COLLEGE OF MEDICINE AND HEALTH SCIENCES
SCHOOL OF MEDICINE AND PHARMACY

ASSESSMMENT OF CHRONOLOGICAL ONSET, TREATMENT ADHERENCE AND QUALITY OF LIFE OF PEOPLE WITH DUO DIAGNOSIS OF MENTAL DISORDERS AND HIV/AIDS AT NDERA NEUROPSYCHIATRIC HOSPITAL

Thesis submitted in partial fulfillment of the requirement for the Award of Master of Medicine in Psychiatry in the College of Medicine and Health Sciences, University of Rwanda.

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DECLARATION

I, Jacqueline INGABIRE, hereby declare and certify that the work presented in this dissertation entitled **"ASSESSMMENT OF CHRONOLOGICAL ONSET, TREATMENT ADHERENCE AND QUALITY OF LIFE OF PEOPLE WITH DUO DIAGNOSIS OF MENTAL DISORDERS AND HIV/AIDS AT NDERA NEUROPSYCHIATRIC HOSPITAL"** is entirely my original work and it has never been presented or submitted in a whole or in part to any other university.

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We, hereby declare that this dissertation has been submitted with our approval as supervisors.

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DEDICATION

I most gratefully dedicate this work to the almighty God who has stayed alongside through my life, my family and friends for their encouragement and sacrifices.

God bless you abundantly.

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First of all, my gratitude goes to Dr. BIZOZA RUTAKAYIRE, Dr Mudenge Charles, Dr. Janvier YUBAHWE, Dr. HABIMANA Jean Chrysostome who sacrificed their time and supervised this work. Your sacrifice, meticulous guidance and corrections made to this achievement.

Many thanks to my family for their sacrifices, encouragement and invaluable support which led to the completion of this dissertation.

For you, all cited or forgotten, who contributed to my studies in Master of Medicine in Psychiatrics, I say thank you.

Dr. Jacqueline INGABIRE

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LIST OF ABBREVIATIONS

ART: Antiretroviral Therapy
AIDS: Acquired Immune Deficiency Syndrome
HIV: Human Immunodeficiency Virus
LMIC: Low and Middle Income Countries
MARS: Medication Adherence Rating Scale
PLHIV: People Living With HIV
PTSD: Post-traumatic Stress Disorder
QOL: Quality of Life
UNAIDS: Joint United Nations Programme on HIV/AIDS
WHO: World Health Organization
CD4: Cluster of Differentiation 4

ABSTRACT

Background: There is high inter-dependency and link of mental health disorders and HIV/AIDS as reported from different studies. Thus, this study assessed the chronological onset of HIV/AIDS and mental disorders, adherence to treatment and quality of life (QOL) in people with HIV/AIDS and mental health disorders at Ndera Neuropsyhiatric Hospital.

Methods: A facility-based cross-sectional study that used MARS questionnaire to assess the adherence rate and the information on the QOL was collected using SF-36 questionnaire and translated in Kinyarwanda (Translated SF-36 and MARS tools). Group comparison of mean scores was done using t-test for normally distributed scores of quality of life domains then Mann Whitney U test and Kruskal Wallis test were used for skewed scores of quality of life domains.

Results: The median age for our participants was 44.9 ± 10.34 years and the majority of participants (75.8%) were females. Of all participants, 56.03% were diagnosed with mental health disorders before being diagnosed with HIV whereas HIV infection was diagnosed before mental disorder in 43.97% of the participants. Of all participants, 17 participants (14.6%) were found to have poor adherence to their psychotropic medications while 5 participants (4.3%) were having poor to their ART medications. There was no observed significant difference in the adherence to both antipsychotics and ARTs across the chronology of diagnosis groups. Differences in QOL were observed in mean role limitation domain across age group and in mean role limitations due to physical activities (p=0.049) and in mean role limitations due to emotional problems across education backgrounds (0.004). A significant difference in the mean QOL in the energy/fatigue domain was also found across the living status (p=0.044) and in the general health domain between male and female participants (p=0.013).

Conclusion: Of our study participants, HIV infection showed to have been diagnosed after the diagnosis of subsequent mental disorder. Patients with duo diagnosis of mental health and HIV are more likely to have poor adherence to their antipsychotics (14.6%) compared to adherence on their ART medications (4.3%). Patients with duo diagnosis of mental disorder and HIV have higher scores of QOL in physical functioning and poor scores of quality of life in social well-being and emotional functioning domain.

Keywords: Quality of Life, adherence, mental health, HIV, mental disorder

CHAPTER I: INTRODUCTION

1.1. Background

About 4.4% of the population in the World are estimated by the World Health Organization (WHO) to suffer from depression and 3.6% suffer from anxiety disorder but when it comes to Africa alone, depression is prevalent at 5.4% (WHO, 2017). On the other hand, HIV/AIDS is among major causes of mortality and/or morbidity especially in low and middle income countries (Ngum, Fon, Ngu, Verla, & Luma, 2017). There is high inter-dependency and link of mental disorders and HIV/AIDS from different previous studies (Chibanda, Cowan, Gibson, Weiss, & Lund, 2016; Coordinating & Issue, 2020; Duko, Toma, & Abraham, 2019; WHO, 2017). Mental health disorders like alcohol-related disorders were found to be associated with HIV infection and interfere with successful HIV/AIDS treatment (Coordinating & Issue, 2020; Duko et al., 2019).

The previously conducted studies reported that the rate of mental health disorders is higher in people living with HIV/AIDS persons without HIV/AIDS and they increase the chance of contracting HIV transmission especially in the LMICs (Duko et al., 2019). Although life expectancy in HIV patients has improved over time due to the anti-retroviral treatment, mental health disorders mainly depression interfere with adherence to antiretroviral treatment and these researchers showed that the rate of depression was high among patients who did not have companions compared to those living with companions and high among participants with low CD4 count and also higher prevalence in participants who are unmarried, unemployed and those with high education level (Ngum et al., 2017). Aboma et al. in Ethiopia found that among adult people living with HIV/AIDS, drinking alcohol, having stage 4 of the disease, having family history of mental illness were statistically associated with common mental health disorders (Motumma, Negesa, Hunduma, & Abdeta, 2019a). Ngum et al. reported that unemployment, age <40 years of age and low CD4 count of <200c/ml were the major risk factors (Ngum et al., 2017).

Many effects from mental illnesses in persons living with HIV/AIDS have been reported from different studies and they include reduction of medication adherence, decrease of accessibility to health care services (Kagee, Saal, Villiers, Sefatsa, & Bantjes, 2017; Motumma et al., 2019a).

1.2. Problem statement

There is a strong inter-relationship HIV infection as previous studies have found where mental health instabilities and disorders may be a risk factor of HIV infection and to poor adherence on antiretroviral treatment and negatively influence the disease progression whereas HIV infection and anti-retroviral treatment may lead to psychiatric disorders like depression, anxiety PTSD (Coordinating & Issue, 2020; Kagee et al., 2017; Motumma et al., 2019a; Pence, 2009).

