$), ($\rho= 0.44$ $p<0.01$) respectively. Thought content corresponds to delusions and hallucinations which are psychotic symptoms. (Silva *et al.*, 2016) Psychosis was found to associate with impaired insight ($\beta= 0.247$ $p= 0.006$) but also can predict level of insight. (Cassidy, 2010) The same result was found in BD depression that, worse insight into having BD depression was associated with psychotic episodes with ($r_{pb}= 0.42$, $p = 0.002$) (Silva *et al.*, 2017)

Literature review has shown that there are different factors which are associated with the level of insight among patients with BD. The clinical symptoms have been shown to correlate with insight impairment among patients with BD. However, a few studies have looked into the association between insight and psychological, social and demographical characteristics of patients with BD, hence necessitated us to undertake this study.

3.0 METHODOLOGY

3.1 Study design

This was a hospital based analytical cross-sectional study that used quantitative approach to assess the insight impairment and its association with clinical and demographic factors among patients with BD. Many studies which were done on insight among patients with BD have been hospital based recruiting inpatients and/ or outpatients therefore this study being also hospital based gives room for findings comparison. (Cassidy, 2010; Silva *et al.*, 2015, 2016, 2017) Due to limited time and budget, the analytical cross-sectional study was an appropriate design to give a snapshot of the insight impairment and associated factors among patients with BD. (Setia, 2016)

3.2 Study area and setting

The study was conducted in Ilala City council, Dar es salaam, Tanzania. Dar es Salaam is a larger commercial city with a population estimate of 6,702,000 in 2020 according to World Economic Forum. The study was conducted at an adult outpatient psychiatry clinic at MNH. MNH is the national referral and teaching hospital receiving many patients with mental disorders from within the city and other nearby regions. The clinic is staffed with mental health specialists who are competent in diagnosing and managing patients with broader range of mental illnesses including BD. From the MNH patient database, the first two quarters of 2019 showed a total of 840 patients with bipolar disorder attended at the adult psychiatry clinic, which makes an average of 140 patients with BD per month.

3.3 Study population

The study population was patients aged 18 and older with BD attending adult outpatient clinic at MNH, Dar es salaam Tanzania from December 2020 to January 2021 and who met inclusion criteria.

3.4 Inclusion criteria

1. Outpatients with BD aged 18 and older attending adult clinic at MNH December 2020 to January 2021
2. Patients with BD who gave consent to participate in the study.

3.5 Exclusion criteria

1. Patients with comorbid neurological illness
2. Patients in acute phase of mental or medical illness and are unstable to consent or comprehend on research tools
3. Patients with comorbid psychotic disorders

3.6 Sample size calculation

Sample size estimation was based on continuous data formula

$N= (Z\delta/E)\ 2$

Where;

Z=confidence interval 95%=1.96

δ = standard deviation =0.57 Insight mean score (Olaya *et al.*, 2012)

E= margin of error of 5% to Insight mean score of 1.89= 0.0945 insight mean score (Olaya *et al.*, 2012)

N= (1.96x0.57)/ 0.0945)2

=139.76

=140

We adjusted for non-response, and added 10%

=140 + 14 when oversampled by 10% the sample size becomes 154

3.7 Sampling procedure and technique

Purposeful sampling was used to identify all patients with BD coming for follow-up clinic among all patients attending clinic.(Palys, 2008) This was done by the research assistants working with the record officers to obtain all the files for the day's clinic then identified files with BD diagnosis. Patients' with the selected files were approached and asked for consent to participate for screening and potentially survey. Patients who disagreed were thanked and allowed to continue with the clinic services. Patients who consented to participate were screened using MINI version 7.0.2 bipolar module and those who screened positive for BD were invited to participate in the survey. If the criteria for BD was not met, the patients were thanked and supported to navigate with the clinic services. In order to meet target number of sample size on time at least 7 patients on the waiting line were interviewed per clinic day for 6 weeks.

It was clearly communicated to the participants that there was no reimbursement for time nor transport. The whole process was done with great care to avoid much interference with normal clinic services routine.

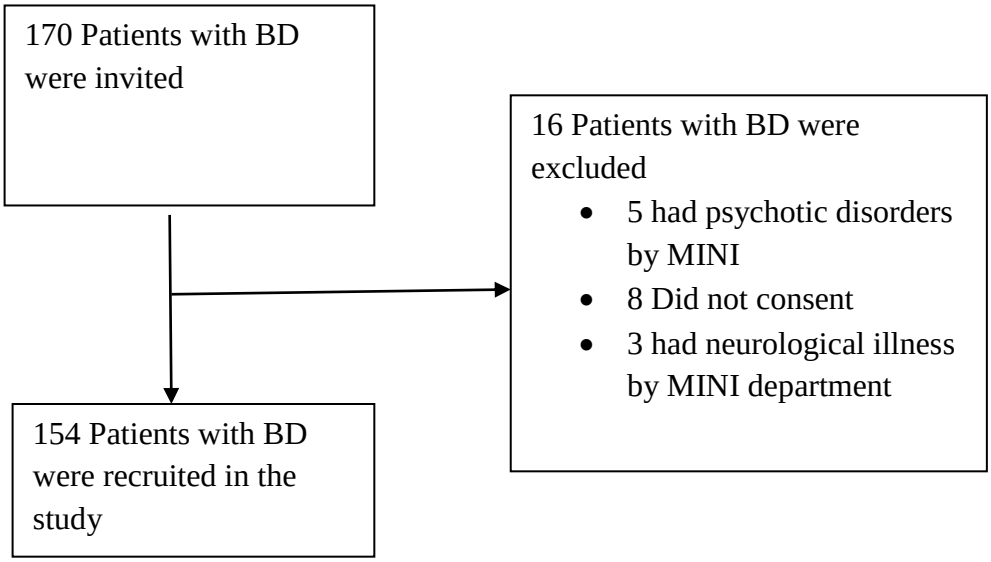

Figure 3: Patients flow chart.

3.8 Variables

Independent variable:

Social- Demographic: Age, Sex, place of residence, education level, marital status, employment status

Clinical characteristics: substance use, medication type, duration of illness, number of admissions, BD phase, BD type, psychotherapy given

Dependent variable

Insight impairment /scores

3.9 Data collection tool

Screening for BD

After identification of patients with diagnosis of BD in the file but also who had met inclusion criteria and agreed to participate in study, participants were screened for BD using Mini International Neuropsychiatric Interview (MINI) version 7.0.2. MINI is a brief structured interview for the major psychiatric disorders in DSM-5 and ICD-10. MINI has similar reliability and validity properties as The Structure Clinical Interview for DSM Disorder, a patient's version (SCID-P) for DSM-III-R and the Composite International Diagnostic Interview (CIDI) but can be administered in a much shorter period of time. It contains modules corresponding to each diagnostic category. MINI mania/ hypomania, depression and psychotic modules were used in screening. The rating was done at the right of each question by circling either YES or NO. It has ability to capture past and/or current manic/ hypomanic episode which is the criteria for diagnosis of BD while current screening for depression will capture patients with BD on depression episode by the time of interview but also ruling out psychotic disorders. MINI was translated to Kiswahili. Manic, depressive and euthymic phases were picked by MINI through presence of mania, depression symptoms or none in the current episode.

Socio-demographic and Clinical characteristic

A structured questionnaire was developed and translated into Swahili language. It was used to collect the social demographic information on patients' age, gender, marital status, educational level, employment status, place of residence, but also clinical characteristics which include illness duration, number of admissions, medication use and type of medications patient uses, psychotherapy if given and substance use.

Insight Impairment

The questionnaire was attached with Insight Scale for Affective Disorders (ISAD) that was used to measure level of insight. Insight was assessed in all four aspects separately. ISAD is a tool specific for assessing insight among patients with affective disorder which was developed by Olaya et al. (Olaya *et al.*, 2012) It has 17 items,1 to 3 item on insight about condition while 4 to 17 item insight about specific symptoms of BD. Each question is in likerts scale, scores are from 0 to 5, where 0 represents the absence of symptoms or a situation which cannot be evaluated; 1 constitutes full awareness of psychiatric morbidity; 3 represents a moderate awareness of psychiatric morbidity; and 5 constitutes the absence of awareness of psychiatric morbidity. In this study, there were some modifications made where by 1 represented absence of awareness; 3 represented a moderate awareness and 5 constituted full awareness of psychiatric morbidity for easy understanding of the Likert scale during interview but during data entry and analysis it was translated back to the original Likert scale.

This tool was validated in Brazil where it was found to have I intra-class correlation coefficient (ICC) values very high ranging from 99-80 among the items, indicating good inter-rater reliability. Cronbach's alpha for the full scale was high (α=90) and when calculating separately Cronbach's alpha for the items 1 to 3 was (α=77) and 4 to17 was (α=89). (De Assis Da Silva *et al.*, 2015).

The instrument was translated forward and backward to make sure it contains the same meaning. Each item was examined to ensure face validity and a transfer of the conceptual meaning in the Kiswahili versions. Final changes to the Kiswahili versions were made after piloting amongst few patients with BD attending adult psychiatry clinic at MNH.

3.10 Recruiting and Training of Research Assistants

Two research assistants who are clinical psychiatric officers in psychiatric department were recruited in the study. They were trained on the ethical issues, sampling procedures, adaptation of questionnaires and study tools. This was done a week before initiation of data collection.

3.11 Pre- testing of the study instruments

The questionnaire was pre-tested among 10 outpatients with BD attending clinic at MNH. Pre-testing helped to check if the questionnaire was understandable but also to estimate time used for interview and make some proper refinements of the questionnaire. These 10 patients were not included later in the study.

3.12 Data management and analysis

Data were coded, entered and analyzed by using Statistical Package for the Social Science (SPSS for windows version 23). After data cleaning, descriptive analysis of the sample on social demographic and clinical characteristics data was done in tables.

Age in years of participants, mean age, standard deviation and range of participants' age were calculated. The age was categorized into four categories; older youth (<24), young and middle aged adults (25-44), older adults (45-64) and elderly (64+) (Ahmad, Boschi-pinto and Lopez, 2001)(Ahmad, Boschi-pinto and Lopez, 2001). Sex was dichotomized into male and female. Marital status was categorized into single (for those who denied having a current intimate partner), married/cohabiting (for those who reported having been married or living with an intimate partners) and separated/divorced/widow.

Education level was categorized into primary, secondary education and higher learning (college/university).

Employment status was grouped into unemployed (for those who reported having no activity to earn income and students), employed and self- employed in either business or agricultural activities)

Age at first BD episode was categorized into early (≤24), middle (25-50) and late (>50) (Prabhakar and Balon, 2010; Coryell, William, Jess Fiedorowicz, Andrew C. Leon, Jean Endicott, 2014; Kennedy *et al.*, 2017). Illness duration was grouped into three percentiles by SPSS (illness duration of three years or less, 3.1 to twelve years and more than twelve years). Number of admissions were also grouped into three groups by SPSS (one or less, two and three admissions or more). Medication use was dichotomized into yes and no while type of medication used was grouped into Antipsychotics, Mood medications (antidepressants, mood stabilizers) and Combination (antipsychotics and mood stabilizers or antipsychotics and antidepressants). In psychotherapy services given was also dichotomized into being given psychoeducation plus other psychotherapy interventions and being given only psychoeducation. The use of substance in the past 12 months was grouped into yes and no and type of bipolar was either bipolar one or two. BD phase state was grouped into euthimic, depressive and manic from the MINI.

In answering the first objective of determining prevalence of insight impairment among patients with BD, the cut point was set at 3, since to the best of my knowledge there is no study done in this settings which used ISAD and indicated or used any cutoff point. Therefore, patients were categorized as having preserved insight when the patients' ISAD total mean score is 3 and below, meaning that patient with moderate to full awareness, and those with beyond a mean score of 3 were considered to have insight impairment.(Olaya *et al.*, 2012).

Bivariate analysis between social- demographic factors, clinical characteristics and ISAD total mean score was done to determine the presence of associations by ANOVA and t- test. All the variables associated with ISAD total mean score, with the p value less than 0.2 in bivariate analysis were further analyzed using multivariate regression analysis to control for the confounding effects. Variables with a p value less than 0.05 were considered significantly associated with insight impairment.

3.13 Ethical issues

Research clearance was sought from MUHAS Senate Research and Publications Committee. Permission to conduct the study was sought at MNH. No data collection was done before ethical clearance.

This study involved patients with BD which is among mental illness, therefore my study population is considered as vulnerable population. Keeping this in mind study involve outpatients who are considered to be stable enough to give an informed consent.

All participants were informed about the study verbally. Information on potential risks and benefits of participating was given. There were almost no health risks which are associated with participating in this study. Participants had the right to withdraw from the study any time they wished. The participants were voluntarily asked to participate in the study and written informed consent was obtained from the participants before interview.

The questionnaires had no identifying information and are kept confidential locked in the cabinet which only the principal investigator has access. The research data obtained will be kept for 3 years after the study dissemination and publication and thereafter destroyed.

4.0 RESULTS

4.1 Descriptive Statistics

4.1.1 Description of participants

4.1.1.1. Social Demographic characteristics of the participants

A total of 154 patients with BD consented and were eligible to participate in the study. This was 91% response rate out of 170 patients who were approached. Half of the participants were female, the mean (SD) age was 36.32 (11.5) years and range was 18- 67 years. Just above half (54.6%) of the participants were single, one third (29.2%) were either married or cohabiting while remaining 16.2% where either divorced/ separated or widow. Slightly higher than a third (37.7%) of participants reported having secondary education level, while about a third reported having primary education level (31.8%)and college or university education level (30.5%). A half (50%) of participants reported being self-employed in either business or agriculture activities. (Table 1)

Table 1: Frequency distribution of socio-demographic characteristics

Variables	**Frequency/mean (SD)**	**Percentage (%)/ Range**
Age Categorization, Mean (SD) Range (years)	36.32 (11.5)	18-67
≤24	23	14.94
25-44	98	63.63
45-64	30	19.48
64+	3	1.95
Sex		
Male	77	50.0
Female	77	50.0
Marital Status		
Single	84	54.6
Married/cohabiting	45	29.2
Divorce/separated/widow	25	16.2
Level of education		
Primary	49	31.8
Secondary	58	37.7
College/ University	47	30.5

Variables	Frequency/mean (SD)	Percentage (%)/ Range
Occupation status		
Employed	35	22.7
Self employed	77	50.0
Unemployed	42	27.3

4.1.1.2 Clinical characteristics of the participants

The mean (SD) age at 1st BD episode was 26.7 (8.5) years and range was 15- 52 years. About half (50.65%) of participants had age at 1st BD episode between 25- 50 years. Mean (SD) of illness duration and number of admissions were 9.8 (9.7) years, and 2.5 (2.96) respectively. A majority (98.7%) of participants reported being using medications at the time of interview. Among those who reported using medications at the time of interview, about a half (49.34%) reported using combination of medications, just below half (45.39%) reported to have being using antipsychotics and 5.26% reported to have being using mood medications. A majority (72.1%) of participants reported to have received psychoeducation only whereas just a third (27.9%) reported to have received combination of psychological interventions (psychoeducation plus others). A majority (87.7%) of participants were found to have Bipolar I disorder. At the time of interview 72.7% had euthymic phase, 15.6% had manic phase and 11.7% had depressed phase. A majority (85.7%) reported not to use substance in the past twelve months. (Table 2)

Table 2: Frequency distribution of clinical characteristics

Variable	Frequency / mean (SD)	Percentage (%)/ Range
Age at 1st BD episode, Mean (SD) Range	26.67 (8.46)	15 - 52
≤24	73	47.40
25-50	78	50.65
>50	3	1.95
Illness duration in years, **Mean (SD) & Range**	9.8 (9.70)	0.08-38
≤3	56	36.36
3< - 12	48	31.17
>12	50	32.47
Number of admissions, Mean (SD) &Range	2.5 (2.96)	0-13
≤1	78	50.65
2	31	20.13
≥3	45	29.22
The use of medications		
Yes	152	98.7
No	2	1.3
Type of medication		
Antipsychotics	69	45.4
Mood medications	8	5.3
Combination	75	49.3
Psychotherapy service		
Psychoeducation plus other psychotherapies	43	27.9
Psychoeducation only	111	72.1
Substance use		
Yes	22	14.3
No	132	85.7
Type of Bipolar Disorder		
Bipolar I	135	87.7
Bipolar II	19	12.3
Bipolar phase		
Euthymic	112	72.7
Depressed	18	11.7
Manic	24	15.6

4.1.1.3 Prevalence of insight impairment among participants

The ISAD total means (SD) score was 2.48 (0.99). About a third (28.6 %) of participants had mean score above three who were categorized as patients with insight impairment. Awareness of treatment efficacy had the lowest mean (SD) score of 2.10 (1.13) while awareness of symptoms had the highest mean (SD) score of 2.88 (0.95). (Table 3)

Table 3: ISAD Scores and Prevalence of Insight Impairment (N= 154)

Variable	**Frequency/Mean (SD)**	**Percentage (%)/Range**
ISAD total mean score, Mean (SD) & Range	2.48(0.99)	1- 4.67
Total mean score ≤3	110	71.4
Total mean score >3	44	28.6
ISAD mean score according to objective, mean (SD) & Range		
Awareness of illness	2.79 (1.46)	1-5
Awareness of treatment efficacy	2.10 (1.13)	1-5
Awareness of consequences	2.60 (1.40)	1-5
Awareness of symptoms	2.88 (0.95)	1.18-4.67

ISAD- Insight Scale for Affective Disorder

SD- Standard Deviation

4.2 Bivariate Analysis

4.2.1 Association between social demographic characteristics, clinical characteristics and Insight impairment.

When assessing the associations between socio demographic characteristics of the participants and insight impairment, it was found that participants who reported to be un employed showed more insight impairment with mean (SD) score of 2.67 (0.89) while self- employed 2.62 (0.95) and employed group had insight mean (SD) score of 1.96 (1.03) with p= 0.001. Other factors like age categories, sex, marital status and education level did not show association. More details have been elaborated in table 4.