According to World Health Organization (WHO) and reports from other researchers, mental disorders are underdiagnosed and/or undertreated in persons living with HIV/AIDS (Motumma, Negesa, Hunduma, & Abdeta, 2019b; Ngum et al., 2017; Sulyman, 2013; Thom, 2009; WHO, 2017).

In Rwanda, the study done previously reported a prevalence of 31% in HIV positive adolescents (Mukangabire et al., 2021). However, there are no other studies done to assess other mental diseases prevalence in persons living with mental illnesses and HIV/AIDS, to assess their chronological onset and to assess the QOL among people living with both HIV/AIDS and mental health disorders.

Thus, this study will assess the chronological onset of HIV/AIDS and mental disorders, treatment adherence and QOL in people with HIV/AIDS and mental health disorders at Ndera Neuropsyhiatric Hospital.

1.3. Research questions

i What is the chronological onset of HIV/AIDS and mental disorders among people living with both conditions?

ii What is their treatment adherence behavior vis-a-vis ARTs and psychotropic medication

iii What is their perceived quality of life?

1.4. Research objectives

1.4.1. General objective

To assess the chronological onset of HIV/AIDS and mental disorders; determine their adherence behavior to ART and Psychotropic medications as well their perceived quality of life.

1.4.2. Specific objectives

i To determine the chronological onset of HIV/AIDS and mental disorders among people living both conditions

ii To determine the treatment adherence behavior vis-à-vis ARTs and psychotropic medications among people living with HIV and mental disorders.

iii To determine the perceived quality of life of people diagnosed with mental disorders and HIV/AIDS

1.5. Significance of the study

There is lack of data on chronological onset of HIV/AIDS and mental disorders, treatment adherence and QOL in persons living with HIV/AIDS (PLHIV) and mental health disorders. To our knowledge, there is no study done yet on the chronological onset of HIV/AIDS and mental disorders, adherence and QOL among PLHIV and mental health disorders in Rwanda. The results of this study will provide the data and inform the literature for further similar studies.

CHAPTER II: LITERATURE REVIEW

2.0. Introduction

This chapter will mainly come back on what is known about this study topic. It will highlight the theoretical literature, the empirical literature, critical review and research gap identification, the theoretical framework as well as the conceptual framework.

2.1. Theoretical literature

This theoretical literature will cover what is known so far about mental health disorders and HIV/AIDS.

2.1.1. Overview on mental disorders

Mental health disorders are defined as disorders of thought, behaviour, emotion, and relationship with others that lead to the impairment of function in one or more activities in life (UNAIDS, 2018).

Mental health disorders include: depression, bipolar disorder, schizophrenia and other psychoses, dementia, and developmental disorders (WHO, 2019). It is estimated that approximately 50 million of the population worldwide have dementia which affects memory, thinking, calculation, orientation, comprehension and judgement (WHO, 2019). Substance abuse is defined as harmful use of psychoactive substances that may lead to dependency and they include alcohol and drugs (WHO, 2017).

There is a reported evidence of relationship between HIV/AIDS and mental health disorders mainly depression, posttraumatic stress disorder (PTSD), and disorders associated with alcohol/drug use (Ciesla & Roberts, 2001; Russolillo et al., 2020; UNAIDS, 2018)

2.1.2. Overview on HIV/AIDS

The WHO estimated that 37.7 million living with HIV in 2020 globally with an incidence 1.5 million infections in 2020 and 680,000 deaths from HIV/AIDS-related illnesses in 2020. It is estimated that 28.2 million people have access to the ARVs worldwide in 2021 and there is a decline in new infections since 2010 by 31% from 2.1 million in 2010 to 1.5 million in 2020. It is reported that 39% of the new HIV infections occur in the Sub-Sharan Africa and higher risk of

attracting HIV infection is greater in people injecting themselves with drugs, and other with risky sexual intercourses (UNAIDS, 2021).

The HIV prevalence in Rwanda is stable since 2005 where it is estimated at 3% among adults but the prevalence is higher among women than in males and the estimated general incidence of HIV infection is 0.08% which is around 5400 HIV cases annually (RPHIA, 2019).

2.1.3. Correlation between mental disorders and HIV/AIDS

It was estimated that mental health disorders play a great role in HIV infection (Remien et al., 2019; WHO, 2017). Mental disorders especially depression, alcohol and drug abuse and PTSD are common in PLHIV and lack of diagnosis and treatment especially in LMIC is still a challenge (Narayan et al., 2014). There are many factors that are reported linked with mental illness in PLHIV and among them Amare et al reported age, living alone, marital status, poor medication adherence, poor social support, advanced clinical stage, stigma and occupation (Motumma et al., 2019a). History of abuse and family history of suicide deaths are also reported as the risk factors of mental illness among PLHIV (UNAIDS, 2018).

In a control study done by Adeluya et al., they reported high rate of psychotic disorders, anxiety disorders and high affective disorders in comparison to the controls without HIV/AIDS and the factors that were associated with having psychiatric disorders were poor social support and advanced stage of the disease (Adewuya et al., 2007). A study by Remien et al reported the same findings that the rate of mental health illnesses is high in PLHIV (Remien et al., 2019) and other researchers reported the same findings (Chibanda et al., 2016; Motumma et al., 2019a; Thom, 2009)

Rene Brandt reported that generalized anxiety disorder was most common among people of old age while bipolar mood disorder was commonly found in young people (Brandt, 2009). Being unemployed, low level of education, low income, poor social support, being unmarried and being a migrant were among the factors that were associated with high prevalence of depression (Munjal, 2014).

Deribew et al. reported that HIV-TB co-infection increased risk of having health disorders and the common risk factors that were identified were lack of source of income, experiencing stigma and poor general health (Deribew et al., 2010). Nathan et al found that mental health disorders were among the commonest causes of admissions in PLHIV (Ford et al., 2015). Lack of

disclosure of HIV status was among the independent factors that were associated with having psychological disorders (Hailemariam & Tenkolu, 2014). A study by Huang et al. reported that employment status, high education level, lack of support and number ART regimen were associated with high risk of having mental disorders (Chen, 2018).

Low resilience and other factors namely being female, being single, having a marital status of divorce and/or widow, having experienced stigma and living with HIV more than ten years were identified as the significant risk factors of having mental disorders (Yimer, 2021).

2.2. Empirical literature

2.2.1. Co-occurrence of Mental health disorders and HIV/AIDS

The study done by Aboma et al in Ethiopia reported the rate of common mental health disorders in PLHIV to be at 28.1% (Motumma et al., 2019b). Amare et al. reported a pooled rate depression of 36.6% (Motumma et al., 2019a) and the same results were reported by Rene Brandt in his systematic review (Brandt, 2009).

Remien et al. reported that the prevalence of depression was 36%, generalized anxiety disorder at 15.8% while in the general population the prevalence was 6.7% and 2.1% respectively (Remien et al., 2019).