In clinical characteristics and insight impairment, analysis showed that participants with illness duration less or equal to 3 years had highest mean (SD) score of (2.78 (0.99) while participants with illness duration of more than 3 years to 12 years and illness duration of more than 12 years had insight mean (SD) score of 2.34 (0.94) and 2.29 (0.97) respectively p= 0.019). Participants with BD I had mean (SD) score of 2.49 (1.02) while BD II 2.40 (0.73) p= 0.016 with interpretation that participants with BD I had less insight compared to BD II. Furthermore, participants in manic phase had the highest mean (SD) score 3.14 (1.08) followed by group with depressive phase 2.41 (0.75) lastly euthymic phase 2.36 (0.95) p= 0.001.

Clinical characteristics like age at 1st BD episode, number of admissions, substance use, use of medications, type of medication used and psychotherapy interventions showed no statistical significant association with ISAD mean score. More details have been shown in table 5.

Table 4: Association between socio- demographic characteristics and ISAD mean score among participants

Variable	Mean (SD)	F	t	p. value
Age*				
≤24	2.81(0.98)			
25-44	2.45(1.03)	1.034		0.352
45-64	2.35(0.82)			
>64	2.33(1.21)			
Sex **				
Male	2.43(0.97)	0.202	-0.730	0.654
Female	2.54(1.01)			
Marital Status*				
Single	2.47(0.86)			
Married/cohabiting	2.49(1.04)	0.01		0.990
Divorce/separated/widow	2.50(1.05)			
Level of education*				
Primary	2.62(1.02)			
Secondary	2.58(0.94)	2.437		0.09
College/ University	2.22(0.98)			
Occupation status*				
Employed	1.96(1.03)			
Self-employed	2.62(0.95)	7.008		**0.001**
Un employed	2.67(0.89)			

Analysis done by ANOVA *

Analysis done by t test**

Table 5: Association between clinical characteristics and ISAD mean score among the participants.

Variable	Mean (SD)	F	t	p-value
Age at 1st BD episode*				
≤24	2.59(1.01)			
25-50	2.36(0.96)	1.676		0.19
>50	3.13(0.84)			
Illness duration in years*				
≤3	2.78(0.99)			
3.1-12	2.34(0.94)	4.066		**0.019**
>12	2.29(0.97)			
Number of admissions*				
≤1	2.53(0.95)			
2	2.60(1.05)	0.916		0.402
≥3	2.32(1.01)			
The use of medications**				
Yes	2.48(0.99)	3.107	-0.503	0.080
No	2.83(0.24)			
Type of medication*				
Antipsychotics	2.42(0.97)			
Mood medications	1.83(0.55)	1.687		0.160
Combination	2.60(1.02)			
Psychotherapy service**				
Psychoeducation plus other psychotherapies	2.48(0.99)	2.107	-1.478	0.080
Psychoeducation only	2.83(0.24)			
Substance use**				
Yes	2.41	1.130	-0.370	0.288
No	2.50			
Bipolar Disorder**				
Bipolar I	2.49(1.02)	5.879	0.472	**0.016**
Bipolar II	2.40(0.73)			
Bipolar phase*				
Manic	3.14(1.08)	6.813		**0.001**
Depressive	2.41(0.75)			
Euthymic	2.36(0.95)			

Analysis done by ANOVA *

Analysis done by t test**

4.3 Multivariate Analysis

Multiple linear regression analysis was performed to determine the directions and strength of independent association between selected identified factors from the bivariate analysis.

In occupational status both un employment and self-employment remained to be positively associated with insight. Patients without employment showed positive association with insight mean score by (β= 0.302; 95% CI 0.235- 1.102; p= 0.003**)** while patients with self-employment by (β= 0.302; 95% CI 0.193- 0.994; p= 0.004**)**. However, illness duration of ≤3 years was independently associated with insight by (β= 0.306; 95% CI 0.246- 1.006; p= 0.001**).** Furthermore, manic phase showed association with insight by (β= 0.286; 95% CI 0.359- 1.191; p= 0.000). Bipolar type failed to show association with insight after controlling for confounders in multiple linear regressions.

Table 6: Regression on Risk factors of Interest on ISAD means score of participants

	Unstandardized coefficients		**Standardized coefficients**			**95% CI for B**	
Predictors	**B**	**Std. Error**	**Beta**	**t**	**P value**	**Lower limit**	**Upper limit**
Level of education							
Post-Secondary (ref)							
Primary	0.333	0.210	0.157	1.582	0.116	-0.083	0.748
Secondary	0.045	0.185	0.022	0.246	0.806	-0.320	0.411
Occupation status							
Employed (ref)							
Self-employed	0.594	0.203	0.302	2.932	**0.004**	0.193	0.994
Un employed	0.668	0.219	0.302	3.047	**0.003**	0.235	1.102

Predictors	Unstandardized coefficients		Standardized coefficients			95% CI for B	
	B	**Std. Error**	**Beta**	**t**	**P value**	**Lower limit**	**Upper limit**
Illness duration in years							
Above 12 (ref)							
≤3	0.626	0.192	0.306	3.260	**0.001**	0.246	1.006
3.1-12	0.078	0.191	0.037	0.409	0.683	-0.299	0.455
Psychotherapy							
Psychoeducation+ other psychotherapies(ref)							
Psychoeducation only	-0.035	0.175	-0.016	-0.198	0.844	-0.381	0.312
The use of medications							
Yes (ref)							
No	1.109	0.735	0.128	1.509	0.134	-0.344	2.563
Type of medication							
Mood medications (ref)							
Antipsychotics	0.789	0.365	0.399	2.162	0.320	0.007	1.460
Combination	0.734	0.367	0.373	1.997	0.480	-0.344	2.563
Bipolar Disorder							
Bipolar II	0.265	0.243	0.088	1.089	0.278	-0.216	0.746
Bipolar I (ref)							
Bipolar phase							
Euthymic (ref)							
Depressed	-0.014	0.269	-0.004	-0.052	0.959	-0.545	0.517
Manic	0.775	0.210	0.286	3.686	**0.000**	0.359	1.191

5.0 DISCUSSION

The aim of this study was to determine the prevalence of insight impairment and associated factors among outpatients with BD attending clinic at MNH. Among socio-demographic and clinical factors which were studied occupation status, illness duration, type of medication use and mood state were found to be independently associated with insight mean score. This is discussed in details below.

5.1 Prevalence of insight Impairment

We found that 28.6% of participants had ISAD mean score above 3 who are considered as patients with impaired insight. These findings are quite different from other studies which found much higher prevalence of insight impairment among patients with BD. A study done among patients with BD in Norway using SUMD found that prevalence of impaired insight was 47% and 94% in remitted and symptomatic patients respectively (Varga *et al.*, 2006) In another study done in Portugal using SUMD shortened version among bipolar I patients in remission found that 64.3% had impaired insight. (Dias *et al.*, 2008) The use of different insight tools (SUMD) can explain the difference of these findings but also the difference in study population among studies where by other studies looked for prevalence of insight impairment in specific groups like patients with either BD I or II, in acute or remission, in manic, depression or euthymic while this study had both patients in euthymic and symptomatic phase however, majority were in euthymic phase.

The fact that participants of the study were outpatients this means they were more stable and likely to have insight which can explain low prevalence of insight impairment. In addition, the low prevalence of insight impairment could be explained by the fact that, this was the hospital based study and to some extent participants might have had insight that drove them to come to the follow up clinic. Furthermore, most of the participants were on psychopharmacological treatment that had controlled the symptoms of BD making them asymptomatic and stable.

5.2 Occupation status

In occupation status, patients who were un employed had lower insight compared to other groups. This can be due to the fact that patients without employment have no sustainable income but also unlikely to be in health insurance system to support their own medications and other management of BD which results into difficulties to control illness symptoms. As we have seen from other literatures that patients of BD in symptomatic phase present with more insight impairment. Other literatures we managed to review did not check if this factor had association or not rather it was used to describe the study population. (Yen *et al.,* 2004)

5.3 Illness duration

The shorter illness duration is associated with impaired insight and to this study the duration was 3 years or less. Similar findings were found in a study done by Assis da Silva et al where by shorter illness duration was one among factors associated with lower insight among patients with BD in mania, depression and mixed type. (de Assis da Silva *et al.*, 2015) but also the same was found in patients with BD I in remission where shorter duration of illness predicted poorer insight (Yen *et al.,* 2004). This can be explained in the context that these patients lack enough experiences between illness and normal lives in the course of manic-depressive episodes that could help them being aware of their condition, treatment and consequences.

5.4 Bipolar phase

Manic phase of BD has shown to be associated with impaired insight in our study whereas similar findings were found in study done in Brazil where Insight in BD was found to be more compromised during manic phases than during periods of depression or euthymia (de Assis da Silva et al., 2015). Studies report that most of the patients in manic phase of BD, experience impaired executive functioning which explain the reason for insight impairment (Dias et al., 2008). From this point of view, treating manic phase first is an important step of managing insight impairment among patients with BD.

5.5 Bipolar type

In this study, type of BD had no statistically significant association with insight mean score while meta-analysis done by Kla´ra La´talova have shown that patients with BD II tend to experience more insight impairment than BD I. but this finding lack scientific reasoning which need more studies to prove it. (Látalová, 2012) With this contradicting finding more studies are needed to look into this factor.

5.6 Age, sex and education level

Results show that there was no association between age, sex, marital status and education level. Silva et al found that older age was a predictor of impaired insight in manic and depressive phase but female was a predictor of impaired insight only in depressive phase. (de Assis da Silva *et al.*, 2015) Furthermore Dais et al found patients with high level of education showed significant better insight towards awareness of medication. (Dias *et al.*, 2008) The difference in results can be due to other study analyzing insight with specific phase of BD or specific objectives of insight with age, sex and education.

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study aimed to assess the prevalence of insight impairment and factors associated among adult patients with BD attending clinic at MHN hospital. The findings revealed that 28.6% of the patients with BD had insight impairment and independent predictors of insight impairment were unemployment, self- employment, illness duration of ≤3 years and manic phase. The results do not support association of other socio- demographic and clinical factors such as age, sex, marital status, education level, age at onset, substance use, type of BD, psychotherapy interventions given, number of admissions, medication use and type of medication.

6.2 Recommendations

From the study findings we recommend the following;

- Mental health practitioners should assess insight among patients with BD using assessment tool which is easy to administer and understand in clinical settings.
- Follow up studies should be done to look into insight among adult patients with BD since there are limited data in our setup so as to compare and understand more on insight among patients with BD.
- Interventions that address modifiable risk factors associated with insight impairment should be instituted like emphasis on proper psychopharmacological treatment of manic phase among patients with BD so as to control symptoms and as a result improving insight impairment.

7.0 LIMITATIONS AND MITIGATIONS

7.1 Study Limitations

- The study used ISAD tool which has not been validated in our set up.
- Recall bias as patients were required to recall things like age when they had first episode of BD episode, number of admissions and medications they are using.
- Social desirability bias which can influence patients to answer what is socially accepted especially in substance use.
- Having only one question on psychotherapy interventions may not be enough to capture psychotherapy input in insight.

7.2 Mitigations

- Having two research assistances plus me with the target of collecting data to at least 7 patients per day helped us to spare enough time to each patient for rapport and time to recall important information like number of admissions, age at first episode etc. Insuring confidentiality and privacy during interview might have helped to reduce social desirability bias.

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APPENDIX

Appendix1: Informed Consent Form – English

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

P.O. Box 65001

DAR ES SALAAM

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To be read and questions answered in a language in which the study subject is conversant (English or Kiswahili)

My name is Fridah Tobias Mtui I am a pursuing master's degree in psychiatry at Muhimbili University of Health and Allied Sciences. I am doing a study on insight impairment and Associated Factors among Patients with Bipolar Disorder as part of my degree award fulfillment. Being one among the patients attending Adult Psychiatric Clinic at Muhimbili National Hospital; I would like to ask you to participate in this study. First I will explain to you about the study and I will be ready to answer any question that you have.

The aim of this study is to determine insight impairment and associated factors among patients with bipolar disorder.

This study will be conducted by me under my supervisor.

This is an academic research and you are required to understand the following which apply to all in the research;

Your participation is completely voluntary and you may withdraw consent at any time in the course of the interview

Refusal to participate will not in any way affect your health services/benefits which you are entitled

After reading the explanation, don't hesitate to ask any questions in case you need clarifications

I will assess you using an instrument which will take about 30 minutes

No invasive procedures such as drawing blood will be involved

All information obtained from this study will remain confidential. Code numbers instead of your name will be used.

Risks and Benefits

If you would like to talk with counselors or mental health personnel after this interview it can be arranged for you.

There will be no direct benefits to you. However, the overall study will be of benefit for providing information that can be used to develop interventions and comprehensive care to patients with impaired insight so as to give out better outcome of Bipolar disorder management.

If you have any questions related to this study, or your health you can contact the principle researcher Fridah Tobias Mtui 0757- 862132 or my supervisor Dr. Samuel Likindikoki 0784-768639. **You can also contact the chairperson of the Research Senate and Publication committee, Dr. Bruno Sunguya- 0685-217272**

P.O. Box 65001 Dar es Salaam

I the undersigned do hereby volunteer to participate in this study. The nature and purpose have been fully explained to me.

I understand that all information obtained will be used for this study only.

SIGNED----------DATE ----------

WITNESSED----------SIGNATURE----------DATE…….

Appendix II:Informed consent form - Swahili

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FOMU YA RIDHAA KUSHIRIKI KWENYE UTAFITI KUHUSU KIWANGO CHA UFAHAMU JUU YA UGONJWA WA HISIA MSETO NA SABABU ZINAZOHUSIA

Jina langu ni Fridah Tobias Mtui: Ninatokea chuo kikuu cha tiba na afya Muhimbili katika idara ya afya na magonjwa ya akili ninafanya, utafiti kuhusu kiwango na sababu zinazohusiana na ufahamu wa ugonjwa wa akili kwa wagonjwa wa hisia mseto wanaouhudhuria kliniki ya magonjwa ya akili katika hospitali ya Taifa ya Muhimbili.

Ikiwa huu ni utafiti wa sayansi ya tiba unapaswa ufahamu yafuatayo kabla ya kushiriki;

Dhumuni la Utafiti huu: Kama nilivyo sema hapo awali dhumuni nikufanya utafiti kuhusu kiwango na sababu za ufahamu wa ugonjwa wa akili kwa wagonjwa wa hisia mseto wanaohudhuria kliniki ya magonjwa ya akili katika hospitali ya Taifa ya Muhimbili.

Namna ya kushiriki: Ushiriki wako kwenye utafiti huu ni wa hiyari kabisa na unaweza kukataa kushiriki au kusitisha mahojiano wakati wowote. Kukataa kushiriki hakutaingilia huduma zako za tiba wala faida unazotakiwa kuzipata hapa kliniki.

Usisite kuuliza swali lolote pale unapoona kuna sababu. Kama ukikubali kushiriki mahojiano yataendeshwa kwa kutumia dodoso maalum.

Madhara: Ikiwa wakati unajieleza ukipata kikwazo na kuona unahitaji mshauri nasaha au mtoa huduma wa afya ya akili kwa mazungumzo zaidi tutakuwa tayari kusaidia

Usiri: Taarifa zako utakazozitoa hazitawekwa hadharani kwa namna yeyote ile kwa hiyo ushiriki wako hautafahamika. Jina lako au taarifa zozote zinazokutambulisha hazitaambatanishwa na taarifa zako utakazozitoa.

Mwisho wa ufafiti taarifa hizi zitafungiwa na baadaye kuharibiwa baada ya kuwekwa na kutunzwa kwenye mfumo wa elektroniki

Kumbuka: Hakutakuwa na faida ya moja kwa moja kwako kutokana na utafiti huu ila matokeo ya utafiti yatasaidia katika mpango wa tiba kwa wagonjwa wa hisia mseto walio na upugufu wa ufahamu juu ya magonjwa ya hisia mseto.

Nani wa kumuuliza: Kama una maswali zaidi ambayo ungependa kuuliza kuhusiana na utafiti huu, tafadhali wasiliana na

Mtafiti Mkuu: Fridah Tobias Mtui 0757- 862132

Idara ya magonjwa ya akili
Chuo Kikuu cha afya Muhimbili
Dr. Bruno Sunguya- 0685217272
Mwenyekiti wa kamati ya utafiti na machapisho ya chuo
S.L.P. 65001 Dar es salaam, Tanzania
Nimesoma au nimeambiwa kuhusu yaliyomo humu ndani. Maswali yangu yamejibiwa. Nakubali kushiriki katika utafiti huu.
Sahihi…….
Mshiriki amekubali…….

Appendix III Screening tool –English

MANIA AND HYPOMANIA.

(➡ MEANS: GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN MANIC AND HYPOMANIC DIAGNOSTIC BOXES)

Do you have any family history of manic-depressive illness or bipolar disorder or any family member who had mood swings treated with a medication like lithium, sodium valproate (Depakote) or lamotrigine (Lamictal)? NO YES

THIS QUESTION IS NOT A CRITERION FOR BIPOLAR DISORDER, BUT IS ASKED TO INCREASE THE CLINICIAN'S VIGILANCE ABOUT THE RISK FOR BIPOLAR DISORDER.

IF YES, PLEASE SPECIFY WHO: _____

C1 a. Have you **ever** had a period of time when you were feeling 'up' or 'high' or 'hyper'

and so active or full of energy or full of yourself that you got into trouble, - or that

other people thought you were not your usual self? (Do not consider

times when you were intoxicated on drugs or alcohol.) NO YES

IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT YOU MEAN

BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS: By 'up' or 'high' or 'hyper'

I mean: having elated mood; increased energy or increased activity; needing less sleep;

having rapid thoughts; being full of ideas; having an increase in productivity, motivation,

creativity, or impulsive behavior; phoning or working excessively or spending more money.