In Nigeria the prevalence of mental illnesses in PLHIV was 13% as reported in the study by Sulyman et al. (Sulyman, 2013). Landon et al. reported almost the same findings where they found that the rate of common disorders was 14% in PLHIV (Seedat, Sa, Ph, & Al, 2008). Another study done by Huang et al. reported that 32.9% of the PLHIV were diagnosed with depression, 27.4% with anxiety and 19% of them had both depression and anxiety (Chen, 2018). Bhatia and Munjal reported a rate of depression to be high as 58.75% which was higher in females than in male participants (Munjal, 2014).

The prevalence of psychological disorders in PLHIV from Hailemariam and Tenkolu was reported at 11.2% (Hailemariam & Tenkolu, 2014). The study done by Hiremath and Desar reported that among their HIV positive participants, 34.5% were diagnosed with depression and having rural background was statistically associated with being depressed (Article, 2022). The study done by Abebe et al, reported that 47.6% of PLHIV had depression and low income and

advanced clinical stage were statistically associated with depression (Id et al., 2022). Harry et al. found psychiatric disorders among HIV positive individuals to be 82.6% (Inter-, 2005).

2.2.2. Medication adherence among people living with both HIV/AIDS and Mental health disorders.

Mental disorders especially depression present as primary barriers to a good ART adherence and treatment failure among PLHIV as reported by many researchers (Hailemariam & Tenkolu, 2014; Pence, 2009). Ngum et al. reported that among their participants, 47.3% were non-adherent to their treatment and the majority of those with poor adherence were participants with depressive disorder (Ngum et al., 2017). Alcohol use was also associated with poor outcomes from treatment meaning high viral load and ART discontinuation (Mayston, Kinyanda, Chishinga, Prince, & Patel, 2012). The study done by Ngum et al reported a rate of depression to be at 26.7% among patients living with HIV/AIDS where 75% of the participants with depression were not adherent to their anti-retroviral treatment (ART) medications compared to 25% of those who were not diagnosed with depression (Ngum et al., 2017). Women who live with HIV/AIDS are reported to be highly affected by depression, anxiety, stress, self-esteem and self-stigma which negatively affect their behavior in seeking health care and adherence to HIV treatment (Coordinating & Issue, 2020).

2.2.3. Quality of Life among people living with Mental disorders and HIV/AIDS

Mental disorders mainly depression and anxiety are reported to affect the QOL of PLHIV (Betancur, Lins, Oliveira, & Brites, 2017; Ezeamama et al., 2016; Peter, Kamath, Andrews, & Hegde, 2014). Depression and other psychological problems are the major predictors of the QOL in PLHIV where they are associated with poor scores of QOL (Shriharsha & Rentala, 2019). Peter et al. reported that anxiety level was statistically associated with all domains of the health-related QOL PLHIV while the level of depression was associated with mean QOL in almost all domains (Peter et al., 2014). Ezeamama et al. reported that the psychosocial interventions in PLHIV can reduce depression and anxiety proportions which are (the latter) associated with poor QOL among PLHIV (Ezeamama et al., 2016). Betancur et al. reported that 59.5% of PLHIV presented with depression while 44.7% had anxiety. They reported that 46.8% of PLHIV had depression and anxiety as the main reasons of not taking their medications properly (Betancur et al., 2017).

2.3. Critical review and research gap identification

Previous studies focused on the prevalence of common mental disorders did not intent to assess the chronological onset of HIV/AIDS and mental disorders, treatment adherence and QOL among PLHIV and mental health disorders. From our literature no single study evaluated or reported about chronological onset of HIV/AIDS and mental disorders in people with dual diagnosis. Furthermore, no single study was identified to have focused on the quality of life of patients living with both mental health disorders and HIV/AIDS in Rwanda.

2.4. Theoretical framework

Different models and frameworks have been used in the past to explore existence of inter-relation of mental health disorders and HIV/AIDS. Those models or frameworks were able to identify a wide range of explanatory factors.