IF NO, CODE **NO** TO **C1b**: **IF YES** ASK:

b. Are you currently feeling ‘up’ or ‘high’ or ‘hyper’ or full of energy? NO YES

C2 a. Have you **ever** been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified? NO YES

IF YES ASK:

Are you currently feeling persistently irritable? NO YES

➡

IS **C1a** OR **C2a** CODED **YES**? NO YES

C3 IF **C1b** OR **C2b** = **YES**: EXPLORE THE **CURRENT** EPISODE FIRST AND THEN THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE

IF **C1b** AND **C2b** = **NO**: EXPLORE **ONLY** THE MOST SYMPTOMATIC **PAST** EPISODE

WHEN EXPLORING THE CURRENT EPISODE, PREFACE EACH QUESTION AS FOLLOWS:

Over the past few days including today, when you felt high and full of energy or irritable, did you:

WHEN EXPLORING THE PAST EPISODE, PREFACE EACH QUESTION AS FOLLOWS:

Over a period of a few days in the past, when you felt most high and most full of energy or most irritable, did you:

Current Episode Past Episode

a. Feel that you could do things others couldn't do, or that you were an NO YES NO YES

especially important person? **IF YES**, ASK FOR EXAMPLES**.**

THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA.

Current Episode ☐ No ☐ Yes

Past Episode ☐ No ☐ Yes

b. Need less sleep (for example, feel rested after only a few hours of sleep)? NO YES NO YES

Current Episode Past Episode

c. Talk too much without stopping, or felt a pressure to keep talking? NO YES NO YES

d. Notice your thoughts going very fast or running together or racing NO YES NO YES

or moving very quickly from one subject to another?

e. Become easily distracted so that any little interruption NO YES NO YES

could distract you?

f. Have a significant increase in your activity or drive, at work, at school,

socially or sexually or did you become physically or mentally restless? NO YES NO YES

This increase in activity may be with or without a purpose.

g. Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)? NO YES NO YES

C3 SUMMARY: WHEN RATING CURRENT EPISODE: NO YES NO YES

IF **C1b** IS **NO,** ARE **4** OR MORE **C3** ANSWERS **INCLUDING C3f** CODED **YES**?

IF **C1b** IS **YES**, ARE **3** OR MORE **C3** ANSWERS **INCLUDING C3f** CODED **YES**?

WHEN RATING PAST EPISODE:

IF **C1a** IS **NO**, ARE **4** OR MORE **C3** ANSWERS **INCLUDING C3f** CODED **YES**?

IF **C1a** IS **YES**, ARE **3** OR MORE **C3** ANSWERS **INCLUDING C3f** CODED **YES**?

CODE **YES** ONLY IF THE ABOVE 3 OR 4 SYMPTOMS OCCURRED DURING THE SAME TIME PERIOD.

RULE: ELATION/EXPANSIVENESS REQUIRES ONLY **3** OF THE **C3** SYMPTOMS, WHILE IRRITABLE MOOD ALONE REQUIRES **4** OF THE **C3** SYMPTOMS.

C4. What is the longest time these symptoms lasted (most of the day nearly every day)?

ASSESS THIS DURATION FROM THE VERY START TO THE VERY END OF SYMPTOMS, NOT JUST THE PEAK.

a) 3 consecutive days or less ☐ ☐

b) 4, 5 or 6 consecutive days or more ☐ ☐

c) 7 consecutive days or more ☐ ☐

C5 Were you hospitalized for these problems? NO YES NO YES

IF YES, CIRCLE **YES** IN MANIC EPISODE FOR THAT TIME FRAME AND GO TO **C7**.

C6 Did these symptoms cause significant problems at home, at work, socially,

in your relationships, at school or in some other important way? NO YES NO YES

C7 Were these symptoms associated with a clear change in the way that you previously functioned and that was different from the way that you usually are? NO YES NO YES

ARE **C3 SUMMARY** AND **C7** AND (**C4C** OR **C5** OR **C6** OR ANY PSYCHOTIC FEATURE IN **K1** THROUGH **K8**) CODED **YES**?

AND

IS "RULE OUT ORGANIC CAUSE (**O2 SUMMARY**)"

CODED **YES**?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

YES	**NO**
MANIC EPISODE	
CURRENT	☐
PAST	☐

IS **C3 SUMMARY** CODED **YES** AND ARE **C5** AND **C6** CODED **NO** AND **C7** CODED **YES**, AND IS EITHER **C4b** OR **C4C** CODED **YES**?

AND

IS "RULE OUT ORGANIC CAUSE (**O2 SUMMARY**)" CODED **YES**?

AND

ARE **ALL** PSYCHOTIC FEATURES IN **K1** THROUGH **K8** CODED **NO**?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **YES** TO CURRENT MANIC EPISODE, THEN CODE

CURRENT HYPOMANIC EPISODE AS **NO**.

IF **YES** TO PAST MANIC EPISODE, THEN CODE PAST

HYPOMANIC EPISODE AS **NOT EXPLORED**.

HYPOMANIC EPISODE

CURRENT ☐ **NO**

☐ **YES**

PAST ☐ **NO**

☐ **YES**

☐ **NOT EXPLORED**

ARE **C3 SUMMARY** AND **C4a** CODED **YES** AND IS **C5** CODED **NO**?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **YES** TO CURRENT MANIC EPISODE OR HYPOMANIC EPISODE,

THEN CODE CURRENT HYPOMANIC SYMPTOMS AS **NO.**

IF **YES** TO PAST MANIC EPISODE OR **YES** TO PAST HYPOMANIC EPISODE, THEN CODE PAST HYPOMANIC SYMPTOMS AS **NOT EXPLORED.**

HYPOMANIC SYMPTOMS

CURRENT ☐ **NO**

☐ **YES**

PAST ☐ **NO**

☐ **YES**

☐ **NOT**

EXPLORED

C8 a) IF MANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK:

Did you have 2 or more of these (manic) episodes lasting 7 days or more (**C4c**) in your lifetime (including the current episode if present)? NO YES

b) IF MANIC OR HYPOMANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK:

Did you have 2 or more of these (hypomanic) episodes lasting 4 days or more (**C4b**) in your lifetime (including the current episode)? NO YES

c) IF THE PAST "HYPOMANIC SYMPTOMS" CATEGORY IS CODED POSITIVE ASK:

Did you have these hypomanic symptoms lasting only 1 to 3 days (**C4a**) 2 or more times in your lifetime, (including the current episode if present)? NO YES

MAJOR DEPRESSIVE EPISODE

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO IN THE DIAGNOSTIC BOX)

A1 a. Were you ever depressed or down, or felt sad, empty or hopeless most of the day, nearly every day, for two weeks? NO YES

IF NO, CODE NO TO **A1b**: IF **YES** ASK:

b. For the past two weeks, were you depressed or down, or felt sad, empty or hopeless most of the day, nearly every day? NO YES

A2 a. Were you ever much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks? NO YES

IF NO, CODE NO TO **A2b**: IF **YES** ASK:

b. In the past two weeks, were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time? NO YES

➡

IS **A1a** OR **A2a** CODED **YES**? NO YES

A3 IF **A1b** OR **A2b** = **YES**: EXPLORE THE **CURRENT** EPISODE.

Over the past two weeks' period, when you felt depressed or uninterested:

a.Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by • }5% of body weight or • }8 lb or • } 3.5 kg, for a 160 lb/70 kg person in a month)?

NO YES

IF **YES** TO EITHER, CODE **YES**.

b. Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?

NO YES

c Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day? Did anyone notice this?

NO YES

d Did you feel tired or without energy almost every day?

NO YES

e Did you feel worthless or guilty almost every day?

NO YES

IF **YES**, ASK FOR EXAMPLES**.** LOOK FOR DELUSIONS OF FAILURE, OF INADEQUACY, OF RUIN OR OF GUILT, OR OF NEEDING PUNISHMENT OR DELUSIONS OF DISEASE OR DEATH OR NIHILISTIC OR SOMATIC DELUSIONS.

THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA.

Current Episode ☐ No ☐ Ye

f. Did you have difficulty concentrating, thinking or making decisions almost every day?

NO YES

g Did you repeatedly think about death **(FEAR OF DYING DOES NOT COUNT HERE),** or have any thoughts of killing yourself, or have any intent or plan to kill yourself? Did you attempt suicide? **IF YES TO EITHER, CODE YES.**

NO YES

A4 Did these symptoms cause significant distress or problems at home, at work, at school, socially, in your relationships, or in some other important way, and are they a change from your previous functioning? NO YES

ARE **5** OR MORE ANSWERS (**A1-A3**) CODED **YES** AND IS **A4** CODED **YES**?

AND

IS "RULE OUT ORGANIC

CAUSE (**O2 SUMMARY**)" CODED **YES**?