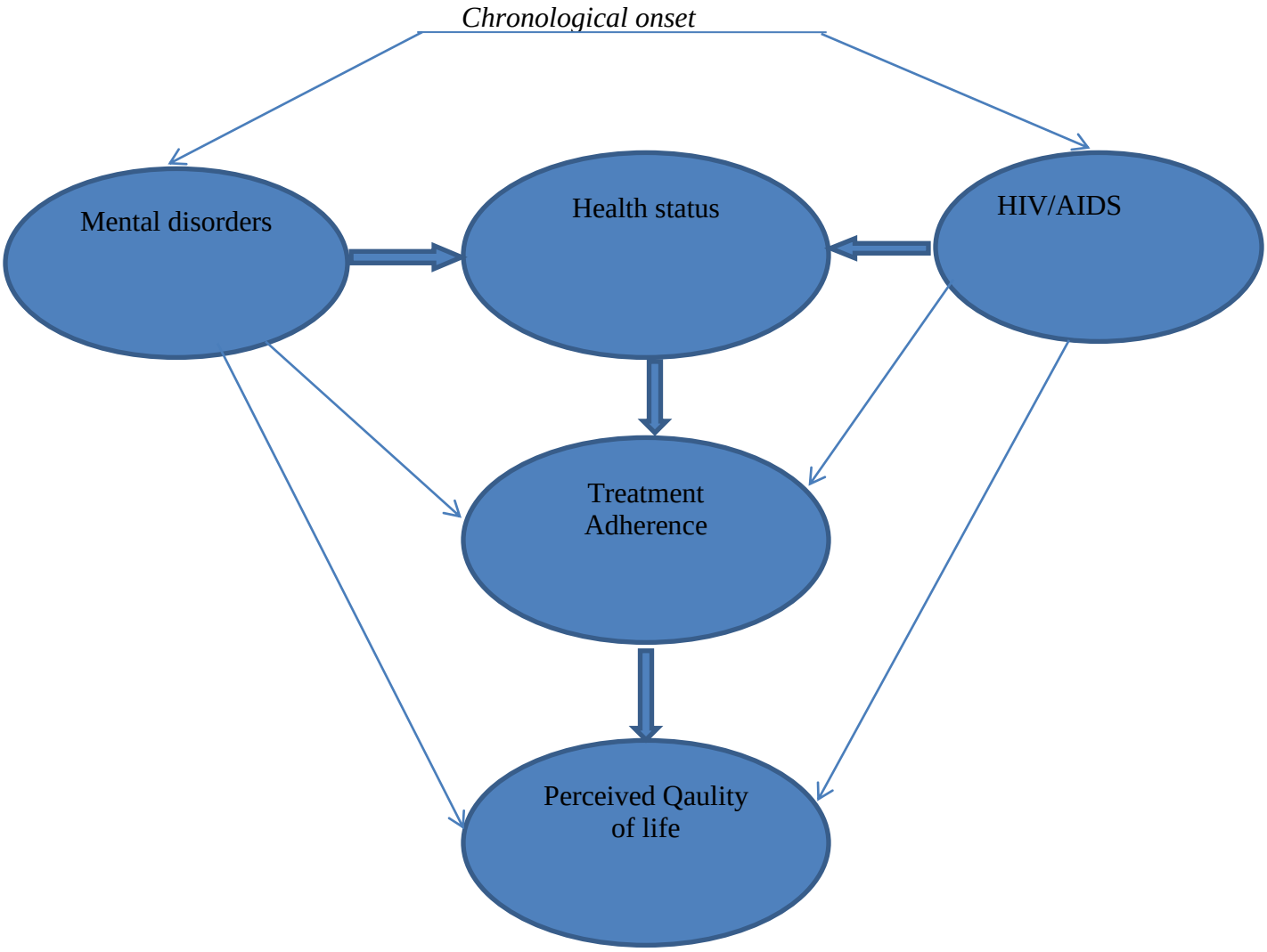
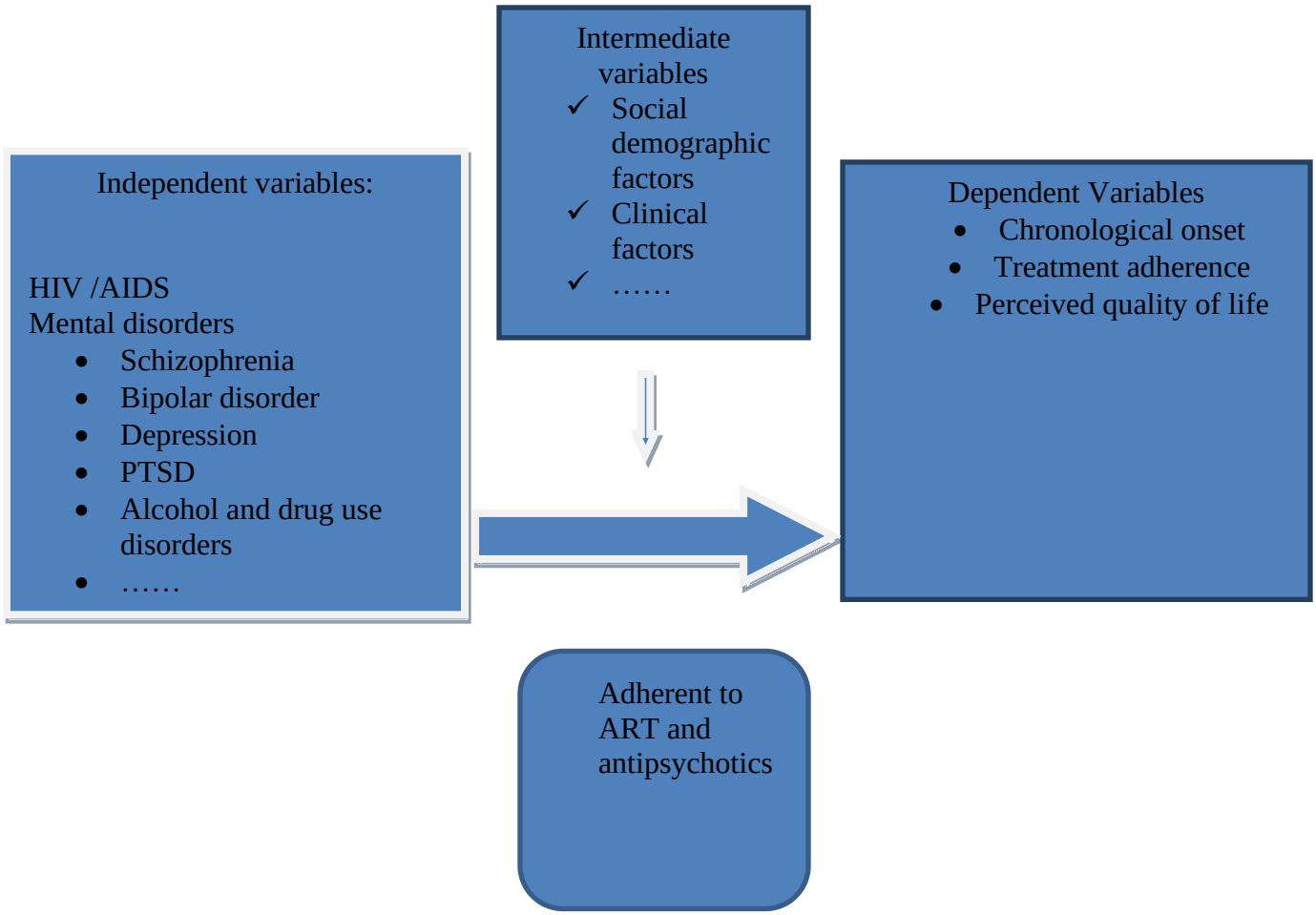


Figure: A schematic diagram showing the co-occurrence of mental health and HIV/AIDS, their chronological onset, related treatment adherence behavior and associated QOL. Adapted from Vidrine, D. J., Amick, B. C., Gritz, E. R., & Arduino, R. C. (2005). Assessing a conceptual framework of health-related quality of life in a HIV/AIDS population. *Quality of life research*, *14*(4), 923-933.

2.5. Conceptual framework



2*: Conceptual framework for the relation between the independent factors, dependent factors.*

CHAPTER III: METHODOLOGY

3.1. Study description

This study assessed the chronological onset of HIV/AIDS and mental disorders, treatment adherence and QOL among PLHIV and mental health disorders at Ndera Neuropsychiatric Hospital.

3.2. Study design

A cross-sectional study that assessed the chronological onset of HIV/AIDS and mental disorders, treatment adherence and quality of life among people with HIV/AIDS and mental health disorders at Ndera Neuropsychiatric hospital.

3.3. Study site

This study was carried out from Ndera Neuropsychiatric Hospital (Ndera NPH) located in Kigali city, Gasabo district, Ndera sector. Ndera NPH was founded by the Congregation of the Brothers of Charity. Currently, the hospital offers different services such as OPD consultations, admissions, occupational therapy, physiotherapy, clinical psychology and neurology.

3.4. Study population

The participants were all patients living with mental illnesses and HIV/AIDS and who are followed in the HIV/AIDS care unit at the Neuropsychiatric hospital of Ndera.

3.5 Selection of study population

3.5.1. Inclusion criteria

In this study, we recruited participants fulfilling the following criteria:

- ✓ People living with mental illnesses and HIV/AIDS,
- ✓ Followed at the HIV/AIDS care unit at Ndera Neuropsychiatric Hospital,
- ✓ 18 years of age and above
- ✓ Ability to understand the relevant information and to give the informed consent,
- ✓ With complete files

3.5.2. Exclusion criteria

- ✓ Absence of the co morbidity (mental illness and HIV/AIDS)
  People who are less than 18 years of age
- ✓ Patients with incomplete files

- ✓ Patients without decision making capacity and unable to understand the relevant information.

3.6. Sampling method and sample size

Given that the population of people with the health events aimed by our study (co-occurrence of HIV/AIDS and Mental Disorder) was relatively small in the study site (N=119), there was no indication to calculate the sample size. Total sampling was used.

3.7. Procedure at enrolment

Enrolled participants were selected from our study population. They were only approached after getting the services they requested for. Those who meet the inclusion criteria and who consented were considered for the study.