SPECIFY IF THE EPISODE IS CURRENT

NO	**YES**
MAJOR DEPRESSIVE EPISODE	
CURRENT	☐

Appendixes IV Dodoso la uchunguzi Kiswahili

'MANIA' NA 'HAIPOMANIA'

(➡ INA MAANISHA: NENDA KWENYE KISANDUKU CHA UTAMBUZI, ZUNGUSHIA HAPANA KATIKA VISANDUKU VYA UTAMBUZI WA 'MANIA' NA 'HAIPOMANIA')

Je, kuna historia ya magonjwa ya akili yahusianayo na hisia mseto katika familia yako au kuwa na ndugu aliyekuwa na mabadiliko ya kihisia na kutibiwa kwa dawa kama Lithium, Sodium Valproate au Lamotrigeni? NDIYO HAPANA

SWALI HILI SIO KIGEZO CHA UGONJWA WA AKILI WA HISIA MSETO, BALI LINAULIZWA KUONGEZA UNGALIFU WA SABABU ZA HATARI ZA UGONJWA WA HISIA MSETO KWA DAKTARI.

Kama ndiyo ni nani?.....

C1 a. Ulishawahi kuwa na kipindi ambacho ulihisi kuwa juu au kuwa na mfumuko na kuwa mtendaji sana au kuwa na nguvu zaidi ya kawaida au kujiingiza kwenye matatizo au watu wengine kukuona hauko katika kawaida yako? (usifikirie kipindi ulipokuwa umetumia vilevi)

NDIYO HAPANA

KAMA MGONJWA ANASHANGAZWA AU HAJUI UNAMAANISHA NINI KWA KUWA JUU AU KUWA NA MFUMUKO, FAFANUA KAMA IFUATAVYO: Kwa kuwa juu au kuwa na mfumko, nina maanisha: kuwa na hisia yenye furaha kubwa, kuwa na nguvu zaidi ya kawaida au kuongezeka kwa shughuli za vitendo, haja ya kulala kidogo, kuwa na mawazo ya haraka, kujaa mawazo, kuongezeka kwa uzalishaji, motisha, ubunifu, au tabia ya kutenda bila kutafakari, kupiga simu au kufanya kazi kuzidi kiasi au kutumia pesa zaidi.

KAMA **HAPANA,** JIBU **HAPANA** KWA **C1b:** KAMA **NDIYO** ULIZA:

b. je kwa sasa una hisia za kuwa juu au kuwa na nguvu zaidi ya kawaida? HAPANA NDIYO

C2 a. Ulishawahi kuwa na hisia za kisirani zilizokaa kwa muda wa siku kadhaa, ambazo zilipelekea kuwa na malumbano au ugomvi wa vitendo, kukaripia watu tofauti na wanafamilia yako? Umegundua au watu kugundua kuwa umezidi kuwa na kisirani au kuguswa zaidi, ukilinganisha na watu wengine katika hali uliyohisi ni halali? HAPANA NDIYO

KAMA HAPANA, CHAGUA HAPANA KATIKA **C2b: KAMA NDIYO** ULIZA:

b. Kwa sasa una hisia za kisirani ambazo zimekuwepo kwa muda?
HAPANA NDIYO

➡

KATIKA **C1a** au **C2a** kuna chaguo la **NDIO?** HAPANA NDIYO

C3 KAMA **C1b** AU **C2b** jibu ni **NDIYO**: CHUNGUZA KWANZA KIPINDI CHA SASA NA BAADAE KIPINDI CHA NYUMA KILICHOKUWA NA DALILI NYINGI, VINGINEVYO

KAMA C1b NA C2b jibu ni **HAPANA**: CHUNGUZA KIPINDI CHA NYUMA TU KILICHOKUWA NA DALILI NYINGI

WAKATI WA KUCHUNGUZA KIPINDI CHA SASA, UTANGULIZI WA KILA SWALI NI KAMA IFUATAVYO:

Katika siku chache zilizopita pamoja na leo, ulipohisi kuwa juu na kuwa na nguvu zaidi ya kawaida au kisirani, je ulikuwa na:

WAKATI WA KUCHUNGUZA KIPINDI CHA NYUMA, UTANGULIZI WA KILA SWALI NI KAMA IFUATAVYO:

Katika kipindi cha siku chache zamani, ulipohisi kuwa juu na kuwa na nguvu zaidi ya kawaida au kisirani, je ulikuwa na:

	Kipindi cha Sasa	Kipindi cha Zamani
a.Hisia kuwa unaweza kufanya vitu ambavyo watu wengine hawawezi kufanya au wewe ni mtu muhimu haswa? **KAMA NDIYO**, ULIZA MIFANO.	HAPANA NDIYO	HAPANA NDIYO
b. Hitaji dogo la kulala (mfano, kujisikia kupumzika baada ya masaa machache ya kulala)?	HAPANA NDIYO	HAPANA NDIYO
c. Kuongea sana bila kusimama au kuhisi msukumo kuendelea kuongea?	HAPANA NDIYO	HAPANA NDIYO
d. Kugundua mawazo yako yanaenda kwa kasi/ mbio/ pamoja au haraka kutoka kwenye mada moja kwenda nyingine?	HAPANA NDIYO	HAPANA NDIYO
e. Kuwa rahisi kuhamishwa, kiasi cha usumbufu kidogo unaweza kukuhamisha?	HAPANA NDIYO	HAPANA NDIYO

MIFANO THABITI NA KUAMINI MAWAZO AMBAYO SI VYA KWELI

Kipindi cha Sasa ☐ HAPANA ☐ NDIYO

Kipindi cha Zamani ☐ HAPANA ☐ NDIYO

f. Kuwa na ongezeko la shughuli za vitendo kazini, shuleni,

kijamii au kingono au kutokuwa na utulivu HAPANA NDIYO HAPANA NDIYO kiakili au kimwili?

Ongezeko la shughuli laweza kuwa au kutokuwa na lengo.

g. Kutaka kujiingiza kwenye shughuli za raha kiasi cha kutotililia

maanani hatari au matokeo (kwa mfano anasa, kuendesha

kizembe au kutokuwa makini katika ngono)? HAPANA NDIYO HAPANA NDIYO

MUHTASARI WA C3: WAKATI WA KUTATHIMINI KIPINDI CHA SASA:

HAPANA NDIYO HAPANA NDIYO

KAMA **C1b** JIBU NI **HAPANA,** MAJIBU MANNE AU ZAIDI YA **C3 PAMOJA NA C3f** YAMEJIBIWA **NDIYO**?

KAMA C1b JIBU NI NDIYO, MAJIBU MATATU AU ZAIDI YA C3 PAMOJA NA C3f YAMEJIBIWA **NDIYO**?

WAKATI WA KUTATHIMINI KIPINDI CHA ZAMANI:

KAMA **C1a** JIBU NI **HAPANA**, MAJIBU MANNE AU ZAIDI YA **C3 PAMOJA NA C3f** YAMEJIBIWA **NDIYO**?

KAMA **C1a** JIBU NI **NDIYO**, MAJIBU MATATU AU ZAIDI YA **C3 PAMOJA NA C3f** YAMEJIBIWA **NDIYO**?

JIBU **NDIYO** TU KAMA DALILI 3 AU 4 HAPO JUU ZILITOKEA KWA WAKATI MMOJA.

KANUNI: HISIA YA FURAHA KUBWA/UKUU INAHITAJI DALILI **3** TU ZA **C3** WAKATI HISIA YA KISIRANI PEKEE INAHITAJI DALILI **4** ZA **C3.**

C4 Ni kwa muda mrefu kiasi gani dalili hizi zilidumu (muda mwingi katika siku karibia kila siku)?

CHUNGUZA TOKA MWANZO HADI MWISHO WA DALILI, SIO KILELE TU

a) siku 3 au pungufu mfululizo ☐ ☐

b) siku 4, 5, 6 au zaidi mfululizo ☐ ☐

c) siku 7 au zaidi mfululizo ☐ ☐

C5 Ulilazwa kwa sababu ya tatizo hili? HAPANA NDIYO HAPANA NDIYO

KAMA NDIYO, ZUNGUSHIA **NDIYO** KATIKA MANIA KULINGANA NA MUDA KISHA NENDA **C7**

C6. Dalili hizi zilisabisha matatizo dhahiri nyumbani, kazini, kijamii, katika mahusiano yako shuleni au katika namna yeyote muhimu? HAPANA NDIYO HAPANA NDIYO

C7. Dalili hizi zilihusiana na mabadiliko ya wazi katika utendaji wako wa awali na jinsi unavyokuwa? HAPANA NDIYO HAPANA NDIYO

MUHTASARI WA **C3** NA **C7** NA (**C4C** AU **C5** AU **C6** AU KIPENGELE

CHOCHOTE CHA 'PSYCHOSIS' **K1** HADI **K8** KIMEJIBIWA

NDIYO?

NA

JE, SABABU ZA KIOGANIKI KUONDOLEWA (**MUHTASARI**

O2) JIBU NI **NDIYO**

NDIYO	**HAPANA**
KIPINDI CHA 'MANIA'	
SASA	☐
ZAMANI	☐

TAJA KAMA NI KIPINDI CHA SASA NA/ AU ZAMANI

MUHTASARI WA C3 JIBU NI **NDIYO** NA **C5 NA C6** JIBU NI **HAPANA** NA **C7** JIBU NI **NDIYO,** NA AMA **C4b au C4C** JIBU NI **NDIYO**

NA

JE, SABABU ZA KIOGANIKI KUONDOLEWA (**MUHTASARI O2**) JIBU NI **NDIYO**

NA

JE, VIPENGELE **VYOTE** VYA PSYCHOSIS KATIKA **K1** HADI **K8** JIBU NI **HAPANA**?

TAJA KAMA NI KIPINDI CHA SASA NA/ AU ZAMANI.

KAMA **NDIYO** KATIKA KIPINDI HIKI CHA MANIA, BASI JIBU

HAPANA KATIKA KIPINDI CHA SASA CHA HYPOMANIA**.**

KAMA **NDIYO** KATIKA KIPINDI CHA ZAMANI CHA MANIA

KIPINDI CHA 'HYPOMANIC'

SASA ☐ **NDIYO**

☐ **HAPANA**

ZAMANI

☐ **HAPANA**

☐ **NDIYO**

☐ **HAKIJA CHUNGUZWA**

BASI JIBU **HAKIJA CHUNGUZWA KATIKA** KIPINDI CHA ZAMANI CHA HYPOMANIA.

MUHTASARI WA **C3** NA **C4a** UMEJIBIWA **NDIYO** NA C5

HAPANA?

TAJA KAMA NI KIPINDI CHA SASA NA/ AU ZAMANI

KAMA **NDIYO** KWA KIPINDI CHA SASA CHA 'MANIA' AU 'HYPOMANIA',

BASI JIBU **HAPANA** KATIKA DALILI ZA SASA ZA 'HYPOMANIA'

KAMA **NDIYO** KWA KIPINDI CHA ZAMANI CHA 'MANIA' AU

NDIYO KWA KIPINDI CHA ZAMANI CHA 'HYPOMANIA',

BASI JIBU **HAZIJA CHUNGUZWA** KWENYE DALILI ZA ZAMANI ZA

'HYPOMANIA'

DALILI ZA HYPOMANIC

SASA ☐ HAPANA

☐ NDIYO

ZAMANI ☐ HAPANA

☐ NDIYO

☐HAZIJA CHUNGUZWA

C8 a) KAMA KIPINDI CHA MANIA NI CHANYA KWA SASA AU ZAMANI ULIZA:

Ulishakuwa na vipindi viwili au zaidi vilivyodumu kwa siku 7 au zaidi **(C4c)** katika wakati wa wako wa maisha? (pamoja na kipindi cha sasa kama kipo). HAPANA NDIYO

b) KAMA KIPINDI CHA MANIA AU ‘HYPOMANIA’ NI CHANYA KWA SASA AMA ZAMANI ULIZA:

Ulishakuwa na vipindi viwili au zaidi vilivyodumu kwa siku 4 au zaidi **(C4b)** katika wakati wako wa maisha? (pamoja na kipindi cha sasa kama kipo). HAPANA NDIYO

c) KAMA KUNDI LA DALILI ZA ‘HYPOMANIA’ LIMEJIBIWA NDIYO ULIZA:

Ulishakuwa na dalili za ‘hypomania’ zilizodumu kwa siku 1 hadi 3 C4a) mara 2 au zaidi katika wakati wa maisha yako, (pamoja na kipindi hiki kama kipo)?
HAPANA NDIYO

A. KIPINDI CHA SONONA

(➡ INA MAANISHA: NENDA KWENYE KISANDUKU CHA UTAMBUZI, ZUNGUSHIA HAPANA KATIKA VISANDUKU VYA UTAMBUZI WA SONONA)

A1 a. Ushawahi kujisikia kusononeka, huzuni au kukosa tumaini muda mwingi wa siku, karibia kila siku kwa wiki mbili? HAPANA NDIYO
KAMA HAPANA, JIBU HAPANA KATIKA **A1b:** KAMA **NDIYO** ULIZA:
b. Kwa wiki mbili zilizopita, umejisikia kusononeka, huzuni au kukosa tumaini muda mwingi wa siku karibia kila siku? HAPANA NDIYO

A2 a. Ushawahi kukosa raha kufanya vitu au kushindwa kufurahia vitu ambavyo ulikuwa ukivifurahia awali kwa muda wa wiki mbili? HAPANA NDIYO

KAMA HAPANA, JIBU HAPANA **A2b**: KAMA **NDIYO** ULIZA:
b. Kwa wiki mbili zilizopita, ulikosa zaidi raha kufanya vitu vingi au kushindwa kufurahia vitu ambavyo ulikuwa ukivifurahia mara nyingi? HAPANA NDIYO
JE **A1a** AU **A2a** JIBU NI **NDIYO**? HAPANA NDIYO

A3 KAMA A1b AU A2b= NDIYO: CHUNGUZA KIPINDI CHA SASA

Katika kipindi cha wiki mbili zilizopita, wakati unajisikia kusononeka au kukosa raha kufanya vitu:

a.Hamu ya kula kupungua au kuongezeka karibia kila siku? Uzito wako ulipungua au kuongezeka bila kuwa na nia hiyo (kwa 5% ya uzito au 3.5kg kwa mtu wa kilo 70 kwa mwezi)? HAPANA NDIYO

KAMA **NDIYO** KWA CHAGUO LOLOTE JIBU **NDIYO.**

b. Ulipata shida kulala karibia kila usiku (shida kupata usingizi, kuamka katikati ya usiku, kuamka mapema alfajili au kulala zaidi)? HAPANA NDIYO

➡

c. Uliongea au kutembea taratibu zaidi ya kawaida au kukosa utulivu karibia kila siku? Kuna mtu aliliona hili? HAPANA NDIYO

d. Ulihisi uchovu au kukosa nguvu karibia kila siku? HAPANA NDIYO

e. Ulihisi huna thamani au kujilaumu karibia kila siku? HAPANA NDIYO

KAMA NDIYO, ULIZA MIFANO. ANGALIA MAWAZO YA KUSHINDWA, KUTOTOSHA, KUJILAUMU AU KUHITAJI KUJIADHIBU AU MAGONJWA AU KIFO

MIFANO IKO DHAHIRI NA MAWAZO YASIYO YA KWELI

Kipindi cha sasa ☐ Hapana ☐ Ndiyo

f. Ulipata ugumu wa kuwa umakini, kuwaza au kufanya maamuzi karibia kila siku?

HAPANA NDIYO

g. Kuwaza kuhusu kifo kujirudia (**WOGA KUHUSU KUFA HAIHUSIANI**), au kuwa na mawazo ya kujiua, au kuwa na nia au mpango wa kujiua? Ulijaribu kujiua? **KAMA NDIYO KWA CHAGUO LOLOTE JIBU NDIYO.**

HAPANA NDIYO

A4 Dalili hizi zilisabisha tatizo dhahiri nyumbani, kazini, shuleni, kijamii, katika mahusiano, au katika namna muhimu na kubadili utendaji wako wa awali?

HAPANA NDIYO

MAJIBU 5 AU ZAIDI (**A1- A3**) NI **NDIYO** NA **A4** JIBU NI **NDIYO**?

NA

SABABU ZA KIOGANIKI **(MUHUTASARI O2)** JIBU **NDIYO?**

TAJA KAMA NI KIPINDI CHA SASA

KIPINDI CHA SONONA

SASA ☐

HAPANA **NDIYO**

Appendix V Questionnaire- English

Please fill the answer the correct answers.

1. GENERAL INFORMATION

Date of interview: {...../...../2020} Questionnaire serial No: .....

Name of interviwer: .....

II. DEMOGRAPHIC CHARACTERISTICS OF RESPONDENT

1. Number of interviewee:.....

2. Age of the interviewee in years…….

3. Residential area of the interviewee……...

4. Sex of the respondent

1. Male
2. Female

5. What is your current marital status?

1. Unmarried
2. Married
3. Divorced/ Separated
4. Widow
5. Cohabiting

6. What is the highest level of school you attended?

1. never went to school
2. primary
3. secondary
4. university

5. postgraduate/ Masters
6. adult education
7. What is the highest (grade/form/year) you completed at that level?

   GRADE/FORM/YEAR . . . . . .