3.8. Data collection and management

Data from patient interview and clinical files review were gathered using a questionnaire. The information on the medication adherence was collected using MARS questionnaire and the information on the QOL was collected using SF-36 questionnaire which is a validated tool and translated in Kinyarwanda (Translated SF-36 and MARS tools). Thereafter, data on hard copies were arranged and entered by the principal investigator in software to produce soft data and these soft data are being kept by the principal investigator.

3.9. Data analysis

Data analysis was done using Stata version 13, and results are presented as follow: Group comparison was done using chi-square test for trend and logistic regression (Binary and multivariable logistic regression analysis). T-test was used to compare the quality of life scores that were normally distributed and non-parametric tests (Mann Whitney U test and Kruskal Wallis test) were used when the quality of life scores were skewed. Statistical significance for associations was taken at the level $p < 0.05$.

3.10. Ethical considerations

3.10.1 Confidentiality

The principal investigator assured the confidentiality and anonymity of the study participants where participants were assigned the unique code numbers. Data on hard copies were locked in a

cupboard which was accessed only by the Principal investigator and soft in a password protected folder on the personal computer of the principal investigator and will be destroyed one year after publication of the results from the study.

3.10.2. Informed consent

Participants were individually given a consent form by the principal investigator after clearly explaining to them the nature of the research project. The content of the consent was loudly read to each participant by the principal investigator in the language that the participant understands well between Kinyarwanda and English. After satisfactory explanations by the later, those willing to participate in the study affixed their signature or fingerprint on the consent form.

3.10.3. Ethical approval

The study protocol was reviewed and approved by the Institutional Review Board of College of Medicine and Health Sciences, University of Rwanda and by the Ethics committee of HNP CARAES Ndera prior to data collection period

3.11. Distribution of responsibilities

The principal investigator had the responsibility to conduct and coordinate all the steps of the study under the supervision of the thesis supervisor. Data collection was done by the principal investigator while the analysis was done with help of a statistician.

3.12. Compensation

There was no compensation to the participants of this study as the study did not receive any funds.

CHAPTER IV: RESULTS

The median age for our participants was 44.9 ± 10.34 years and the majority of participants (75.8%) were females. Of all the participants, 42% at least attended secondary school, 45.6% attended primary school. The majority (59.4% were in the second economic category followed by 23.3% who were in the third category and the remaining 17.2% were in category I. Eighty two percent of the participants were living with family members or companion while 17.2% were living alone. Twenty four percent of the participants reported to have good social support, 64.6% reported to have fair social support and 11.2% reported poor social support. Of the total number of participants, 98.2% were on the first line of antiretroviral treatment and considering the frequency of mental health disorders, schizophrenia was the most prevalent at 59.4% followed by Schizo-affective disorder at 14.6%, then Drug induced psychosis at 10.3% and Bipolar disorder at 7.7% (Table 1).

Table 1: Sociodemographic and clinical characteristics

Characteristics	Frequency	%
Age (Mean ± SD)	44.95 ± 10.34	
Gender		
Male	28	24.14
Female	88	75.86
Education		
Illiterate	14	12.07
Primary	53	45.69
Secondary	41	35.34
University	8	6.9
Economic status		
Ubudehe 1	20	17.24
Ubudehe 2	69	59.48
Ubudehe 3	27	23.28
Living status		
Alone	20	17.24
With family member/companion	96	82.76
Social support		
Poor	13	11.21
Fair	75	64.66
Good	28	24.14
Type of ARTs treatment		
First line	114	98.28
Second line	2	1.72

Mental disorder		
Schizophrenia	69	59.48
Schizo-affective disorder	17	14.66
Drug induced psychosis	12	10.34
Bipolar disorder	9	7.76
Major depressive disorder	5	4.31
Epilepsy with psychotic symptoms	2	1.72
PTSD	1	0.86
Brief psychotic disorder	1	0.86

Considering the chronology of HIV and mental disorders, we found that among all participants, 56.03% were diagnosed with mental health disorders before being diagnosed with HIV and that HIV infection was diagnosed before mental disorder in 43.97% of the participants (Table 2).

Table 2: Chronological onset of HIV/AIDS and mental disorders among people living both conditions

Variables	**Number**	**%**
HIV diagnosed before Mental disorder	51	43.97
Mental disorder diagnosed before HIV	65	56.03

There was no observed statistically significant difference in the adherence to both antipsychotics and ARTs across the chronology of diagnosis groups (Table 3).

Table 3: Association of chronology of duo diagnosis and medication adherence

Adherence	**Chronology of diagnosis**		**P value**
	Mental health diagnosed before HIV	**HIV diagnosed before Mental health**	
Adherence to antipsychotics			
Poor adherence	11 (16.92%)	6 (11.76%)	0.436
Good adherence	54 (83.08%)	45 (88.24%)	
Adherence to ARTs			
Good adherence	2 (3.08%)	3 (5.88%)	0.460

Poor adherence	63 (96.92%)	48 (94.12%)

The median MARS score for the psychotropic medications was 9 out of 10 with 17 participants (14.6%) having poor adherence to their psychotropic medications while 99 participants (85.3%) had good adherence to their mediations. The median MARS score for ART was 10 out of 10 with only 5 participants (4.3%) having poor adherence and 95.7% having good adherence to their ART medications (Table 4).

Table 4: Treatment adherence behavior vis-a-vis ARTs and psychotropic medications among people living with HIV and mental disorders

Variables	Number	%
Total MARS score for Anti-psychotics/10		
Median (Q1-Q3)	9 (7-10)	
Adherence to Antipsychotics		
Non-adherent	17	14.66
Adherent	99	85.34
Total MARS score for ARVs/10		
Median (Q1-Q3)	10 (9-10)	
Adherence to ARVs		
Non-adherent	5	4.31
Adherent	111	95.69

Among the nine domains of Health-Related quality of life (HRQOL), the mean score in the Physical functioning domain was the highest (52.26 ± 12.64) followed by pain domain (48.83 ± 9.68) then general health domain (45.91 ± 9.89), then health change (42.83 ± 15.39), Energy/fatigue domain (40.7 ± 7.68), role limitations due to emotional problems (36.14 ± 10.12), role limitations due to physical health (33.59 ± 11.16), then social functioning (15.23 ± 4.95) and the domain with the lowest mean score was emotional well-being with 14.54 ± 3.55 [Table 5].

Table 5: Overview of domains of quality of life among people diagnosed with mental disorders and HIV/AIDS

Domain	Study participants (N=116)			
	Mean [SD]	Median	Minimum	Maximum
Physical functioning	52.26 [12.64]	50	25	100
Pain	48.83 [9.68]	45	32.5	87.5
General health	45.91 [9.89]	45	25	90
Health change	42.83 [15.39]	50	25	75
Energy/Fatigue	40.74 [7.68]	40	20	65
Role limitations due to emotional problems	36.14 [10.12]	33.3	0	67.7
Role limitations due to physical health	33.59 [11.16]	25	25	55
Social functioning	15.23 [4.95]	25	0	65
Emotional well-being	14.52 [3.55]	15	0	55

A significant difference in QOL in the mean role limitation due to physical activities domain was observed across the age groups where participants in age group <35 years had higher scores and participants in the advanced age group (56-75 years) showed to have lower scores (p=0.049). The difference in QOL in the mean role limitation due to emotional problems domain was also observed across education categories where the scores increased as the level of education increased (p=0.004). There were no observed differences in mean scores of physical functioning domain across groups of all presumed predictors (Table 6).