8. What do you do for living?

   1. Farmer/Peasant

   2. Business/Self employment

   3. Employed with salary

   4. Student/no job

III. ILLNESS CHARACTERISTICS

9. Age at first episode of bipolar Affective Disorder? .....

10. Disease duration in years…….

11. Number of admission so far…….....

12. Are you using any medication to manage bipolar Affective Disorder?

    1. Yes
    2. No

13. Which medications are you using?

    1. Antipsychotics
    2. Mood stabilizers
    3. Antidepressants
    4. In combination……

14. What psychotherapy intervention for bipolar disorders have you ever been given?

    1. Psychoeducation
    2. Psychoeducation + other intervention
    3. None

15. Substance use (in current 12 months)

    1. Yes

    2. No

    a. Cannabis 1) Yes 2) No ……...

    b. Alcohol 1) Yes 2) No ……

    c. Tobacco 1) Yes 2) No ……

    d. Other (mention) ……

INSIGHT SCALE FOR AFFECTIVE DISORDER (ISAD)

In scale of 0 to 5 indicate your awareness in the following where by

0 indicating item cannot be evaluated	3 moderate aware
1 not aware	4 aware
2 slight aware	5 very aware

Tick where applicable

s/no		0	1	2	3	4	5
16.	To what extend are you aware that you are suffering from affective disorder?						
17.	How aware are you on efficacy of treatment for current symptoms or preventing relapse?						
18.	To what extend are you aware of consequences of illness on your work, family and social life?						
19.	To what extend are you aware that you are suffering from a depressed/expansive or irritable mood?						
20.	To what extend are you aware that you are suffering from a marked increase/reduction in pleasurable activities?						
21.	To what extend are you aware that you are suffering from a significant increase/loss of weight (as appropriate)						
22.	To what extend are you aware that you are suffering from insomnia or hypersomnia (as appropriate)						
23.	To what extend are you aware that you are suffering from sluggishness or psychomotor agitation?						
24.	To what extend are you aware that you are suffering from fatigue or an excess of energy?						
25.	To what extend are you aware that you are suffering from feelings of uselessness or guilt?						
26.	To what extend are you aware that you are suffering from slowed speech orverbosity/garrulousness?						
27.	To what extend are you aware that you are suffering from bradypsychia /idea flight (as appropriate)?						
28.	To what extend are you aware that you are having a short attention span/showing distractibility?						
29.	To what extend are you aware that you are having an						

	untidy appearance?						
30.	To what extend are you aware that you are having symptoms of confusion-disorientation?						
31.	To what extend are you aware that you are having poor social relationships?						
32.	To what extend are you aware that you are suffering from delusions and hallucinations?						

Thank you for your participation.!

Appendix VI Dodoso la Kiswahili

SEHEMU YA 1: Maelezo binafsi na ya hali ya ugonjwa

1. Umri (miaka) ……

2. Mahali unapoishi …….
3. Jinsi
    1. Mwanamume
    2. Mwanamke …….
4. Hali yako ya ndoa kwa sasa
    1. Nimeoa/Nimeolewa
    2. Sijaoa/Sijaolewa
    3. Tumeachana/Tumetengana
    4. Mjane
    5. Naishi na mwanamke/bwana .....
5. Je una elimu gani?
    1. Sijasoma
    2. Elimu ya msingi
    3. Elimu ya sekondari
    4. Elimu ya chuo/chuo kikuu
    5. Nina shahada ya pili/stashahada .....
    6. Elimu ya watu wazima
6. Una kiwango gani cha juu (miaka, kidato, darasa) cha elimu uliyonayo?.....
7. Una shughuli gani ya kujikimu kimaisha?
    1. Mkulima
    2. Mfanyabiashara/ nimejiajiri
    3. Nimeajiriwa
    4. Mwanafunzi/sina kazi .....

TABIA ZA UGONJWA

8. Ulikuwa na umri gani wakati wa mlipuko wa kwanza wa ugonjwa? (miaka).....

9. Una muda gani toka uanze kuugua? (miaka) .....
10. Ushalazwa mara ngapi hadi sasa kwa ajili ya ugonjwa wa akili? .....
11. Unatumia dawa yoyote kwa ajili ya ugonjwa wa akili?
    1. Ndio
    2. Hapana .....
12. Ni dawa gani unatumia?
    1. Antisaikotiki
    2. Tukiza mhemko
    3. Dawa za mfadhaiko
    4. Kwa mjumuisho ainisha .....
13. Kwa muda gani sasa umekuwa ukitumia dawa hiyo/ hizo .....
14. Umeshawahi kupata huduma gani ya tiba ya kisaikolojia?
    1. Elimu ya kisaikolojia
    2. Elimu ya kisaikolojia + nyingine
    3. Sijawahi pata .....
15. Je unatumia kilevi chochote kwa muda wa miezi 12 iliyopita?
    1. Ndiyo
    2. Hapana .....

    Ni aina gani ya kilevi umekuwa ukitumia kwa miezi 12 iliyopita?

    a. Bangi 1. Ndiyo au 2. Hapana.....
    b. Pombe 1. Ndiyo au 2. Hapana.....
    c. Tumbaku 1. Ndiyo au 2. Hapana.....
    d. Nyingine (Taja).....

UFAHAMU

SKELI YA UFAHAMU KWA MAGONJWA YA KIHISIA

Katika skeli ya 0-5 elezea ufahamu wako katika yafuatayo ikiwa;

0 inaashiria hakihusiki au hakiwezi kutathiminiwa 3 anafahamu wastani

I891 hafahamu 4.anafahamu

2anafahamukidogo 5.anafahamu vizuri

s/no.		0	1	2	3	4	5
16.	Ni kwa kiwango gani una fahamu kwamba unaumwa ugonjwa wa akili unaoathiri hisia?						
17.	Kwa kiwango gani una fahamu ufanisi wa matibabu unayoyatumia katika kutuliza dalili za ugonjwa au kuzuia dalili za ugonjwa kurudia tena?						
18.	Kwa kiwango gani una fahamu kuwa ugonjwa wako umechangia kuleta mabadiliko katika kazi, familia na maisha yako ya kijamii?						
19.	Kwa kiwango gani una fahamu kuwa unasumbuliwa na hisia ya kinyonge/ kututumua au kisirani						
20.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na ongezeko/ punguzo kubwa la shughuli za kufurahisha (yoyote inayohusika)						
21.	Ni kwa kiwango gani una fahamu kuwa umepungua/ kuongezeka uzito kwa kiasi kikubwa (yoyote inayohusika)						
22.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na hali ya kukosa usingizi au kuwa na usingizi zaidi (yoyote inayohusika)						
23.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na kufanya mambo polepole au haraka?						
24.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na uchovu uchovu au kujihisi mwenye nguvu kuliko kawaida?						
25.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na hali ya kujisikia haufai kuwa na hatia						
26.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na hali ya kuongea polepole/ haraka						
28.	Ni kwa kiwango gani una fahamu kuwa unasumbuliwa na hali ya kuwa na kasi/polepole katika mawazo						
29.	Ni kwa kiwango gani una fahamu kuwa una umakini wa muda mfupi/ hali ya kuvurugwa kirahisi						
30.	Ni kwa kiwango gani una fahamu kuwa una muonekano usio nadhifu?						
31.	Ni kwa kiwango gani una amini kuwa unafahamu kuwa una dalili za kuchanganyikiwa						
32.	Ni kwa kiwango gani una fahamu kuwa una mahusiano hafifu ya kijamii						
33.	Ni kwa kiwango gani unafahamu kuwa unasumbuliwa na hali ya kuona, kusikia, kuhisi au kunusa vitu ambavyo havipo au kuamini wazo ambalo si la kweli?						

Appendix VII Approval for 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: 26/10/2020

MUHAS-REC-10-2020-410
Fridah Tobias Mtui
MMed in Psychiatry and Mental Health, School of Medicine
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: INSIGHT IMPAIRMENT AND ASSOCIATED FACTORS AMONG ADULT PATIENTS WITH BIPOLAR DISORDER ATTENDING CLINIC AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

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: 26/10/2020
EXPIRATION DATE OF APPROVAL: 25/10/2021

STUDY DESCRIPTION:
Purpose:
The purpose of this study to determine insight impairment according to four objects (insight about symptoms, the condition itself, need for treatment and social consequences) and associated factors among patients with Bipolar Disorder

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-%20264.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 VIII 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.226//2018

27th October, 2020

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

Re: INTRODUCTION LETTER

The bearer of this letter is Fridah Tobias Mtui, 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: **"INSIGHT IMPLAIREMENT AND ASSOCIATED FACTORS AMONG ADULT PATIENTS WITH BIPOLAR DISORDER ATTENDING CLINIC AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM."**

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. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Medicine, **MUHAS**
cc: Fridah Tobias Mtui

Appendix IX Permission to collect data at MNH

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

MUHIMBILI NATIONAL HOSPITAL

In reply please quote;

Ref. No.: MNH/TRCU/Perm/2020/0014 **Date: 04th November, 2020**

Head of Department,
Psychiatry
Muhimbili National Hospital

RE: PERMISSION TO COLLECT DATA AT MNH.

Name of Student	**Fridah Tobias Mtui**
Title	**"Insight Impairment and Associated Factors Among Adult Patients with Bipolar Disorder Attending Clinic at Muhimbili National Hospital, Dar es salaam".**
Institution	**Muhimbili University of Health and Allied Sciences**
Supervisor	Dr. Samuel Likindikoki
Period	04th November 2020, to 31th December, 2020

Approval has been granted to the above mentioned student to collect data at MNH.

Kindly ensure that the student abide to the ethical principles and other conditions of the research approval.

Sincerely,

HEAD, TEACHING, RESEARCH & CONSULTANCY UNIT
P.O. Box 65000
DAR ES SALAAM

Dr. Faraja Chiwanga
Head of Teaching, Research and Consultancy Unit