Table 6: Factors influencing physical functioning, role limitation-physical and role limitation-emotional domains of quality of life among participants.

Variables	N	Physical functioning		Role limitation-Physical		Role limitation-Emotional	
		Mean [SD]	p	Mean [SD]	p	Mean [SD]	p
Age							
<35	26	53.4 [11.5]		34.5 [11.4]		36.3 [9.1]	
36-55	77	52.0 [13.3]	0.788	34.4 [11.3]	**0.049**	36.1 [9.2]	0.528
56-75	13	51.1 [11.2]		26.9 [6.9]		35.8 [16.5]	
Gender							
Male	28	53.0 [13.1]	0.814	34.8 [11.6]	0.469	35.7 [12.6]	0.723
Female	88	52.0 [12.5]		33.2 [11.1]		36.3 [9.3]	
Education							
Illiterate	14	52.5 [8.7]		28.5 [7.7]		35.6 [8.9]	
Primary	53	52.1 [12.9]	0.939	33.4 11.4]	0.265	34.6 [6.5]	**0.004**
Secondary	41	51.9 [11.7]		35.2 [11.5]		36.2 [11.7]	

University	8	54.4 [21.3]		35.6 [12.4]		47.2 [16.6]	
Economic status							
Ubudehe 1	20	52.5 [7.8]		28.7 [8.2]		36.6 [10.3]	
Ubudehe 2	69	51.1 [12.1]	0.715	35.3 [11.7]	0.076	36.1 [8.9]	0.952
Ubudehe 3	27	55.0 [16.2]		32.9 [10.6]		35.8 [12.8]	
Living status							
Alone	20	52.7 [12.3]		31.0 [10.2]		34.1 [3.7]	
With family member/companion	96	52.15 [12.7]	0.833	34.1 [11.3]	0.283	36.5 [10.9]	0.474
Social support							
Poor	13	53.1 [8.3]		31.5 [10.8]		35.8 [9.3]	
Fair	75	50.9 [11.7]	0.532	34.6 [11.5]	0.447	35.8 [8.6]	0.949
Good	28	55.3 [15.9]		31.7 [10.1]		36.9 [13.8]	
Type of ARVs treatment							
First line	114	52.2 [12.7]	0.855	33.5 [11.1]	0.655	36.2 [10.2]	0.688
Second line	2	52.5 [10.6]		37.5 [17.7]		33.3 [0.0]	
Adherence to Antipsychotics							
Non-adherent	17	51.8 [13.2]	0.167	33.4 [11.1]	0.622	33.8 [2.4]	0.578
Adherent	99	54.7 [8.5]		34.7 [11.5]		36.5 [10.8]	
Adherence to ARVs							
Non-adherent	5	52.1 [12.8]	0.378	33.5 [11.2]	0.577	33.3 [0.0]	0.521
Adherent	111	55 [8.6]		36.0 [11.4]		36.3 [10.3]	

A significant difference in the mean quality of life in the energy/fatigue domain was observed across age groups with scores increasing as the participants become younger (p=0.05). A significant difference in the mean quality of life in the energy/fatigue domain was also observed across the living status where participants who were living alone showed to low scores in the energy domain (p=0.044). A significant difference in the mean quality of life from the social functioning was observed across the living status where patients who live with family members had more scores compared to patients who live alone (p=0.048). There were no observed mean differences in the scores of emotional domain across the groups of all factors (Table 7).

Table 7: Factors influencing energy/fatigue, emotional well-being and social functioning domains of quality of life among participants.

Variables	N	Energy/Fatigue		Emotional well-being		Social functioning	
		Mean [SD]	p	Mean [SD]	p	Mean [SD]	p
Age							
<35	26	39.2 [7.5]		15.5 [7.1]		16.4 [5.6]	
36-55	77	41.8 [7.7]	**0.05**	14.5 [6.6]	0.601	14.1 [7.5]	0.271
56-75	13	36.9 [5.9]		14.8 [4.4]		14.6 [5.1]	
Gender							
Male	28	41.7 [6.4]	0.392	14.6 [6.3]	0.197	15.0 [5.0]	0.668
Female	88	40.4 [8.1]		14.3 [6.6]		16.6 [7.4]	
Education							
Illiterate	14	39.3 [6.4]		13.5 [6.3]		16.2 [6.4]	
Primary	53	40.6 [8.2]	0.736	14.3 [6.9]	0.905	15.1 [7.3]	0.92
Secondary	41	41.7 [7.9]		14.4 [6.3]		15.0 [6.8]	
University	8	39.4 [4.2]		14.7 [6.0]		14.9 [6.7]	
Economic status							
Ubudehe 1	20	40.0 [7.8]		15.2 [7.8]		15.9 [7.1]	
Ubudehe 2	69	41.7 [8.2]	0.287	13.6 [6.9]	0.242	14.6 [7.5]	874
Ubudehe 3	27	38.7 [5.6]		12.8 [3.8]		16.0 [5.5]	
Living status							
Alone	20	40.1 [7.6]		14.1 [7.9]		12.6 [8.4]	
With family member/companion	96	43.7 [7.4]	**0.044**	15.8 [6.2]	0.248	17.1 [6.6]	**0.041**
Social support							
Poor	13	40.4 (8.5]		16.1 [8.1]		14.6 [8.6]	
Fair	75	41.3 [8.1]	0.702	14.2 [6.8]	0.601	15.2 [6.5]	0.844
Good	28	39.5 [5.9]		13.5 [5.0]		16.0 [7.3]	
Type of ARVs treatment							
First line	114	40.7 [7.7]	0.619	13.1 [6.5]	0.41	16.2 [6.9]	0.463
Second line	2	42.5 [3.5]		15.1 [5.6]		15.4 [8.8]	
Adherence to Antipsychotics							
Non-adherent	17	40.8 [7.4]	0.609	13.3 [6.6]	0.798	54.7 [9.2]	0.5
Adherent	99	40.0 [9.3]		16.0 [6.5]		52.9 [6.5]	
Adherence to ARVs							
Non-adherent	5	41.0[11.9]	0.319	13.7 [5.4]	0.161	15.6 [10.9]	0.214
Adherent	111	40.7 [7.5]		15.2 [6.5]		16.9 [6.6]	

A difference in the mean QOL in the general health domain was found between male and female participants where women showed to have more scores compared to male participants (p=0.013). There were no observed differences in both pain and health change domains across all the factors (Table 8).

Table 8: Factors influencing pain, general health and health change domains of quality of life among participants.

Variables	N	Pain		General health		Health change	
		Mean [SD]	p	Mean [SD]	p	Mean [SD]	p
Age							
<35	26	48.9 [7.3]		46.3 [7.5]		43.2 [18.1]	
36-55	77	48.7 [9.8]	0.848	46.2 [10.8]	0.852	42.4 [15.2]	0.837
56-75	13	49.2 [12.8]		43.5 [8.5]		44.2 [10.9]	
Gender							
Male	28	48.4 [9.4]	0.48	41.6 [8.6]	**0.013**	42.8 [16.5]	0.974
Female	88	48.9 [9.8]		47.3 [9.9]		42.8 [15.1]	
Education							
Illiterate	14	47.3 [5.1]		44.6 [5.3]		44.6 [17.5]	
Primary	53	48.3 [9.9]	0.572	45.7 [10.8]	0.764	43.3 [14.8]	0.584
Secondary	41	50.5 [10.7]		46.3 [7.7]		40.8 [16.5]	
University	8	46.5 [8.0]		47.5 [18.3]		46.8 [8.8]	
Economic status							
Ubudehe 1	20	49.3 [10.7]		43.7 [10.1]		43.7 [19.7]	
Ubudehe 2	69	48.5 [9.3]	0.942	45.8 [9.2]	0.361	43.4 [14.6]	0.785
Ubudehe 3	27	49.3 [10.1]		47.7 [11.3]		40.7 [14.1]	
Living status							
Alone	20	50.2 [13.5]		44.7 [9.7]		47.5 [19.7]	
With family member/companion	96	48.5 [8.7]	0.798	46.1 [9.9]	0.612	41.8 [14.3]	0.237
Social support							
Poor	13	47.8 [5.3]		47.7 [10.7]		44.2 [23.2]	
Fair	75	49.0 [9.9]	0.936	45.1 [8.6]	0.847	42.9 [13.9]	0.947
Good	28	48.8 [10.7]		47.2 [12.5]		41.9 [15.3]	
Type of ARVs treatment							
First line	114	48.6 [9.3]	0.732	46..0 [9.9]	0.272	42.9 [15.2]	0.646
Second line	2	61.2 [26.5]		40.0 [7.1]		37.5 [17.6]	
Adherence to Antipsychotics							
Non-adherent	17	49.5 [10.6]	0.592	46.2 [11.6]	0.887	41.2 [17.5]	0.561
Adherent	99	48.7 [9.6]		45.8 [9.6]		43.1 [15.1]	

Adherence to ARVs								
Non-adherent	5	55.0 [14.6]	0.223	49.9 [9.8]	0.961	40.0 [15.1]	0.551	
Adherent	111	48.5 [9.4]		45.7 [9.6]		42.9 [15.1]		

CHAPTER V: DISCUSSION

As of our knowledge, our study is the first one in Rwanda to evaluate the chronological onset of both mental disorders and HIV in patients with the duo diagnosis and the medication adherence to both psychotropic and ARV medications. In the present study, 56.0% were reported to have been diagnosed with mental disorders before HIV which might implicate the effect of mental health disorders in the transmission of HIV as reported by previous reports (Remien et al, 2019; WHO, 2015).

In our study, the highest mean score in quality of life using SF-36 tool was physical functioning domain with the mean value of 52.26 (SD=12.64). Our results are in accordance with the results from the findings of other studies done previously which reported physical functioning domain to be the domain with highest mean scores, even though the mean score in physical functioning was high compared to them and their mean scores were ranging from 13.2 (±2.10) to 15.9 (±3.05) (A. A. Fatiregun, K. C. Mofolorunsho, n.d.; Yadav, 2010). Our finding is also the same as the findings of the study done in Nigeria by Odili et al who reported higher mean quality of life scores in physical functioning domain (Valentine U Odili , IsibhakhomhenB Ikhurionan, Stella F Usifoh, 2019).

The current study results showed that the mean score of QOL from social functioning was 15.23 (SD=4.95) which is almost the same as the results from the study done by Peter et al who reported that the mean social functioning score was 12.1 (±3.67) using WHOQOL-HIV BREF with physical domain being the domain with the highest mean scores and social functioning having lowest mean scores (Peter et al., 2014). High QOL in the social functioning domain reflects low level of stigmatization and HIV- or mental health disorder-related discrimination among our study participants as this domain covers different social aspects like social support, personal relationships perceptions and social inclusion as reported by Remien et. al (Remien et al., 2019).

Our results showed that social support was not associated with any of the mean QOL from any domain which is different from the findings of previous studies done which revealed that people with family support were had higher QOL scores compared to those without family support (Peter et al., 2014).

Our findings also showed that female participants were more likely to have more mean scores of QOL in general health domain compared to males. This may indicate how male patients who

have the duo diagnosis of HIV and mental disorder in our community need to have more counseling and education sessions about their disease conditions. Our results also revealed that education level id associated with high mean scores of QOL in role limitation due to emotional problems where mean scores of QOL in this domain increase progressively with increase in educational level and this indicate how important it is to take more care (counselling) of patients with lower education level for better integrating them in the societies and get social support to minimize the risk of stigma.

Mental health disorders present as primary barriers to a good ART adherence and treatment failure among PLHIV as reported by many researchers even though our results show good rate of adherence to both ARVs and antipsychotics where according to MARS scores we found that only 4.3% of the participants were not adherent to ARVs and 17% were not adherent to psychotropic medications but there was no observed difference in the adherence to both antipsychotics and ART according to the chronology of diagnosis and this shows an important area of focus when following up the patients with mental health disorders and HIV who might neglect or fear antipsychotics and only take their ARVs medications and rate of adherence was found to be low compared the one from Ngum et a. who reported that 47.3% were non-adherent to their treatment (Ngum et al., 2017).

CHAPTER VI: CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

Of our study participants, HIV infection showed to have been diagnosed after the diagnosis of subsequent mental disorder in the majority of patients and 14.6% of participants and 4.3% of participants found to have poor adherence to their antipsychotics and ARTs respectively. Patients with duo diagnosis of mental disorder and HIV have higher scores of QOL in the physical functioning domain and they seem to have poor scores of life in social functioning and emotional well-being domains.

6.2. Recommendations

To health care providers:

- ✓ To follow closely patients with mental health disorders and HIV infection for their adherence to psychotropic medications
- ✓ To increase the patients' psychoeducation on the increased risk of being infected with HIV, when you have a mental disorder

To researchers:

- ✓ Further studies are recommended to explore the possible causal relationship between HIV infection and mental disorders
- ✓ To explore why people with dual diagnosis of mental disorders and HIV have high adherence to ARVs than psychotropics medications.

To Family members

- ✓ To increase the psychoeducation in order to reduce stigmatization, therefore improve social life of people living with mental disorders and HIV

6.3. Limitations

- ✓ This is a single centered study that included the sample of participants from one health facility, meaning that patients with HIV infection and mental health who are followed from other health facilities were not included which limits the generalization of the study results to the general population.

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ANNEXES

1. Informed consent form

Title of study**: "Assessment of Chronological Onset, Treatment Adherence and Quality of Life among People with Duo Diagnosis of Mental Disorders and HIV/AIDS at Ndera Neuropsychiatric Hospital"**

This informed consent form is for patient or caretakers who will be recruited for participating in the study, entitled **"Assessment of Chronological Onset, Treatment Adherence and Quality of Life among People with Duo Diagnosis of Mental Disorders and HIV/AIDS at Ndera Neuropsychiatric Hospital"**

The main investigator is Jacqueline INGABIRE, a resident in psychiatry at the University of Rwanda.

Part I: Information Sheet

Introduction

Jacqueline INGABIRE, a postgraduate student at the University of Rwanda, is doing a research on **"Assessment of Chronological Onset, Treatment Adherence and Quality of Life among People with Duo Diagnosis of Mental Disorders and HIV/AIDS at Ndera Neuropsychiatric Hospital"**. We are going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can freely ask them.

Purpose of the research

People living with HIV/AIDS may be subjected to different types of Mental Health Disorders and also people having mental health disorders may be vulnerable to get infected with HIV and this can have an impact on their clinical wellbeing, mediation adherence and disease outcome. This study will generate the data, and then we will formulate recommendations for improving the quality services that we are giving to patients with mental health disorders living with HIV/AIDS. We request you to be a part of this important research. But Before agreeing to participate in this study, it is important that you know the purpose of this study and knowing the nature of the questions. Don't hesitate to request for clarification for unclear information.

Prevalence, Timing and Clinical Impact of Mental Health Disorders among People Living with HIV/AIDS: A Case Study of Ndera Neuropsychiatric Hospital.

The researchers are interested in knowing the prevalence, timing and clinical impact of mental health disorders among people living with HIV/AIDS.

Questions are about?

Questions are addressed to patients with mental health disorders living with HIV/AIDS and who are followed at Neuropsychiatric Hospital of Ndera for different mental health issues. Those questions are related to the types of mental health disorders, medication adherence and their quality of life. The time required to respond on the planed questions is around 15 minutes.

Who do we want to talk to?

We want to talk to patients diagnosed with mental health disorders and who live with HIV/AIDS and followed in the outpatient department of HNP Ndera for at least 6 months and over. It is voluntary participation; there is no push and no law. If you don't want to participate, you don't need to explain why.

When you agree to participate:

- ✓ You sign/ write you names that prove that you have accepted to participate in this study.

If there are questions that you don't feel comfortable to answer, you are free to skip that question.

Right to refuse or withdraw

You are allowed to stop the participation at any time.

Incentives

There are no incentives for your time, your participation is voluntary.

Confidentiality

Your names and other provided information will not be shared with anybody rather than the research team unless you provide your permission.

Dissemination of results

The results from this research will be used to improve quality of care in Rwandan hospitals. There is no personal interest or direct benefits are intended for researchers.

Who are conducting this research?

This research is led by a student from University of Rwanda, doing her Master's degree in psychiatrics at the University of Rwanda, College of Medicine and Health Sciences.

Who to contact

If you want more information about project, you can contact the researcher on the following contacts:

Jacqueline Ingabire: Phone number: + (250) 783111373 or at email: jackie4rwd@yahoo.com

The Direction of Institutional Board of CMHS, at phone number 0788563311 or email: sundayfrax@gmail.com

Part II: Certificate of consent

1. I prove that I have read or been informed on this research **"Assessment of Chronological Onset, Treatment Adherence and Quality of Life among People with Duo Diagnosis of Mental Disorders and HIV/AIDS at Ndera Neuropsychiatric Hospital"**, I was given time to ask questions and they are well answered.
2. I understand that to participate in this research is voluntary and I can quit any time without providing any reasons.
3. I agree to have part in the study entitled **Assessment of Chronological Onset, Treatment Adherence and Quality of Life among People with Duo Diagnosis of Mental Disorders and HIV/AIDS at Ndera Neuropsychiatric Hospital.**

Participant

Name of participant: ……Signature Date:…../…../20…

Interviewer

Name of the researcher: …….Signature Date:…../……/20…

2. Questionnaire

Demographic information

Record ID	……
Age in years	……years
Gender	Male 1 Female 2
Province of origin	Kigali City 1 Eastern Province 2 Western Province 3 Northern Province 4 Southern Province 5
Occupational status	Farmer 1 Business 2 Public servant 3 Employed 4 Other 5 If other, specify…….
Religion	Catholic Protestant Muslim None
Highest education level attained/completed	None 1 Primary 2 Secondary 3 University 4
Socio-economic status	Ubudehe 1 1 Ubudehe 2 2 Ubudehe 3 3 Ubudehe 4 4
Living status	Alone 1 With companion/family 2
Social support	Poor 1 Fair 2 Good 3
Smoking	Yes 1 No 2
Alcohol consumption	Yes 1 No 2

Clinical characteristics and outcomes

History of mental health in the family	Yes 1 No 2
Duration of HIV diagnosis	……Years
Duration of Mental health disease diagnosis	……Years
HIV status of the partner	Positive 1 Negative 2 Don't know 3 No partner 4
Partner died due to HIV/AIDS	Yes 1 No 2
Recent CD4 count of the patient	……
Started HAART treatment	Yes 1 No 2
Duration of HAART treatment	……..months
Type of HAART treatment	First line 1 Second line 2
Other comorbidities	Yes 1 No 2
If yes, type of comorbidity	Hypertension 1 Diabetes 2 TB 3 Heart diseases 4 Liver diseases 5 Other to specify……..
Ever perceived HIV stigma?	Yes 1 No 2
HIV/AIDS stage	Stage 1 Stage 2 Stage 3 Stage 4
Type of main mental health disorder (ICD10 diagnosis)	……..

Medication adherence questions (using MARS)

MARS (MEDICATION ADHERENCE RATING SCALE) QUESTIONNAIRE

	Question	Answer
1	Do you ever forget to take your medication?	Yes / No
2	Are you careless at times about taking your medication?	Yes / No
3	When you feel better, do you sometimes stop taking your medication?	Yes / No
4	Sometimes if you feel worse when you take the medication, do you stop taking it?	Yes / No
5	I take my medication only when I am sick	Yes / No
6	It is unnatural for my mind and body to be controlled by medication	Yes / No
7	My thoughts are clearer on medication	Yes / No
8	By staying on medication, I can prevent getting sick.	Yes / No
9	I feel weird, like a 'zombie' on medication	Yes / No
10	Medication makes me feel tired and sluggish	Yes / No

MARS: *A score between 1 to 5: nonadherence on medication,*

A score between 6 to 10: good adherence on medication

Quality of Life Questions from SF-36 tool (attached in PDF)

Ethical approval

UNIVERSITY of RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 19th /April /2022

Dr Ingabire Jacquelline
School of Medicine and Health Sciences, CMHS, UR

Approval Notice: No 270/CMHS IRB/2022

Your Project Title ***"Assessment of Chronological Onset, Treatment Adherence and Quality Of Life among People Living with Duo Diagnosis of Mental Disorders and HIV/AIDS"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
		Yes	No (Reason)	
Name of Members	**Institute**		**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Stefan Jansen	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Prof Gishoma Darius	UR-CMHS	X		
Prof Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 14th April 2022, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

Email: researchcenter@ur.ac.rw P.O Box 3286 Kigali, Rwanda www.ur.ac.rw

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 19th April 2022

Expiration date: The 19th April 2023

Prof Stefan JANSEN
Ag. Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR