EFFECTIVENESS OF A FAMILY-CENTERED SUPPORT INTERVENTION IN IMPROVING TREATMENT ADHERENCE AMONG TUBERCULOSIS PATIENTS IN JINJA, UGANDA

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DECLARATION AND APPROVAL

This thesis is my original work and has not been presented for a degree in any other University or for any other award.

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DEDICATION

I dedicate this work to my daughter Kemigisa Alinaitwe Rania, my wife Nakiranda, Mum, Dad, siblings, and Prof. Tom Ngabirano for their continuous support.

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ABSTRACT

Tuberculosis (TB) claimed the lives of 1.4 million individuals globally in 2021. Uganda has a high occurrence of TB, with an incidence rate of about 200 cases per 100,000 individuals. Jinja, a district in Eastern Uganda, has a case notification rate (225 per 100,000 individuals) higher than the national average. Poor adherence to TB treatment impedes disease control, slowing down the target to end TB by 2035. Uganda's treatment adherence rate ranges between 65% and 74%, which is lower than that of similar countries. Despite the implementation of community-based directly observed therapy, the adherence levels have persistently remained poor. With limited evidence on the effect of family involvement in improving TB treatment adherence, this study investigated the effect of a family-centered TB (FaCeTB) treatment support intervention on the level treatment adherence among patients in Jinja. The study utilized a before-and-after non-equivalent quasi-experimental design with both intervention and control study groups. The nurse invited the patient and one accompanying family member to an engagement session at the TB clinic. During the session, orientation, TB treatment health education, and the assignment of adherence support roles to the family caregiver were accomplished. The study enrolled patients with pulmonary tuberculosis who had undergone ≥2 weeks of first-line therapy. Treatment adherence was assessed using the Medication Adherence Rating Scale. The data was analyzed using SPSS v25. The descriptive statistics comprised of frequencies, percentages, median, mean, and standard deviation (SD). Mann-Whitney U test and Wilcoxon Signed-Rank test were used to evaluate the effect of the intervention on treatment adherence. The Mount Kenya Ethics Research Committee and the Mbale Regional Referral Hospital Ethics Committee provided ethical clearance. Research approval was obtained from the Uganda National Council of Science and Technology. The study enrolled 147 participants, with 73 in the intervention arm and 74 in the control arm. A total of 127 patients were successfully followed up, where 67 were in the intervention group and 60 in the control group. The mean age was 37.85±13.89 years. More than one-half (55.8%) of the patients were male, and 36.7% were HIV-positive. In the baseline assessment, overall, 65.3% of the patients had a high level of TB treatment adherence. The level was 71.2% in the intervention group and 59.5% in the control group. One-third (68.7%) of the patients reported a high level of perceived family support. Caregivers offered actual treatment support in the form of medication reminders, motivation, and both emotional and practical support. After the intervention, the overall adherence increased to 74.8%. In the intervention group, the level increased to 91.0%, while in the control group, it decreased to 56.7%. The adherence scores after the intervention were significantly higher in the intervention study arm than in the control arm (p=0.000), with a medium to large effect size (r=0.474). Supportive family involvement is vital in supporting patients during the TB treatment period, and it should be embraced as routine practice in Uganda to achieve optimal TB treatment adherence levels.

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LIST OF ABBREVIATIONS AND ACRONYMS

CB-DOT: Community-Based Directly Observed Therapy

DOT: Directly Observed Therapy

DR-TB: Drug-Resistant Tuberculosis

E: Ethambutol

FaCeTB: Family-Centered TB intervention

H: Isoniazid

HIV: Human Immuno-deficiency Virus

MARS: Medication Adherence Scale

PCC: Patient-Centered Care

PTB: Pulmonary tuberculosis

R: Rifampicin

TB: Tuberculosis

WHO: World Health Organization

Z: Pyrazinamide

CHAPTER ONE

INTRODUCTION

1.1. Introduction

This chapter discusses the study's background information, the problem being addressed, the research objectives, the specific questions being investigated, the study hypothesis, the significance and rationale for conducting the study, and the conceptual definitions utilized in the study.

1.2. Background

Mycobacterium tuberculosis is a key contributor to the global illness burden, responsible for the occurrence of over 10 million new cases of tuberculosis (TB) every year. It is estimated that TB was responsible for 1.4 million and 1.3 million fatalities worldwide in 2021 and 2022, respectively (WHO, 2022, 2023), becoming one of the leading causes of mortality by a single infectious agent. It is worrying that about 60% of all cases worldwide are concentrated in ten countries located in Southeast Asia and Sub-Saharan Africa, and yet these two regions are responsible for eighty percent of the total mortality rate worldwide. For this trend to be reversed, there is a need for enhanced dedication if TB is to be eradicated by the year 2035 (Chakaya et al., 2021; WHO, 2019).

The incidence of TB in Uganda is currently at 200 cases per 100,000 of the population, which is much higher than the global estimate of 133 occurrences per 100,000 individuals, making Uganda one of the 30 high-burden countries (WHO, 2022, 2024). The district of

Jinja, situated in the eastern part of Uganda, is one of the country's fifteen districts with a case notification rate ranging from 225 to 419 with every 100,000 people. In addition, the district has a TB treatment success rate (70%) lower than the set global target of 85% (MOH, 2021), demonstrating a high need for adherence-promoting interventions.

Despite the current progress in the detection and treatment of TB, Uganda continues to face a substantial challenge of poor treatment adherence. The TB treatment period has been characterized by higher levels of loss to follow-up, low treatment completion rates, and low cure rates (Baluku et al., 2022). According to Okethwangu and colleagues, non-adherence has not only kept patients in infectious states for longer periods but has also increased the risk of developing drug-resistant tuberculosis (DR-TB), experiencing treatment failure, and increasing the risk of TB-related mortality (Okethwangu et al., 2019).

Eastern Uganda is experiencing much-reduced levels of treatment adherence, with one in three patients (35%) having poor TB treatment adherence (Wanyama, 2017). According to studies conducted in sub-Saharan Africa (Gebremariam et al., 2021; Gugssa Boru et al., 2017), TB treatment adherence is influenced by several factors that span multiple dimensions, including individual, treatment-related, social, family, and health-system-related factors. This, therefore, requires multi-dimensional approaches to improve adherence levels. While the majority of conventional efforts to improve treatment adherence have focused primarily on the individual patient, they have neglected to take into account the patient's social context. There have been several approaches suggested, including digital adherence technologies (DATs) and directly observed therapy (DOT) (Alipanah et al., 2018; C. A. Berger et al., 2020; Ggita et al., 2018; Katende et al., 2022). In Uganda, however, the

capacity to expand and maintain these strategies has been hindered by issues associated with prioritizing patient needs (Bojorquez et al., 2018) and multiple implementation barriers within the specific local context (Chiang et al., 2023; Makabayi-Mugabe et al., 2022; Mukora et al., 2023; R. R. Thompson et al., 2022). As a result, the ability to scale up and implement these strategies sustainably has been greatly limited in Uganda.

The fragmented biomedical-based current approach to TB care needs to be replaced by a more inclusive and integrated model that contextualizes patients' treatment-related challenges to their social and family well-being (Grigoryan et al., 2022; Odone et al., 2018). A treatment management approach that integrates the family into the care process has been recommended (WHO, 2017). This shift is being made in recognition of the significant role that families play in influencing the health habits of individual family members. The family can play a significant role in enhancing the quality of life of patients who are receiving TB treatment (Saidi & Manaf, 2023) by helping them resolve the several challenges faced during the treatment period.

In the treatment of tuberculosis (TB), a family-centered strategy involves engaging family members in the care process and providing them with the resources they need to assist patients in optimizing their adherence to their treatment regimen. Even though the National Tuberculosis and Leprosy Control Program places a strong emphasis on including treatment supporters into TB care (MOH, 2017), there is minimal family participation and support from healthcare practitioners in Uganda (C. A. Berger et al., 2020). There is a dearth of research in Uganda on the role of supportive family involvement in ensuring that patients are adherent to their TB treatment. Moreover, there is a paucity of publicly available

statistics on patient adherence and family support in Jinja. The purpose of this research was therefore to evaluate the effectiveness of family-centered tuberculosis (FaCeTB) support intervention in promoting adherence to tuberculosis treatment in Jinja, Uganda.

1.3. Statement of the problem

The patient's inability to adhere to their TB treatment regimen as recommended by the healthcare providers is a crucial factor contributing to treatment failure and an increase in TB-related mortality. In Jinja, on an annual basis, there are between 225 and 400 TB cases identified per 100,000 of the population, a rate higher than the national average. The persistently high number of TB cases has been partly attributed to poor treatment adherence, which results in prolonged periods of infectiousness with subsequent increases in infection transmission. Regardless of adherence-promoting approaches such as Directly Observed Therapy (DOT) and Digital Adherence Technologies (DATs), optimal TB treatment adherence is persistently low, indicating a gap for further improvement. Poor treatment adherence affects most countries with a high TB burden, resulting in poor treatment outcomes and increased suffering among patients. For instance, in the Indian subcontinent, poor adherence has been reported as a major challenge among TB patients in India, Bangladesh, Bhutan, the Maldives, Nepal, Pakistan, and Sri Lanka (Shringarpure et al., 2023). A considerable proportion of patients (37%) in China (Xu et al. 2017) were found to be non-adherent. On the other hand, optimal treatment adherence in Eastern Kenya at 75% was comparable to that in Central Uganda at 76%. It is worse in Eastern Uganda, given that 35% are not adherent. The unsatisfactory levels of treatment adherence underscore the need for effective adherence-promoting approaches in Uganda and specifically in Jinja District.

Healthcare professionals often assign tasks to family members to help support ambulatory patients in taking their TB medications. A study from high-TB-burden countries indicated that support to patients received from family members is vital in ensuring that patients are adherent to their treatment regimen (Risnawati et al., 2024). Stigmatization, neglect, and lack of compassion from family members can deter patients from seeking care to fulfill their appointments for drug refills, as indicated in Ghana (Appiah et al., 2023). A systematic review in Ethiopia showed that the family's role in providing financial assistance, setting medication reminders, and nutritional support are key factors positively associated with high treatment adherence (Nezenega et al., 2020). It is of great concern that Global reports indicate that TB patients do not get optimal support during the treatment period to achieve better adherence levels (Chakaya et al., 2021). It is even common in Uganda that health professionals do not provide adequate support (C. A. Berger et al., 2020) to patients and their family supporters, nor do they appropriately assign caregivers specific support roles and responsibilities. As such, the patient's family support system has not been fully utilized to overcome TB-related challenges and optimize TB treatment adherence. In addition to this, there is a paucity of published evidence in Uganda regarding the effectiveness of family members' supportive engagement in the TB treatment process in improving TB treatment adherence levels. The major aim of this study, therefore, was to determine whether a family-centered intervention for tuberculosis treatment support was effective in improving treatment adherence among patients.

1.4. Purpose of the study

The purpose of this study was to provide a family-centered TB treatment support intervention to patients and their caregivers and evaluate its effectiveness in improving the patients' adherence to TB treatment.

1.5. Objectives of the study

1.5.1. Broad objective

To determine the effectiveness of a family-centered TB (FaCeTB) treatment support intervention in improving adherence to treatment among patients receiving care at treatment centers in Jinja district, Eastern Uganda.

1.5.2. Specific objective

i. To assess the level of TB treatment adherence among patients before the implementation of a family-centered TB (FaCeTB) support intervention at treatment centers in Jinja, Eastern Uganda.
ii. To determine the level of family support received by TB patients at treatment centers in Jinja, Eastern Uganda.
iii. To evaluate the effectiveness of the FaCeTB support intervention in improving treatment adherence among patients at treatment centers in Jinja, Eastern Uganda.

1.6. Study questions

i. What is the level of TB treatment adherence among patients before the implementation of the FaCeTB intervention at treatment centers in Jinja, Eastern Uganda?

ii. What is the level of family support among TB patients at treatment centers in Jinja, Eastern Uganda?

iii. Does a family-centered TB (FaCeTB) support intervention improve treatment adherence among TB patients at treatment centers in Jinja district, Eastern Uganda?

1.7. Study hypotheses

1.7.1. Null hypothesis

There will be no significant difference in the distribution of treatment adherence scores between the intervention and control study arms post-intervention

1.7.2. Alternative hypothesis

There will be a significant difference in the distribution of treatment adherence scores between the intervention and control study arms post-intervention.

1.8. Justification of the study

It is projected that tuberculosis will be eradicated all across the world by the year 2035, which will guarantee that never again will any human being be afflicted by this disease. Nevertheless, it is quite probable that the majority of countries situated in high-burden zones will be unable to achieve this objective, as demonstrated by the patterns that are currently in

place. Countries with limited resources, like Uganda, must establish TB treatment adherence promotion programs that are both cost-effective and sustainable while also being acceptable to the people. This is especially important to address the problem of low adherence. The purpose of this research was to determine whether or not the participation of family members in the process of improving adherence to tuberculosis treatment is effective.

1.9. Significance of the study

This study is significant as it addresses the critical issue of TB treatment adherence in Jinja, Eastern Uganda, by assessing adherence levels before the implementation of the FaCeTB intervention and examining the role of family support in TB care. By evaluating the impact of a family-centered TB (FaCeTB) support intervention, the study provides valuable insights into how social and familial dynamics influence adherence, contributing to the development of more effective TB management strategies. The findings will inform healthcare policies, guiding the integration of family-centered approaches into TB treatment programs to enhance patient outcomes. Ultimately, the study has the potential to improve TB control efforts by promoting interventions that enhance treatment adherence and patient support.

1.10. Scope of the study

During this study project, an intervention was carried out in which patients and one of their family members or significant others met the research nurses to participate in TB treatment adherence, engagement, and support sessions. The goal of this intervention was to encourage patients to stick to their treatment regimens. During the intervention phase of the study, the family caregivers of the patients were provided with health information to enhance their knowledge and competence in assisting patients in obtaining optimal medication adherence.

Formal role delegation was effectively carried out to enhance the family members' understanding of their support responsibilities. For all patients in the control study group, routine care was provided.

1.11. Study limitations and delimitations

To measure treatment adherence, the study employed a self-reported approach, indicating that the influence of social desirability bias might have affected the accuracy of the responses. The investigator ensured that the participants were adequately educated about the importance of the evaluation, which was intended to facilitate progress rather than to pass judgment or impose punishment. This was done to mitigate the likelihood of this bias occurring.

1.12. Definition of operating terms

Medication adherence

According to Chakrabarti, medication adherence pertains to the extent to which the patient follows the prescribed medication regimen as directed by the healthcare professional (Chakrabarti, 2014). This encompasses the procedure of commencing medicine intake, the specific time at which the drug is consumed, the amount of medication taken, the frequency at which the drug is consumed, and the cessation of the drug altogether. It may encompass the proportion of prescribed medications that are ingested, the proportion of days with the correct number of doses taken, the proportion of doses taken at the correct time, the number of days skipped to avoid medication (drug holidays), or the minimum interval between doses (Chakrabarti, 2014). In this specific study, the term "high adherence" was defined as a score

of 6-11 points on the medication adherence rating scale, and “low adherence” referred to scoring 12 or more points on the MARS.

Family

This refers to two or more people whose relationship is either biological, legal, or emotional, and the patient should be the one who identifies someone they consider to be their family member (Parsh & Aaron, 2016). In this study, a family caregiver/family supporter will be any family member, either residing with the patient or identified by the patient as someone close and helpful to them during TB care.

Family-centered care

Family-centered care, or FCC, is an approach to healthcare that prioritizes the involvement of the patient's loved ones in promoting their health. This approach stresses collaboration and partnership between healthcare providers and family members and is applicable in both hospital and home care settings (Parsh & Aaron, 2016). This approach integrates the decisions of the patient's care with the patient's life experiences. Based on the results of this study, family-centered care refers to involving a specific person who is recognized by the patient as a family member in the efforts to enhance adherence to tuberculosis treatment.

Family-Centered TB Intervention

This was an approach to TB care in which the investigators promoted the initiation, engagement, and support of family caregivers and patients to promote their active participation in helping patients adhere to their TB treatment.

Tuberculosis Patients (TB)

In this study, TB patients were individuals with pulmonary tuberculosis (pTB) disease initiated on the first line of treatment for the very first time.

CHAPTER TWO

LITERATURE REVIEW

2.1. Introduction

The literature section of this study analyzes the existing evidence about adherence to tuberculosis (TB) treatment. The literature is structured to include evidence regarding adherence levels, both with and without adherence promoting interventions. In addition, the study examined the patients' subjective beliefs on family support as well as active support received from family members.

2.2. Level of Pre-intervention TB Treatment Adherence

To eliminate the tuberculosis (TB) epidemic by the year 2035, it is key that all patients are treated and supported for strict adherence to their treatment regimen (Uplekar & Raviglione, 2015). The term treatment adherence refers to the extent to which a patient voluntarily performs the therapeutic acts as mutually agreed upon with the healthcare provider (Aremu et al., 2022). Treatment adherence is considered to be more than just taking medications; it also includes other behavioral measures such as attending necessary appointments, refilling prescriptions, and performing lifestyle modifications as appropriate (Chakrabarti, 2014; While, 2020). Adherence is a designation that indicates the patient is taking an active role in the management of their treatment plan.

Although there have been several initiatives designed to encourage patients to adhere to their tuberculosis treatment regimen (Karumbi & Garner, 2015; Khachadourian et al., 2020; Musiimenta et al., 2019; Zimmer et al., 2021), only a few studies have examined the level

of TB treatment adherence before the implementation of an adherence-promoting intervention. The majority of the studies that have been conducted to determine baseline treatment adherence levels have utilized cross-sectional designs and have been observational. An evaluation of non-adherence levels in a randomized controlled study involving the provision of psycho-education was conducted in Ethiopia (Tola et al., 2016). The study demonstrated a non-adherence level of 19.4% and 19.6% among patients in the intervention and control arms.

According to the findings in China (Xu et al., 2017), an observational study found that only 65.4% of patients achieved the preferred level of treatment adherence, with 34.6% of the patients having poor commitment to the TB treatment regimen. In Kosovo (Krasniqi et al., 2017), it was found that 14.5% of patients had a low level of adherence, but this particular study did not include information regarding the duration for which adherence was assessed, and it only included patients within the second phase of treatment. According to the findings of a cross-sectional study carried out in Ghana, a review involving both self-reported data and medical records, 81.6% of patients were adherent to the tuberculosis treatment regimen (Dogah et al., 2021).

Twenty-one percent of tuberculosis patients in the northwestern region of Ethiopia were not adherent to their treatment regimen, according to the findings of an evaluation that was carried out over the preceding thirty days in that region, with previous defaulters having the lowest level of nonadherence (Mekonnen & Azagew, 2018). In the same area, it was discovered that the rate of non-adherence during the continuation phase was 35.8% (Gashu et al., 2021). This level is higher than the level found by Mekonnen and Azagew,

highlighting that variation in adherence levels in a similar setting could be influenced by multiple factors.

While assessing TB treatment adherence, the duration of medication use considered can be key. A study conducted in Ethiopia found that assessing adherence over a longer period of medication use yielded higher levels of non-adherence than using a shorter duration. The percentage of individuals who did not adhere to their prescribed medication was 16.5% in the previous month and 10% in the most recent four days (Ajema et al., 2020). Gebremariam and colleagues also observed a similar pattern where the proportion of good adherence for the most recent month was 90.6% and 96.6% in the most recent four days (Gebremariam et al., 2021). This is understandable because longer periods are likely to result in forgetfulness and response bias.

In the Eastern region of Africa, poor adherence to TB treatment is also prevalent. For instance, in Kilifi, Kenya, it was discovered that non-adherence was affecting one-quarter (25%) of the patients (Chebet et al., 2022). Comparable results were reported in Kampala, an urban area in Uganda, where 26% of the population had poor adherence to their treatment regimen. The assessment was a self-reported value that measured being adherent as taking ≥90% of the prescribed doses over the past four weeks (Hassard et al., 2017). On the other hand, this is not the case when seen from a peri-urban to rural perspective, as in Eastern Uganda, where the rate of treatment adherence is fairly low at 65% (Wanyama, 2017). Nevertheless, both urban and peri-urban settings would benefit from the implementation of adherence-promoting interventions.

Even though the World Health Organization (WHO) deems a level of adherence of 90% to be ideal, there is no consensus regarding the level at which a patient can be classified as

adherent or nonadherent. According to the findings of some studies, adherence can be defined as taking at least 90% of the prescribed dosage (Mekonnen & Azagew, 2018), 80% or more as prescribed (Akamike et al., 2020), or even 95% (Wanyama, 2017). Furthermore, adherence has been documented differently, with some studies considering the higher end of the adherence continuum and identifying it as adequate, high, or good adherence, and others considering the lower end of the adherence continuum and documenting it as poor, low, or non-adherence. The lack of homogeneity in the conceptual definition of TB treatment adherence, therefore, requires that there is careful consideration while interpreting and comparing findings on adherence levels from different settings. The methodological variation could also contribute to the observed diversity of the findings.

2.3. Family Support in TB Treatment Adherence

A family is a concrete unit comprised of two or more interrelated and interdependent groups of people, often living in a related household (Dermott & Fowler, 2020). In healthcare, family members have been identified and categorized differently. Depending on the setting, names such as informal caregivers, caregivers, family caregivers, caretakers, or significant others have been used (Fana & Sotana, 2021; Sadigh et al., 2017). The family forms an influential unit of individual behavior, but TB patients receiving ambulatory care maintain the right to make their own decisions regarding the involvement of a third party in their treatment process.

For patients to accept treatment support, they should be able to perceive the availability and effectiveness of such support in helping them adhere to TB treatment. Additionally, for the support to be included as part of the treatment approach, the patient needs to perceive the

support as a positive and enabling initiative. Several elements could interfere with the understanding and intentions of the family members' engagement when it comes to the promotion of treatment adherence. To ensure that the patient is not alienated from the family and vice versa, continuous assessment and support are required, particularly in improving awareness, providing necessary information, and alleviating anxiety through emotional support (Kokorelias et al., 2019). The outcome of the engagement should be that the patient and family are adequately empowered, engaged, and activated (Pelletier & Stichler, 2014), willing to work together to promote treatment adherence. It is, therefore, the nurses' and the healthcare system's responsibility to establish an atmosphere that is conducive for collaborative engagement of the patient and their families to promote optimal treatment adherence.

2.3.1. Level of Family Support in TB Treatment Adherence

Family support is a vital component of healthcare, and different family members can take on several support roles as a supportive system for patients. Initially, females played a big part in supporting patients towards recovery, but recently, males have become active in the family supportive roles (Sadigh et al., 2017). Additionally, children are a subgroup of supporters who are increasingly taking on the responsibility of family caregivers, particularly in situations where their loved ones are afflicted with illness (Hunleth, 2017).

It is essential, as stated by the World Health Organization (WHO, 2017), to provide high-quality patient-oriented care to TB patients to bring the epidemic to an end. Because of this, the WHO has established a people-centered policy, emphasizing care beyond the provision of anti-TB drugs, with a recommendation of coordinated task shifting to ensure that patients suffering from tuberculosis (TB) receive uninterrupted ambulatory treatment (WHO, 2017).

It is, however, challenging given that the majority of the patients' home-based responsibilities are primarily the responsibility of the patient's family members, yet they rarely receive optimal support to perform such support roles.

In Sub-Saharan Africa, there is variation in the extent to which family members are involved in promoting TB treatment adherence. Family support forms the largest support system available to patients. For instance, in Ethiopia, over one half (58.1%) of patients are being supervised by a family member during the treatment period (Gebremariam et al., 2021). TB treatment observation by a family member is also common in Uganda, where 78.5% of patients are being supervised by a family member such as a husband, mother, father, or brother (Wanyama, 2017).

There are occasions when the patient's adherence to their tuberculosis therapy is compromised due to an inner drive to discontinue treatment. This is a regular occurrence, particularly in cases where the treatment results in unpleasant outcomes and extreme weariness, such as severe drug-related side effects (Appiah et al., 2023; Nortey et al., 2024). Additionally, patients may become reluctant to take their medications, especially in the continuation phase (Appiah et al., 2023; Mekonnen & Azagew, 2018) since overt signs and symptoms have resolved. In situations like these, the caregiver might not be in a position to assist the patient in taking the medication by simply observing them. The supporters must act as a source of inspiration, encouragement, and motivation for the patient to achieve optimal adherence and treatment outcomes.

It is, therefore worth mentioning that family supporter roles can go beyond medication supervision to include responsibilities such as reminding the patient to take their medications, encouraging and motivating them, providing emotional care, and informing

and communicating to them about the complications that may arise if they do not adhere to therapy (Chiang et al., 2023; Nyasulu et al., 2018). Moreover, the patient may be unable to go to the treatment center to collect their refills for several reasons. Family caregivers can ensure a constant supply of TB drugs by assisting patients in refilling their prescriptions at designated healthcare facilities (Fana & Sotana, 2021). In addition, family caregivers may accompany patients to treatment clinics as a form of encouragement and motivation for adherence.

Regarding the provision of dietary support and enhancing the nutritional status of tuberculosis patients, family caregivers were found to play a significant role in Malawi. According to Nyasulu and colleagues (Nyasulu et al., 2018), the family's duties may not only include providing food to the patients but also encouraging them to eat. This was necessary because the patients occasionally had challenges with their appetite. In situations where the patient is unable to feed themselves, the family members have also assisted in feeding the patient (Sadigh et al., 2017; Samal, 2017).

It is important to realize that adherence is determined by several different circumstances. Some of the negative mental processes that can lead to incorrect coping, bewilderment, withdrawal, and carelessness among patients include fear, distress, anxiety, and sadness. When combined with the negative effects of the medication, the patient may experience feelings of being overwhelmed (Abbas Ali et al., 2024; Aggarwal, 2019). The supportive role of family members should, therefore, not be confined to drug supervision only (Lutfian et al., 2024), because doing so could result in neglecting other family contributions that could help promote treatment adherence. The patient's family members can fulfill several responsibilities promoting treatment adherence, but this will depend on their capabilities and

the level of assistance they receive from the healthcare system.

Given the current state of evidence in TB care, the family is capable of executing a multi-dimensional approach (Scheurer et al., 2012) to assist patients in adhering to their treatment course. Unfortunately, it is important to note that not all patients can get true family assistance or perceive the existence of such help in the same way (Nadon et al., 2023). This is understandable given that patients come from a wide range of backgrounds, reside in a variety of social and economic contexts, and have varying degrees of access to essential tools that are designed to encourage adherence.

Other factors, such as family size, can also influence the availability and perception of family support. In Pakistan, it has been found that patients residing in large families receive superior support compared to those residing in families of smaller sizes. In addition to this, patients from low socioeconomic origins and female patients have been shown to receive inadequate support (Saqib et al., 2019). As a further point of interest, it was discovered that patients who had low literacy levels and those who were younger had lower levels of family support in comparison to their counterparts (Nadon et al., 2023). Particularly when planning interventions to promote treatment adherence, these socio-economic aspects should be given careful consideration.

2.4. Family-centered interventions and TB treatment adherence

When it comes to tuberculosis (TB), the issue of low treatment adherence has been addressed by designing and executing different adherence-promoting strategies. In most of the interventions to improve TB treatment adherence, the patient has been the unit of focus, with minimal emphasis put on the patient's family.

Interventions that take up a family-centered approach to promoting adherence must be able to make proper use of the resources that families have available to them when it comes to patient care. Family resources can be material and unambiguous, such as money, food, and objects that help provide comfort. There is also the possibility of resources taking the shape of intangible and limitless forms of assistance, such as love, motivation, the exchange of information, and emotional connection, amongst other things (Putra et al., 2019; Theofilou, 2023).

A family-centered intervention is a technique that is well-suited to promote adherence to TB treatment in an African setting. This is because African societies generally place a strong emphasis on the family unit (Oosterom et al., 2022). In promoting TB treatment adherence, the patient should not be treated as a solitary unit but as an individual who lives in an interconnected society. The patient's family members should be encouraged to actively participate in the treatment process and make effective use of the support networks available in promoting adherence to TB treatment. Communication and information sharing that is open and objective, respect for skills, experiences, and knowledge, working together in partnership, collaboration, and decision-making through negotiation, while taking into consideration the context, are all essential in achieving family-centered care (Kokorelias et al., 2019).

A randomized controlled trial was conducted in Armenia (Khachadourian et al., 2020) during the continuation phase of tuberculosis treatment. In this experimental study, patient family support involved participating in counseling sessions with patients. After that, patients and their families received regular reminders through telephone conversations. The patients in the intervention arm of the study achieved an optimal adherence (100%), whereas

the patients in the control group had an adherence level of 87.3%, and the two were significantly different. In addition, there was a discernible reduction in feelings of hopelessness and social condemnation among the family members who supported the patients (Khachadourian et al., 2020).

A pilot study conducted in Armenia, utilizing a quasi-experimental design, employed a family-centered strategy (Truzyan et al., 2018). The majority of the counseling sessions were carried out in the patient's own home, and the results of the study showed improvement in the patient's knowledge about tuberculosis and improvement in the perceived efficacy of adherence to tuberculosis treatment.

In Uganda, the majority of care facilities use community-based directly observed therapy (CB-DOT), with seven out of ten utilizing family members as treatment supervisors (C. Berger et al., 2020; C. A. Berger et al., 2020). This indicates that the family has taken on an important role in serving as treatment supervisors to enhance the community-based approach of DOT. In addition, patients have shown a strong preference for CB-DOT due to ethical considerations, particularly in situations when the drug is to be supervised by a close individual, such as a member of the patient's family or a close friend (Hassard et al., 2017).

When employing a family-centered approach, it is necessary to take into account the preferences of the patient while also supporting the members of the patient's family who are actively involved in the monitoring of the patient's adherence behavior. It is concerning that such a strategy has not been evaluated for effectiveness in sub-Saharan Africa, and yet the region has a high burden of TB and poor treatment adherence levels. There is, therefore, a high need to implement a study that evaluates treatment adherence levels in the presence and absence of a family-based supportive intervention.

2.5. Conceptual Model

The study was guided by Nola Pendar's health promotion model (Khodaveisi et al., 2017). The model defines health as a constantly changing state beyond the boundaries of disease symptomatology, with external influences able to positively influence health promotion. Patients are more likely to promote their health when inspired and supported by other people around them. Families, peers, and care providers are vital influences that can enable patients to perform self-care activities. As guided by this model, the study postulates that adherence to TB treatment will be influenced by interpersonal relationships. Through external influences from the family and the Nurse, the patient's perceived self-efficacy and awareness will be enhanced. The patient will, therefore, adhere to treatment when immediate caregivers and significant others commit to assisting them in promoting TB treatment adherence.

2.5.1. Conceptual Framework

INDEPENDENT VARIABLES **DEPENDENT VARIABLE**

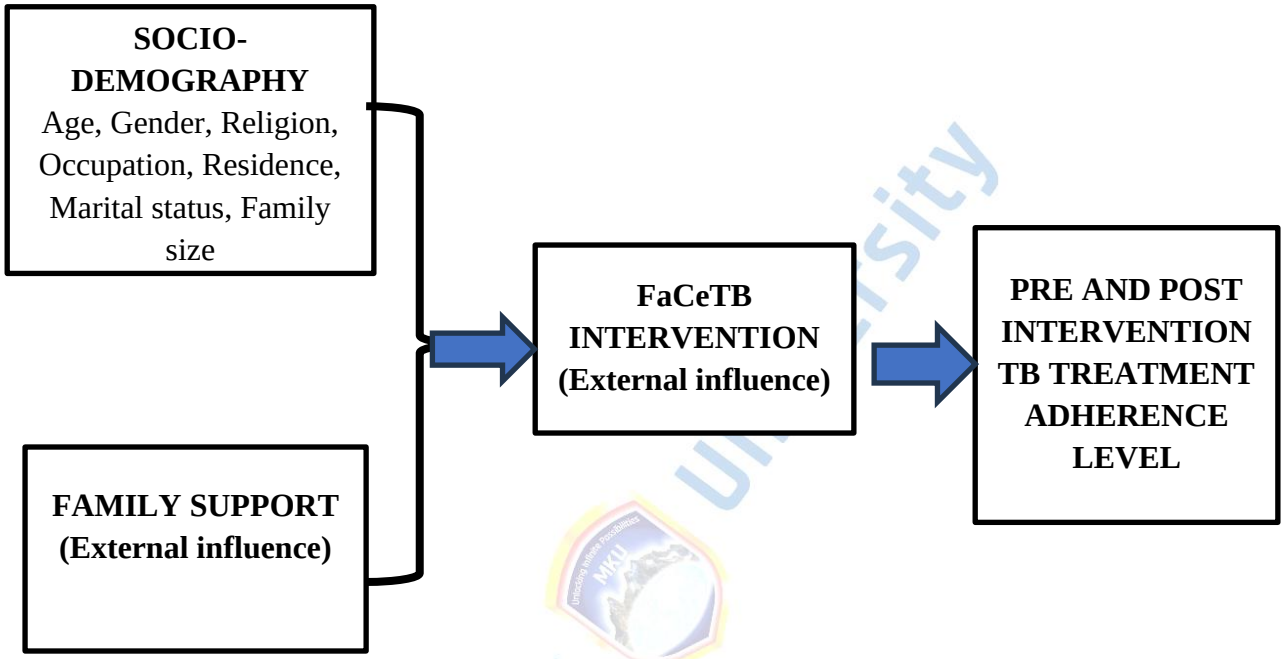

Figure 1. Conceptual Framework

2.6. Summary of Literature Review

The tuberculosis treatment period poses several challenges to patients, and they are at a greater risk of defaulting from their treatment regimen. Current evidence of TB treatment adherence indicates that there is great variability in the proportion of patients who are adherent to their treatment regimen. Good adherence to tuberculosis ranges from as low as 65% in Uganda and China to as high as 96% in Ethiopia. There are several countries that are unable to meet the requirements that are thought to be ideal for promoting adherence to optimal levels. When interpreting these data, it is crucial to exercise caution because

numerous studies have adopted varying approaches in measuring the degree to which patients adhere to their treatment regimen.

Some studies employed self-reported scales, while others used biochemical markers, treatment refill cards, or a mix of two or more of these approaches to measure adherence. As a result, there is no harmonization and synchrony about the methods that are used to measure adherence. There are a variety of cutoffs for good adherence, which can range anywhere from 85 percent to 95 percent of the prescribed treatment. Additionally, a number of studies have taken into consideration days, weeks, or even months prior to the assessment, which means that there is also a degree of variation in the time ranges that are evaluated. Furthermore, the evaluation of adherence during either the intensive or continuation phase may result in very different levels of adherence.

Although Community-based Directly Observed Therapy (DOT) is currently the standard of operation in promoting treatment adherence, the degree of adherence is still rather low, especially in sub-Saharan Africa and Uganda in particular. There is a possibility that the differences in the effectiveness of the approaches are the result of variations in the implementation. A lack of support for laypeople who are assisting in the implementation of CB-DOT could be the cause of unsatisfactory results since there is limited training from the healthcare providers on their roles and responsibilities.

Patients' family members are already playing a big role in an effort to promote treatment adherence. However, it is challenging for family caregivers to fully participate in the process of improving adherence due to limited assistance accessible to them regarding the treatment adherence support roles. This could, therefore, result in a negative attitude toward TB patients with subsequent abandonment of the patient support roles. The purpose of this was

to implement a patient and family supportive intervention and evaluate its effectiveness in improving adherence to the tuberculosis treatment regimen.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1. Introduction

This chapter provides an elaborate account of the methodologies and instruments employed in conducting this research. The section encompasses various aspects, including study design, study location, study population, inclusion and exclusion criteria, sample size estimation, sampling strategy, delivery of the FaCeTB intervention, data collection tools, and data collection processes. Furthermore, the strategies utilized in data management and the blueprint for data analysis have been meticulously outlined.

3.2. Study design

A non-equivalent group quasi-experimental design was utilized in this research study, with the study population divided into two independent halves: an intervention study arm and a control study arm. Maciejewski (Maciejewski, 2020) described the approach typical for a non-equivalent quasi-experimental design as utilized in this study. The intervention group received the FaCeTB intervention package (Appendix III), and the control group received routine care as recommended by the government of Uganda's Ministry of Health. The two study groups were assessed before and after the implementation of the intervention. This study design was chosen to facilitate the evaluation of the effect of the intervention, both before and after the intervention, as well as within the two study groups.

3.3. Study Area

The research was conducted in Jinja District, located in the southeastern part of Uganda. The study included patients from five different tuberculosis treatment centers, which were Jinja Regional Referral Hospital (JRRH), Walukuba, Mpumudde, and Bugembe Health Center Four (HCIV), all located in Jinja City, and Buwenge General Hospital (BGH), located in Jinja District Local Government. These treatment clinics were purposively selected because they provide care to a large number of TB patients. Jinja was selected because it is one of the districts in Uganda with a high tuberculosis case notification rate (MOH, 2021). By its location in the southeastern region of Uganda, the Jinja Regional Referral Hospital functions as a tertiary referral and teaching hospital, receiving a large number of patients from primary healthcare facilities within the region.

3.4. Target population

The target population consisted of persons diagnosed with pulmonary tuberculosis and initiated on tuberculosis treatment. Jinja has an estimated case notification rate of 215. Given that the approximate population is about 500,000 people, the targeted population was about 2300 people.

3.5. Eligibility criteria

3.5.1. Inclusion criteria

Individuals who were at least 18 years old, diagnosed with TB disease, and initiated on TB treatment were eligible for inclusion in this study. After the patients were initiated on TB

treatment, they had to wait for a minimum of two weeks before they could be recruited into the study. Only patients who consented voluntarily took part in this study.

3.5.2. Exclusion criteria

The study excluded patients admitted, patients who had experienced failure of the first-line regimen, patients with extrapulmonary tuberculosis, and patients who were started on treatment for drug-resistant tuberculosis. This decision was made because these patients were currently receiving intensive clinic-based care from the care providers, involving direct observation of therapy.

3.6. Sample size estimation

A two-proportion-difference hypothesis was utilized to get an estimate of the total number of participants required. As reported by Wanyama (2017), we considered an adherence level of 65% to be the initial proportion (p1) of the adherence. Considering an effect size of 20%, the second proportion, p2, was projected to be 85% after the intervention. The estimation assumed that the sample would power the study to 80%, considering a two-sided chance of type I error of 5%. The formula used was $n = \frac{(Z\alpha/2xZ\beta)^2 x\{p1(1-p1) + p2(1-p2)\}}{(p1-p2)^2}$, where $Z\alpha/2$ represents the critical value of 1.96 (for a confidence level of 95%), $Z\beta = 0.84$ (for 80% power), p1 = the baseline adherence level = 0.65, p2 = the expected adherence rate after intervention = 0.85, and **n** denotes the required sample size for each study group. The sample size was calculated following the steps below;

Calculating the critical value term

$(Z\alpha/2+Z\beta)^2 = (1.96+0.84)^2 = 7.84$

Calculating the variance for both proportions

$p1(1-p1) = 0.65 \times (1-0.65) = 0.65 \times 0.35 = 0.2275$

$p2(1-p2) = 0.85 \times (1-0.85) = 0.85 \times 0.15 = 0.1275$

Summing up the variances

$p1(1-p1) + p2(1-p2) = 0.2275+0.1275 = 0.355$

Calculating the difference in proportions

$(p1-p2)^2 = (0.65-0.85)^2 = (-0.20)^2 = 0.04$

Calculating the sample size per group

$n = 7.84 \times 0.355/0.04$

$n = 2.7824/0.04 = 69.56$

Therefore, the sample size per group is 70 patients

Final sample size calculation

Since there are two study groups (intervention and control), considering an enrolment ratio of 1:1, the estimated total sample size was $2 \times 70 = 140$

3.7. Sampling method

To recruit all of the individuals in the study arms, the study utilized a method known as sequential sampling. The recruitment of participants took place at the time when patients

had moved to the TB clinics to refill their drugs. This was done to guarantee that all eligible patients took part in the study. Due to a limited timeframe, it was necessary to make use of this approach to achieve the desired sample size within the time and resource constraints. To avoid discussion of the intervention among patients and possible contamination of the study outcome, all participants arriving at the study clinic in the same week were recruited into the same study arm. In the first week of enrollment, all patients attending the clinic were recruited into the intervention arm. In the second week, participants who came in were enrolled in the control arm. This was done for the subsequent weeks intermittently until the desired sample size was achieved.

3.8. Study variables

3.8.1 Independent variables

The primary predictor or independent variable was family support (both perceived and actual support). Other independent variables included family size and socio-demographic parameters, including age, gender, residence, level of education, occupation, and family size, as well as clinical characteristics.

3.8.2 Dependent variable

Pre- and post-intervention adherence to tuberculosis treatment was the outcome/dependent variable assessed using the Medication Adherence Rating Scale (MARS).

3.9 Data collection tools

During in-person interviews, the interviewer used semi-structured questionnaires to gather data from the study participants. To capture the patients' responses, an offline KoboCollect application was used. Afterward, the data was synchronized with the online database. To assess the level of adherence to TB treatment, the Medication Adherence Rating Scale (MARS) was used (Anghel et al., 2019; Chan et al., 2020). A Likert scale was used to assign a numerical value to each item, with values ranging from one to four. Six items were adopted from the MARS (appendix II), and this resulted in a rating for treatment adherence ranging from six to twenty-four points. The lower scores represented higher adherence levels to treatment, and the higher the scores, the poorer the patient was in adhering to their TB treatment. Perceived family support was assessed using eight items adopted from the Multidimensional Scale of Perceived Social Support (MSPSS) scale (Zimet et al., 2016), as presented in Appendix II. Each scale item was graded on a one to four-point Likert scale, and the scores ranged from 8 to 32 points. The higher the scores on this scale, the better the family support level received by patients. The data collection tool was translated into Luganda and Lusoga, the most common languages used by people in the study setting.

3.10. Study Tool Validity and Reliability

To ensure the validity of the data collection tool, the research supervisors and TB treatment specialists at Jinja Regional Referral Hospital examined the questionnaire to guarantee its accuracy in capturing adherence behaviors. Face validity was further enhanced through pre-testing the data collection tool on ten tuberculosis patients at Budaka Health Center IV, a non-study health facility. The site was selected because it serves a geopolitically identical

population to the target population. The data obtained from the pre-test was not included in the final analysis but was used to make changes in the tool. Criterion validity was assessed by comparing the adherence categories obtained from the MARS and TB medication refill appointments obtained from the drug dispensing log. The two were significantly associated, as indicated by a $p<0.0001$, indicating that the MARS tool was accurate in predicting high and low adherence levels. To further enhance the validity and reliability of the MARS, we used a Likert scale with four responses per scale item rather than the original Yes/No binary responses in the original 10-item scale. The internal consistency of the Medication Adherence Rating Scale has been proven through its evaluation among psychotic patients (K. Thompson et al., 2000). The Multidimensional Scale of Perceived Social Support scale has also been proven as a reliable and valid tool for assessing perceived support (Wongpakaran et al., 2011). The current research study revealed that both the Medication Adherence Rating Scale and the Multidimensional Scale of Perceived Social Support tool had a strong level of internal consistency, as indicated by Cronbach's alpha coefficients of 0.72 and 0.93, respectively.

3.11. Family-Centered TB Support Intervention

As part of the FaCeTB support intervention, a member of the patient's family or significant other was invited to actively participate in assisting the tuberculosis patient in adhering to the recommended drug regimen. The interventional study done in Armenia by Truzyan et al. (2018) served as a model for the implementation of the current intervention. The guideline on tuberculosis disease for patients and families, issued by the Center for Disease Control and Prevention (CDC, 2015), served as the basis for the development of the intervention

(Appendix III). The components implemented during the intervention have been described below.

3.11.1 FaCeTB Intervention Package

The intervention aimed to enhance TB treatment adherence by increasing awareness and self-efficacy among patients and their family members regarding the need to adhere to the treatment regimen. The conversation regarding the management of tuberculosis treatment adherence focused on family engagement in patient care. This was done through the use of an informational and supportive approach as elaborated below;

I. Engagement and integration. The patient was requested to invite one active family member to a meeting with the research team at the clinic. The meeting involved three parties: the patient, the family member, and the research nurse. The meeting date was in line with the medication refill date as indicated on the patients' refill cards. This provided an opportunity to introduce the collaborative approach to care and also identify patient and caregiver concerns.

II. TB information support. The nurse discussed TB disease information with the patient/family caregiver duo to promote awareness and communicate the urgent need for optimal disease control.

III. Treatment information support. TB treatment was discussed in detail to include the regimen and its duration, components of good adherence to medication, benefits of TB medication adherence, and dangers of poor adherence.

IV. Delegation of responsibilities. The nurse then introduced and delegated key roles (as indicated in Appendix III) to the family members to help the patient achieve optimal treatment adherence. The delegated roles included;

- Reminding the patient to take their TB medication regularly every day at the same time.
- Ensuring that the patient's medication is available by reminding them to go for their refills, helping them with refills, or going with them to the health facility during scheduled appointments.
- Keeping the medicines in a place where the patient can readily access them.
- Encouraging patients especially when they feel overwhelmed and unwilling to take their medications.
- Reporting side effects to the primary care providers and helping patients fetch adjunct drugs for side effects.
- Treating the patient with courtesy and compassion while eliminating any sources of bias.
- Assisting the patient with daily activities of living such as feeding, and hygiene chore.

3.11.2 Intervention Delivery Strategy

The FaCeTB intervention was implemented at the TB clinic through face-to-face interaction between a trained study nurse, the patient, and his/her family member. Every patient/caregiver duo received an information brochure (Appendix III) containing the information discussed in the face-to-face meeting.

3.12. Data Collection Procedures

Data collection was conducted at TB treatment clinics by registered nurses trained at the diploma level. The research assistants received research training under the guidance of the

principal investigator. Data were collected at two independent time points: before and after implementation of the intervention. Before the intervention, data were collected on the patient's socio-demographic and clinical characteristics, perceived and actual family support, and adherence to tuberculosis treatment. The post-intervention evaluation assessed the level of treatment adherence at a minimum of two weeks after the intervention. Quantification of both adherence and perceived support was achieved by utilizing numerical outcomes. After the Principal Investigator completed the validation process, the data forms were synchronized with the online Kobo Toolbox database.

3.13. Data analysis procedures

The analysis process was performed using SPSS version 25. For the descriptive analysis, median, mean and standard deviation were computed for continuous variable. Frequencies and proportions were computed for all categorical variables. Patients with adherence scores ranging from 6 to 11 points were categorized as having a high level of adherence to their tuberculosis treatment. Patients with scores between 12 and 24 were categorized as having a low level of adherence to their tuberculosis treatment. Subsequently, the overall patient count was converted into ratios, which were then presented as proportions using bar charts. Patients were categorized as having a high perceived level of family support if their scores on the Multidimensional Scale of Perceived Social Support Scale fell within the range of 22 to 32 points. Conversely, patients with a score ranging from 8 to 21 points were classified as having a low perceived level of support. The data was visually presented via bar charts. The patients' responses on the different forms of actual support received were presented as binary outcomes in a tabular format for comparison.

The Shapiro-Wilk and the Kolmogorov-Smirnov tests were used to check for the distribution of adherence scores. We found that the data violated normality ($p<0.0001$), and therefore, nonparametric tests were used to assess the differences in adherence scores. The Mann-Whitney U test was used to compare the adherence scores between the intervention and control study arms, both before and after the intervention. To evaluate the changes in adherence scores within the same groups (Control and Intervention arms) before and after the intervention, the Wilcoxon Signed-Rank test was used. Median scores, Interquartile range, p-values, and corresponding Z-scores were computed. Obtaining a p-value <0.005 indicated a statistically significant difference in the median scores before and after the intervention, as well as within and between the study groups. Effect size (r) was also computed to determine the magnitude of the differences in adherence.

3.14. Ethics Considerations

The study received approval from the Mount Kenya University (MKU) Institutional Ethics and Research Committee (permit number 2394) and the Mbale Regional Referral Hospital Research and Ethics Committee (reference number MRRH-2023-358) to ensure that it was ethically sound. After receiving approval, the Uganda National Council of Science and Technology (registration number HS3583ES) authorized the conduct of the research. Obtaining administrative authorization from the Jinja District Local Government, the Jinja City Council, and all tuberculosis treatment centers involved was an essential part of the approval processes of this study. In addition, the data acquired from the participants was obtained without any individual identifying information being included in the data. Patients were provided with comprehensive information regarding the study to enable them to make

an informed decision regarding their participation. Every participant in the study provided written informed consent.

CHAPTER FOUR

RESEARCH FINDINGS AND DISCUSSIONS

4.1. Introduction

This chapter presents the study's findings, including the results collected from both the control and intervention groups before and after the intervention. Initially, a cohort of 147 individuals diagnosed with pulmonary tuberculosis was assessed. The control group consisted of 74 participants, making up 50.3% of the overall sample, whereas the intervention group had 73 individuals, accounting for 49.7% of the entire sample. Before the follow-up, one patient died, and 19 patients could not be reached because they missed their clinic visits or were transferred to healthcare facilities not included in the study. Consequently, in the post-intervention evaluation, a total of 127 patients were successfully followed up with, indicating a response rate of 86.4%. The control group accounted for 47.2% of the sample, whereas the intervention group comprised 52.8%.

4.2. Characteristics of participants at Jinja District TB treatment centers

The survey found that 63.9% of the participants reside in Jinja District, while the remaining 36.1% come from various districts, including Alebtong, Buikwe, Bugweri, Iganga, Kampala, Kamuli, Kole, Luuka, Mayuge, Mbale, and Yumbe. Jinja, with its regional referral hospital, attracts patients from many districts of Uganda. The participants' ages ranged from 18 to 81 years, with an average age of 37.85±13.89. Male participants constituted the majority (55.8%), while a big proportion (44.2%) were married, and one in five (20.4%) were unemployed. Based on the data presented in Table 1, it can be seen that 67.3% of the

participants live in homes that are residential to four or more family members. There were no statistically significant differences in socio-demographic parameters between the control and intervention groups, indicating that the study groups were similar in terms of socio-demographic features.

Table 1. Socio-demographic characteristics of study participants at TB treatment centers in Jinja

Variable	Intervention	Control	Totals	p-value
	Frequency (%)	Frequency (%)	n (%)	
Residence				
Jinja	51(69.9)	43(58.1)	94(63.9)	0.170
Elsewhere	22(30.1)	31(41.9)	53(36.1)	
Age in years				
Young adults (18-35)	34(46.6)	38(51.4)	72(49.0)	0.622
Middle & older adults (>35)	39(53.4)	36(48.6)	75(51.0)	
Gender				
Male	44(60.3)	38(51.4)	82(55.8)	0.320
Female	29(39.7)	36(48.6)	65(44.2)	
Marital status				
Married	31(42.5)	34(45.9)	65(44.2)	0.741
Single	42(57.5)	40(54.1)	82(55.8)	
Level of education				
No formal schooling	16(21.9)	15(20.3)	31(21.1)	0.641
Completed Primary	26(35.6)	23(31.1)	49(33.3)	
Completed Secondary	25(34.2)	25(33.8)	50(34.0)	
Completed Tertiary	6(8.2)	11(14.9)	17(11.6)	
Occupation				
Unemployed	14(19.2)	16(21.6)	30(20.4)	0.433
Farmer	16(21.9)	08(10.8)	24(16.3)	
Business	22(30.1)	22(29.7)	44(29.9)	
Technical worker	16(21.9)	21(28.4)	37(25.2)	
Professional worker	05(6.8)	07(9.5)	12(8.2)	
Family size				
1 person	03(4.1)	11(14.9)	14(9.5)	0.503
2-3 people	19(26.9)	15(20.3)	34(23.1)	
≥4 people	51(69.9)	48(64.9)	99(67.3)	
Usual family caregiver(s)				
Children	13(17.8)	17(23.0)	30(20.4)	0.527
Spouse	26(35.6)	25(33.8)	51(34.7)	
Siblings	09(12.3)	11(14.9)	20(13.6)	
Parent	24(32.9)	23(31.1)	47(32.0)	
Friend	08(11.0)	11(14.9)	16(10.9)	
No one	04(5.5)	03(4.1)	07(4.8)	

Regarding clinical characteristics, one in three (36.7%) of the TB patients were co-infected with HIV. The majority of the patients (81.0%) were categorized as Pulmonary Bacteriologically Confirmed (PBC) TB. About three in four (73.5%) were taking other medications in addition to anti-TB drugs. Patients experienced a series of drug side effects, with the most commonly experienced at 65.3% being body weakness (Table 2).

Table 2. Participants' clinical characteristics

Variable	Intervention	Control	Totals
	Frequency (%)	Frequency (%)	n (%)
HIV status			54(36.7)
Positive	30(41.1)	24(32.2)	
Negative	43(58.9)	50(67.6)	93(63.3)
TB disease categorization			
PBC	56(76.7)	63(85.1)	119(81.0)
PCD	17(23.3)	11(14.9)	28(19.0)
Missing refill appointments			
Yes	22(30.1)	32(43.2)	54(36.7)
No	51(69.9)	42(56.8)	93(63.3)
Having other disease condition(s)			
Yes	36(49.3)	35(49.3)	71(48.3)
No	37(50.7)	39(52.7)	76(51.7)
Taking other medications			
Yes	57(78.1)	51(68.9)	108(73.5)
No	16(21.9)	23(31.1)	39(26.5)
Body weight at diagnosis			
Below 52	36(49.3)	32(43.2)	68(46.3)
52 and above	37(50.7)	42(56.8)	79(53.7)
Side effects experienced			
Loss of appetite	40(54.8)	27(36.5)	67(45.6)
Nausea and/or vomiting	29(39.7)	21(28.4)	50(30.4)
Brown urine and/or yellow eyes	47(64.4)	46(62.2)	93(63.3)
	37(50.7)	33(44.6)	70(47.6)
Tingling, numbness	53(72.6)	43(58.1)	96(65.3)
Body weakness	46(63.0)	29(39.2)	75(51.0)
Body pain	10(13.7)	08(10.8)	18(12.2)
Change in vision			

4.3. Level of TB treatment adherence among patients at treatment centers in Jinja before the implementation of the FaCeTB intervention

Before the intervention, 65.3% of patients had a high level of adherence to their TB medication, with the median score being 10 points. A bigger proportion (71.2%) of patients in the intervention group had a higher adherence level than 59.5% in the control group (Figure 2). Table 3 displays the range of adherence scores in the intervention group, which ranged from 27.4% to 82.2%. In contrast, the control group's adherence scores ranged from 36.5% to 67.9%. At an average score of 1.37(SD±0.77), patients had the best scores in the scale item *"I took my medication only when I felt sick."* The worst scores were observed in the item "*taking my TB medication has been an important part of my daily activities,*" with an average score of 1.95(SD±0.78).

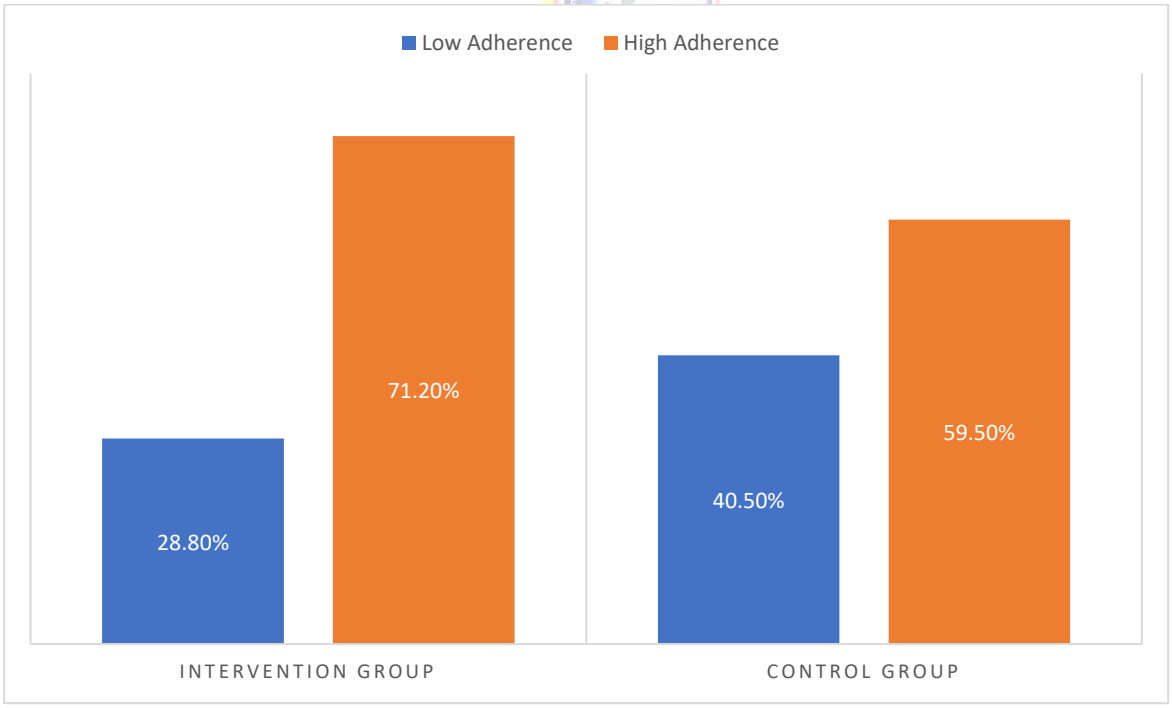

Figure 2. The proportion of patients with high and low TB treatment adherence before the FaCeTB intervention

Table 3. Participants' responses on the adherence rating scale before the intervention

Adherence scale items	Patient scores, n (%)			
	1	2	3	4
In the past 2 weeks, I have forgotten to take my TB medication				
Control	40(54.1)	13(17.6)	16(21.6)	05(6.8)
Intervention	43(58.9)	20(27.4)	08(11.0)	02(2.7)
Total	*83(56.5)*	*33(22.4)*	24(16.3)	07(4.8)
In the past 2 weeks, taking TB medication has been an important part of my daily activities*	27(36.5)			01(1.4)
Control	20(27.4)	25(33.8)	21(28.4)	00(0.0)
Intervention	47(32.0)	36(49.3)	17(23.3)	01(0.6)
Total		*61(41.5)*	38(25.9)	
In the past 2 weeks, when I felt better, I stopped taking my TB medication				
Control	50(67.6)	03(4.1)	19(25.6)	02(2.7)
Intervention	36(49.3)	15(20.5)	22(30.1)	00(0.0)
Total	86(58.5)	18(12.2)	41(28.0)	02(1.3)
In the past 2 weeks, when I felt worse while taking the TB medication, I stopped taking it				
Control	49(66.2)	12(16.2)	10(13.5)	03(4.1)
Intervention	43(58.9)	16(21.9)	13(17.8)	01(1.4)
Total	92(62.5)	28(19.0)	23(15.6)	04(2.9)
In the past 2 weeks, I took my TB medication only when I was sick	49(66.2)			
Control	60(82.2)	17(23.0)	04(5.4)	04(5.4)
Intervention	109(74.1)	10(13.7)	02(2.7)	01(1.4)
Total		27(18.4)	06(4.1)	3.4
In the past 2 weeks, I have stayed on TB medications to prevent it from getting worse*	29(39.2)			09(12.2)
Control	31(42.5)	33(44.6)	03(4.1)	02(2.7)
Intervention	60(40.8)	37(50.7)	03(4.1)	11(7.5)
Total		70(47.6)	06(4.1)	

** The responses to these two scale items were scored to represent 1 for strongly agree, 2 for agree, 3 for disagree, and 4 for strongly disagree. For all other statements, the responses were never for 1, rarely for 2, sometimes for 3, and usually for 4.*

4.4. Level of family support received by TB patients in Jinja

The level of family support for patients undergoing TB treatment was evaluated using two methods: subjective perception of family support and actual availability of family support. The Multidimensional Scale of Perceived Social Support (MSPSS) was used to measure perceived family support, specifically focusing on the family support sub-scale. The scale included eight components, with each component being assigned a number ranging from 1 to 4 (Table 4). The allocation of patients among the various responses to the scale items is comparable between the intervention and control study groups. The proportion of patients in the control group who expressed strong agreement and agreement with the support statements varied from 58.9% to 78.3%, whereas in the experimental group, it ranged from 60.6% to 83.6% (Table 4).

Before implementing the FaCeTB intervention, 68.7% of patients reported a good level of perceived family support. The percentage of patients in the intervention group was 74.0%, which exceeded the percentage of patients in the control group, at 63.5% (Figure 3). Nevertheless, this distinction did not achieve statistical significance.

After the delivery of the FaCeTB intervention, the overall level of high perceived family support among patients increased from 68.7% to 74.8%. The level achieved among intervention patients indicated an increase higher (by 8.1%) than the 3.2% increment observed among patients in the control arm (**Figure 4**).

Table 4. Patients' scores on the perceived family support scale before the intervention

Family support statements	Patients' scores, n (%)			
	4	3	2	1
In the past 2 weeks, there has been a special person who is around when I am in need.				
Control	25(33.8)	31(41.9)	14(18.9)	04(5.4)
Intervention	21(28.8)	33(31.8)	11(15.1)	08(6.0)
Total	46(31.3)	64(43.5)	25(17.0)	12(8.2)
In the past 2 weeks, there has been a special person with whom I can share my sorrows				
Control	29(39.2)	20(27.0)	20(23.3)	05(6.8)
Intervention	30(41.1)	23(31.5)	17(23.3)	03(4.1)
Total	59(40.1)	43(29.3)	37(25.2)	08(5.4)
In the past 2 weeks, my family has really tried to help me				
Control	27(36.5)	26(35.1)	17(23.0)	04(5.4)
Intervention	35(47.9)	18(24.7)	18(24.7)	02(2.7)
Total	62(42.2)	44(29.0)	35(23.8)	06(4.1)
In the past 2 weeks, I have got the help I needed from someone in my family				
Control				
Intervention	26(35.1)	32(43.2)	13(17.6)	03(4.1)
Total	29(39.7)	31(42.5)	11(15.1)	02(2.7)
	55(37.1)	63(42.9)	24(16.3)	05(3.4)
In the past 2 weeks, I have had a special person who is a real source of comfort to me				
Control	31(41.9)	24(32.4)	14(18.9)	05(6.8)
Intervention	26(35.6)	30(41.1)	13(17.8)	04(5.5)
Total	57(38.8)	54(36.7)	27(18.4)	09(6.1)
In the past 2 weeks, I have been able to talk about my problems with someone in my family				
Control	29(39.2)	22(29.7)	18(24.3)	05(6.8)
Intervention	28(38.4)	32(43.8)	08(11.0)	05(6.8)
Total	57(38.8)	54(36.7)	26(17.7)	10(6.8)
There is a special person in my life who cares about my feelings				
Control	29(39.2)	27(36.5)	15(20.3)	03(4.1)
Intervention	31(42.5)	30(41.1)	07(9.6)	05(6.8)
Total	60(40.8)	57(38.8)	22(15.0)	08(5.4)
In the past 2 weeks, there has been someone in my family willing to help me make decisions				
Control	28(37.8)	19(25.7)	17(23.0)	10(13.5)
Intervention	28(38.4)	24(32.9)	14(19.2)	07(9.6)
Total	56(38.1)	43(29.3)	31(21.1)	17(11.5)

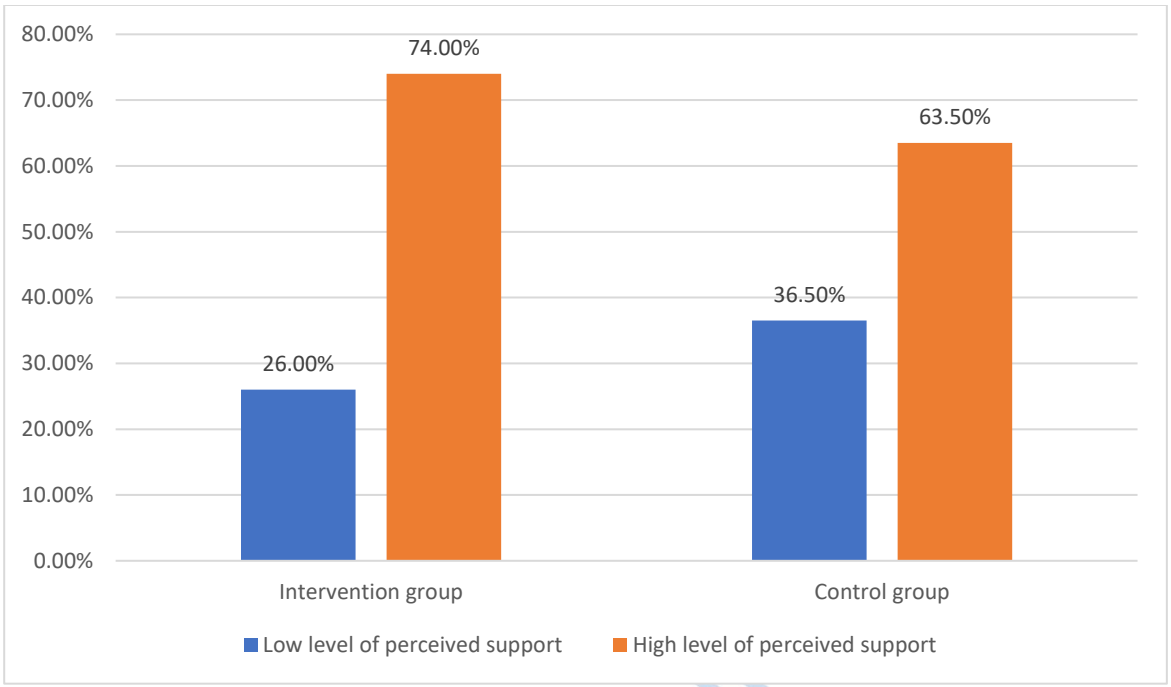

Figure 3. Level of participants' perceived family support before the intervention

Patients who scored 8-21 points on the MSPSS were categorized as having low perceived family support, and those who scored 22-32 were categorized as having high perceived family support.

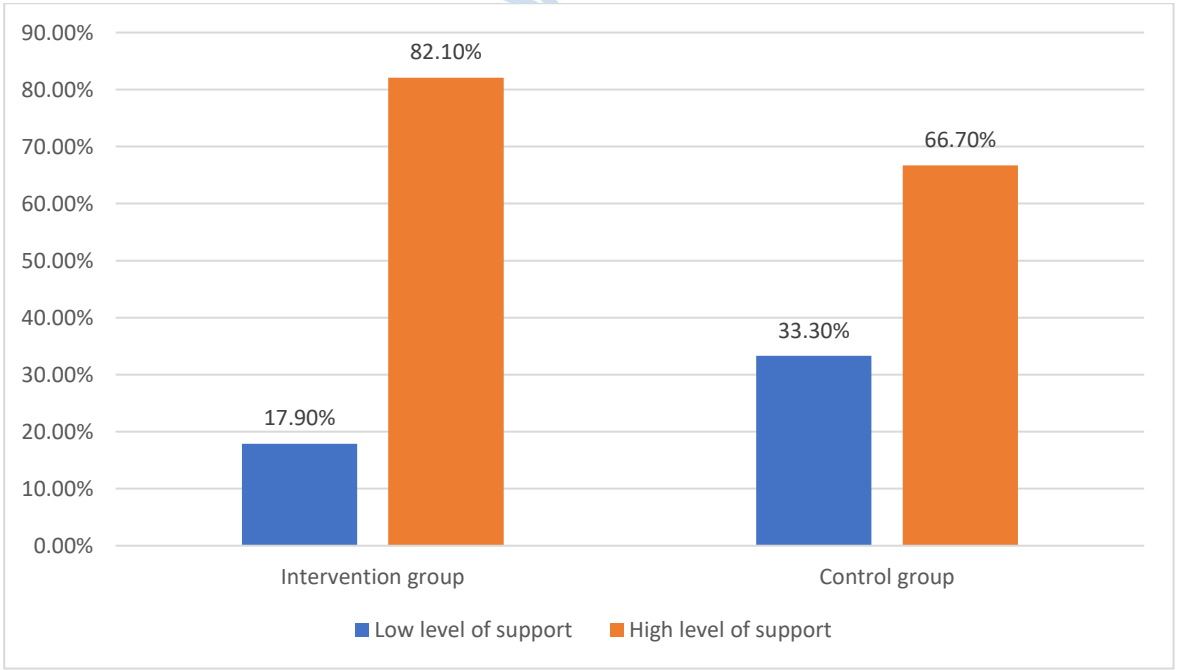

Figure 4. Level of participants' perceived family support* after the FaCeTB intervention

**Patients who scored 8-21 points on the MSPSS were categorized as having low perceived family support, and those who scored 22-32 were categorized as having high perceived family support.*

Regarding the current level of actual family support received by patients, the study revealed that family members assist in reminding patients to take their prescriptions, offering tangible assistance, promoting medication adherence, and aiding patients in obtaining medication refills. The most prevalent kind of assistance obtained by patients was medication reminders, with percentages of 65.3% and 70.9% before and after the intervention, respectively. Following the intervention, there was a notable improvement in all types of support provided to the patients, except assistance with medicine refills. Control arm participants had a contrasting trend, as all types of support, except medicine refills, declined (Table 5).

Table 5. Availability of different forms of family support among TB patients before and after the FaCeTB intervention

Categories of support	Intervention	Control	Totals
Medication reminders			
Pre-intervention	67.1%	63.5%	65.3%
Post-intervention	80.6%	60.0%	70.9%
Emotional support			
Pre-intervention	28.8%	25.7%	27.2%
Post-intervention	43.3%	16.7%	30.7%
Encouragement			
Pre-intervention	52.1%	44.6%	48.3%
Post-intervention	70.1%	41.7%	56.7%
Helping with medication refills			
Pre-intervention	31.5%	12.2%	21.8%
Post-intervention	23.9%	13.3%	18.9%
Material support*			
Pre-intervention	50.7%	60.8%	55.8%
Post-intervention	64.2%	28.3%	47.2%

*In this table, the number of patients in the intervention arm was 73 and 67 before and after the intervention, respectively. In the control arm, it was 74 and 60 patients before and after the intervention, respectively. *The forms of material support included food, money, and support with activities of daily living.*

4.5. Effectiveness of the FaCeTB intervention on improving TB treatment adherence among patients in Jinja

After implementing the FaCeTB intervention, there was a 9.5% increase in the proportion of patients who demonstrated high levels of adherence (from 65.3% to 74.8%). The median adherence score was 10(IQR=6) before the intervention and 7(IQR=6) after the intervention (Table 7). The intervention group experienced a notable enhancement, with a 19.8% rise in the percentage of patients categorized as highly adherent. Before the intervention, the percentage of patients in this group who had high adherence was 71.2%, which increased to 91.0% following the intervention. On the other hand, the control group observed a reduction in the proportion of patients with high adherence, declining by 2.8% from 59.5% before the intervention to 56.7% afterward (Figure 5). The post-intervention outcomes of the two study groups differed by 22.6% (19.8% + 2.8%), with the intervention group demonstrating better median scores 6(IQR=1) than the control group 11(IQR=6), as shown in Table 7.

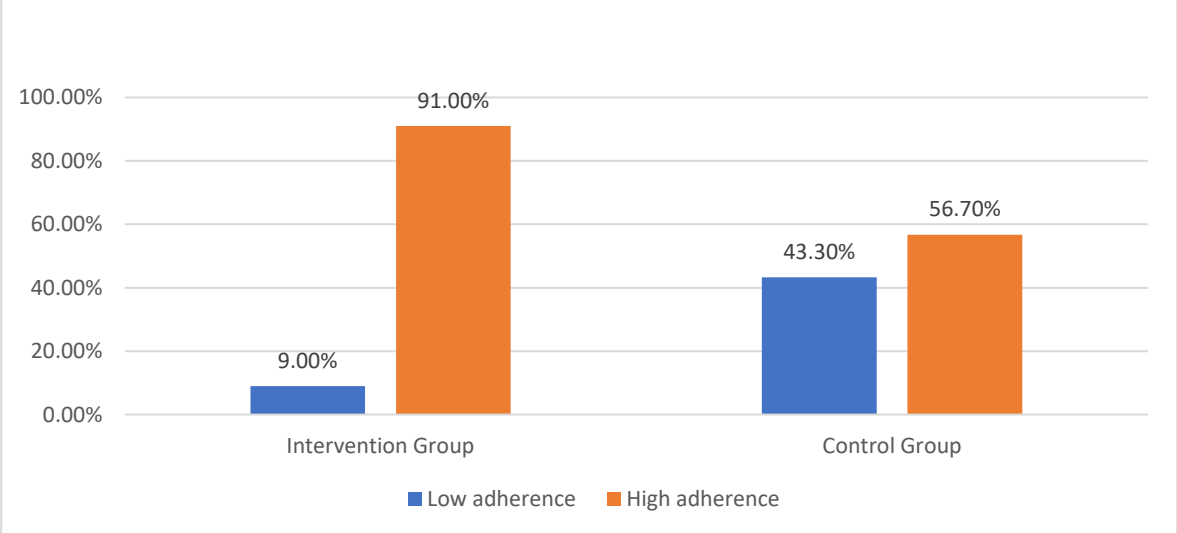

Figure 5. The proportion of patients with high and low TB treatment adherence after the FaCeTB intervention

The intervention group had a higher percentage of patients (ranging from 71.6% to 92.5%) who scored 1 on the adherence scale items, indicating a high level of adherence. In comparison, the control group had a lower range of percentages (ranging from 31.7% to 55.0%) on the same scale (Table 6).

Table 6. Participants' responses on the adherence rating scale before the intervention

Adherence scale items	Patient scores, n (%)			
	1	2	3	4
In the past 2 weeks, I have forgotten to take my TB medication				
Control	33(55.0)	20(33.3)	07(11.7)	00(0.0)
Intervention	62(92.5)	04(6.0)	01(1.5)	00(0.0)
Total	95(74.5)	24(19.0)	8(6.5)	00(0.0)
In the past 2 weeks, taking TB medication has been an important part of my daily activities*				
Control	19(31.7)	34(56.7)	07(11.7)	00(0.0)
Intervention	48(71.6)	14(20.9)	05(7.5)	00(0.0)
Total	67(52.8)	48(37.8)	12(9.4)	00(0.0)
In the past 2 weeks, when I felt better, I stopped taking my TB medication				
Control	27(45.0)	14(23.3)	17(28.3)	02(3.3)
Intervention	58(86.6)	05(7.5)	03(4.5)	01(1.5)
Total	85(66.9)	19(15.0)	20(15.7)	03(2.4)
In the past 2 weeks, when I felt worse while taking the TB medication, I stopped taking it				
Control	29(48.3)	19(31.7)	12(20.0)	00(0.0)
Intervention	55(82.1)	07(10.4)	04(6.0)	01(1.5)
Total	84(66.1)	26(20.5)	16(12.6)	01(0.8)
In the past 2 weeks, I took my TB medication only when I was sick				
Control	33(55.0)	19(31.7)	08(13.3)	00(0.0)
Intervention	58(86.6)	07(10.4)	02(3.0)	00(0.0)
Total	91(71.7)	26(20.5)	10(7.8)	00(0.0)
In the past 2 weeks, I have stayed on TB medications to prevent it from getting worse*				
Control	26(43.3)	29(48.3)	04(6.7)	01(1.5)
Intervention	56(83.6)	09(13.4)	01(1.5)	01(1.5)
Total	82(64.6)	38(30.0)	5(3.9)	2(1.5)

**The responses to these two scale items were scored to represent 1 for strongly agree, 2 for agree, 3 for disagree, and 4 for strongly disagree. For all other statements, the responses were never for 1, rarely for 2, sometimes for 3, and usually for 4.*

Table 7. Comparison of adherence level by study arm and study time point

Study arm	Time point	n	Median scores (IQR)	High adherence n (%)	Low adherence n (%)
Control	Pre-intervention	74	9.00(6.00)	44(59.5)	30(40.5)
	Post-intervention	60	11.00(6.00)	34(56.7)	26(43.3)
Intervention	Pre-intervention	73	10.00(5.00)	52(71.2)	21(28.8)
	Post-intervention	67	6.00(1.00)	61(91.0)	06(9.0)
Total	Pre-intervention	147	10.00(6.00)	96(65.3)	51(34.7)
	Post-intervention	127	7.00(6.00)	95(74.8)	32(25.2)

Before the intervention, a Mann-Whitney U test showed no significant difference in adherence scores between the intervention and control groups (p=0.592). However, after the intervention, a significant difference in adherence scores was observed between the two study arms (p=0.000) with a moderate to large effect (r=0.474), as shown in Table 8. The null hypothesis was supported by the adherence scores before the intervention but was rejected after the intervention.

Table 8. Mann-Whitney U test comparing the adherence scores between the intervention and control study arms both before and after the intervention

Study Arm	n	Median (IQR)	U-statistic	Z-score	p-value	Effect size (r)
Before intervention						
Control	74	10.00(6.00)	2563.50	-0.536	0.592	0.044
Intervention	73					
After intervention						
Control	60	7.00(6.00)	936.50	-5.344	0.000	0.474
Intervention	67					

**The average post-intervention difference in adherence score (2.95 points) between the intervention and control study arms was statistically significant.*

A Wilcoxon Rank-Signed test revealed a change in adherence scores from pre-intervention (Median = 10) to post-intervention (Median = 7), p=0.000, indicating that the change within

each study group was statistically significant (Table 9). The results indicate that the intervention had a significant effect on adherence in the intervention group.

Table 9. Wilcoxon Signed-Rank test results for adherence before and after the FaCeTB intervention

Measure	Median (IQR*)	Z-score	p-value	Effect size (r)
Overall				
Pre-intervention	10.00(6.00)			
Post-intervention	7.00(6.00)	-4.51	0.000	**0.40**
Control arm				
Pre-intervention	9.00(5.75)			
Post-intervention	11.00(6.00)	-0.623	0.533	0.051
Intervention arm				
Pre-intervention	10.00(5.00)			
Post-intervention	6.00(1.00)	-4.72	0.000	0.419

*Interquartile range

4.6. Discussion of results

This study evaluated the effectiveness of a family-centered support intervention in enhancing adherence to tuberculosis (TB) treatment among patients at Jinja TB treatment centers using a quasi-experimental approach. Adherence levels were assessed in both the intervention and control study groups before and after the intervention. Furthermore, the study examined perceived and actual support provided by family members to TB patients. The socio-demographic characteristics of patients were similar between the intervention and control groups.

4.6.1. Level of treatment adherence before the FaCeTB intervention

Before the intervention was put into effect, it was found that 65.3% of patients showed high levels of adherence, while 34.7% had poor adherence to their tuberculosis therapy. Insufficient adherence to treatment raises concerns of treatment failure, development of

drug-resistant tuberculosis (DR-TB), and extending the period during which patients can spread TB to others.

The levels of adherence observed in this study are similar to those reported in Eastern Uganda by Wanyama (Wanyama, 2017) and in China by Xu and colleagues (Xu et al., 2017), emphasizing the need for adherence improvement in our specific context. Despite the passage of over 7 years, the current levels of adherence should have been greater in comparison to earlier studies. This indicates a deficiency or inadequate implementation of attempts to promote better medication usage, highlighting the need to explore creative strategies to achieve optimal adherence to TB therapy.

The current study demonstrates a notable disparity in adherence levels when compared to regional studies. The study conducted by Mekonnen and Azagew (2018) reveals that 53% of individuals in Ethiopia who previously struggled to comply with their treatment are now successfully adherent. This can be attributed to the fact that individuals who have previously failed to adhere to their treatments are more prone to receiving a prolonged course of treatment for tuberculosis (TB). The study conducted by Xu et al. (2017) indicated that a longer duration of treatment is linked to insufficient adherence to the treatment plan.

Based on our investigation, the level of compliance was lower compared to the rates reported in Ethiopia (96.6% Gebremariam et al., 2021), Kosovo (85.5%, according to Krasniqi et al., 2017), and Ghana (81.1%, according to Dogah et al., 2021). The large disparity can likely be attributed to deploying more effective approaches in these nations to raise adherence. Furthermore, the variations in the locations where the studies were conducted and the characteristics of the patients, which have been proven to be separate factors that can predict

outcomes, according to Iweama et al. (2021), might account for the diversity in the degrees of adherence to tuberculosis treatment.

Upon comparing the adherence levels across the two study arms, it was found that the intervention group exhibited a greater initial adherence level compared to the control arm, indicating that a higher proportion of patients in the intervention group adhered to their tuberculosis therapy.

The results of Tola et al. (2016) oppose this outcome, as their research cohorts displayed a discrepancy of only 0.2%. The two research studies' differences indicate variations induced by different study approaches. Because the current trial lacks random assignment, there is a potential for an imbalanced distribution of several predictors of TB treatment adherence between the two groups. The disparity in distribution may have played a role in the variations found in the first levels of adherence.

4.6.2. Level of family support during TB care

The effectiveness of the family-centered support intervention, which promotes adherence, is greatly enhanced by the involvement of family members. Before the intervention, 68.7% of the patients indicated receiving substantial support from their relatives. There is a noticeable difference between the level of help patients receive and their expectations, as indicated by the fact that 31.3% of patients have reported receiving inadequate assistance. This tendency has been proven in previous investigations (Theofilou, 2023).

Family members must possess a thorough understanding of the patient's needs and the most efficient strategies to help the patient overcome obstacles that hinder their adherence to the treatment plan. The perceived support level in this study surpasses the reported levels of perceived support in Indonesia (62.8%, Nursasi et al., 2022) and India (49.7%, Nadon et al.,

2023). The discrepancy may be attributed to variations in the evaluation scales employed to measure family support, as well as disparities in the specific needs of each patient and their distinct sociocultural attributes.

The present study has confirmed that when family participation is directed and organized, it leads to a rise in the reported level of family support perceived by patients. Patients in the intervention group had a more substantial increase compared to those in the control group. Theofilou (2023) states that patients can receive assistance from their families in various ways, highlighting their multifaceted role as a source of support. Throughout the current study, it was vital for the family to provide patients with reminders to ensure they followed the specified prescription schedule.

Medication adherence is of utmost significance for patients, particularly during the maintenance period of therapy, when they may experience few symptoms and numerous commitments. A study conducted in Eastern Uganda found that some family members were in charge of overseeing the administration of TB drugs (Wanyama, 2017). In regards to the current study, family members were able to engage in activities that extend beyond the supervision of medication to roles such as assisting with medication refills and providing encouragement and emotional support.

The diverse range of support services available suggests that family caregivers possess a comprehensive grasp of the many needs of patients, enabling them to facilitate optimal adherence to treatment. Additional research has shown comparable findings, including the use of medication reminders, emotional support, and motivation, the provision of nutritional and material resources (Chiang et al., 2023; Nyasulu et al., 2018), and assistance to patients in obtaining their medication from the tuberculosis clinics (Fana & Sotana, 2021).

It is crucial to note that the level of actual support found in the present study is far lower compared to what was uncovered in previous research studies. The study conducted by Nursasi and colleagues (2022) found that 72% of individuals in Indonesia reported receiving satisfactory emotional support, while 68% reported receiving adequate material aid. Despite the implementation of the support intervention in our study, the levels remained incomparable. This could signify inequalities in the extent of family engagement with the healthcare system and the assistance provided to family members. This emphasizes the need for the ongoing participation of families in the management of tuberculosis in Jinja.

For the patient to be adherent to the treatment program, they have to feel capable, well-empowered, and confident to achieve self-management, and it has been found that patients' efficacy can be improved, especially through family support initiatives such as information-sharing, reminders, and encouragement (Putra et al., 2019). It is, therefore, worrying that in our study, the most widely available form of support (medication reminders) was received by only 65.3% of the patients, and yet the levels of the different forms of actual support were highly variable, indicating divergence. Support may therefore not be readily available to some patients, as elaborated by one in five of the patients reporting failure to receive any form of tangible support from their families. Such a support deficiency relates to a high vulnerability to threats of demotivation, social isolation, stigmatization, lack of essential resources, and risk of dropout from the treatment program, and potential for treatment failure. Similar to our findings, a study by Kilima and colleagues (Kilima et al., 2024) demonstrated that regardless of how vital family support can be in TB care, some patients may fail to access it.

The ability of family members in Uganda to offer assistance to patients and promote treatment adherence may be constrained because they undertake treatment support responsibilities without getting adequate guidance and training (C. A. Berger et al., 2020). The current study aimed to engage family members and enhance their ability to support patients in adhering to TB treatment. The intervention resulted in a notable enhancement in the availability of different types of assistance to patients in the intervention group, but no such increase was detected in the control group. This implies that when healthcare workers intentionally involve families, it has a positive effect on the availability of both perceived and actual support during TB care.

4.6.3. Effectiveness of the FaCeTB intervention in improving TB treatment adherence among patients in Jinja

After implementing the FaCeTB intervention, there was a noticeable improvement in the average adherence ratings, as well as an increase in the percentage of patients who showed high levels of adherence. The observed change in the intervention arm can largely be attributed to the family support intervention. With this kind of support, patients can attain optimal levels of adherence.

The findings documented in central Uganda by Hassard and colleagues (Hassard et al., 2017) and in Western Kenya (Chebet et al., 2022) are similar to the general level of adherence seen following the intervention in our study. However, the percentage of patients in the intervention group who exhibited high levels of adherence was more than what was observed in these specific conditions, further highlighting the role of our intervention.

The findings of further research conducted in Ethiopia (Tola et al., 2017) and Kosovo (Krasniqi et al., 2017) also indicated decreased levels of adherence when compared to the

intervention group. The discrepancy can be attributed to the focused and family-centered involvement in the current study investigation. This engagement facilitated the patient and their family in fostering compliance with TB treatment, which played a crucial role in the investigation.

In terms of family engagement, a comparable intervention aimed at enhancing treatment adherence (Khachadourian et al., 2020b) achieved a 100% rate, surpassing the level observed in the present scientific study. This may be indicative of the difference in methodologies employed to implement the intervention. In contrast to the study conducted in Armenia, the current investigation did not involve any continuous telephone follow-ups.

The contrasting trend seen between the two study groups during the whole tuberculosis treatment process underscores the need to involve and assist family members in order to enhance treatment adherence. Tola et al. (2016) saw a comparable trend in Ethiopia, where they conducted a study and discovered that patients in the control group, who were receiving normal care, had a gradual decline in their level of adherence. This conclusion further emphasizes the necessity of implementing strategies that involve the participation of families to enhance adherence to tuberculosis treatment.

The distribution of adherence scores demonstrated that better scores were obtained after the intervention and that the intervention study group had relatively better scores than the control group after the intervention. Based on these findings, a study conducted in Indonesia by Parwati and colleagues demonstrated similar assertions that implementing an intervention can greatly improve adherence to tuberculosis treatment (Parwati et al., 2021). The intervention resulted in a shift in adherence scores, which can be attributed to the inclusion of family members as a source of support to patients.

The FaCeTB intervention, which aimed to improve adherence to tuberculosis treatment, relied on the active involvement of family members to provide a supportive environment for the patient. This participation played a crucial role in the intervention's success. Consequently, timely reminders, motivational words, and emotional assistance were given. Prior research has established that the presence of support is linked to several factors, such as improved treatment adherence (Shahin et al., 2021) and the adoption of self-care practices by patients (Hasan et al., 2024). A well-packaged family support intervention can have a substantial contribution toward achieving optimal levels of adherence to tuberculosis treatment, similar to those observed in other regions. Therefore, it is an essential approach for increasing the number of individuals in Uganda who adhere to their treatment as the country strives to end the TB epidemic by 2035.

CHAPTER FIVE

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

5.1. Introduction

Tuberculosis, an infectious illness, has caused significant morbidity and mortality in Uganda. The implementation of antibiotic therapy has played a vital role in mitigating the adverse effects of tuberculosis. Nonetheless, inadequate adherence to therapy is causing treatment failure, thus leading to the heightened transmission of TB throughout the population. The primary objective of this research study was to enhance the levels of adherence to tuberculosis therapy among patients in Jinja. To accomplish this, a tuberculosis (TB) support intervention that specifically targeted engaging the family as a supportive network for patients was implemented. The study determined the initial level of treatment adherence and family support among patients and then assessed the two parameters later after implementing the intervention. This section will provide a concise summary of the study's findings, which will serve as the foundation for drawing conclusions and providing recommendations for practical implementation, education, policy development, and research.

5.2. Summary of the study findings

The first objective of this study was to assess the level of TB treatment adherence among patients before the implementation of a family-centered TB (FaCeTB) support intervention at treatment centers in Jinja, Eastern Uganda. It was found that 65.3% of tuberculosis patients had a high level of adherence to their TB treatment, and 34.7% had a low adherence level.

There was a disparity in the percentage of adherent patients between the intervention (71.2%) and control (59.5%) study arms; nevertheless, the observed difference did not reach the threshold for statistical significance.

The second objective was to determine the level of family support received by TB patients at treatment centers in Jinja, Eastern Uganda. To achieve this objective, both perceived and actual family support were assessed. Two-thirds (68.7%) of patients reported having a high level of perceived support from their families, and 31.3% reported a low level of perceived support. Regarding actual family support, family members played a vital role in reminding patients to take their medication, providing emotional support and encouragement, providing material support, and assisting patients to refill their medications.

The third objective was to evaluate the effectiveness of the FaCeTB support intervention in improving treatment adherence among patients at treatment centers in Jinja, Eastern Uganda. to achieve this, we compared the proportions of patients with high and low adherence levels before and after the intervention as well as the distribution of adherence scores between and within the study arms both before and after the intervention. After the intervention was implemented, the overall proportion of patients with high adherence levels increased from 65.3% to 74.8%. The intervention group exhibited a significant increase from 71.2% to 91.0%, while the control group had a slight decrease from 59.5% to 56.7%. Overall, the adherence level significantly improved after the intervention, with the median scores reducing from 10.00 before the intervention to 7.00 after the intervention (p=0.000). The intervention arm obtained better adherence scores than patients in the control arm, and the difference was statistically significant. The intervention achieved a medium-to-large effect

size (0.419 to 0.474), suggesting a substantial difference in adherence scores pre- and post-intervention.

5.3. Conclusions

Based on the results presented above, it can be concluded that the adherence level to tuberculosis treatment in this study is low when compared to other countries. The patients who are receiving treatment at tuberculosis treatment centers in the Jinja District have diverse levels of adherence at various time points, requiring that a continuous and individualized approach to promoting compliance be adopted for each patient.

Family members in Jinja are a crucial source of support that may be accessed in multiple dimensions, which is essential for appropriate adherence to tuberculosis treatment. Through consistent participation in educational sessions with the patient and the family supporter, providing TB information, and formally delegating roles from the healthcare providers to family members, it is possible to enhance both the perceived and actual levels of support to the patient.

An intervention engaging the patient's family in TB treatment can significantly improve the patient's adherence to their tuberculosis medicine. If appropriate supportive measures are not provided, patients' adherence levels may decrease to sub-optimal levels, as demonstrated among the patients in the control group.

5.4. Recommendations for practice

The tuberculosis treatment adherence level in Jinja is sub-optimally low and exhibits temporal variations. It is necessary for treatment institutions to regularly conduct ongoing adherence assessments to accurately evaluate the updated levels of adherence. Family

involvement in tuberculosis care can greatly improve TB treatment adherence. To promote adherence to tuberculosis treatment, treatment clinics must involve family members in the care of patients. Patients should be required to bring their family members to instructional seminars on tuberculosis and its treatment as routine practice. In addition, healthcare personnel must receive training on adherence to ensure that patients are fully informed about the complex nature of the necessary patient assistance.

5.5. Recommendations to the authorities for implementation

Leaders at the level of health facilities and the Ministry of Health should create a policy framework and guidelines to promote family involvement and support the implementation of family-centered care in tuberculosis treatment. Because it ensures a standardized implementation approach, this phase is highly significant. The hospital management must identify local characteristics that could either facilitate or impede the implementation process and reveal these facts.

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APPENDICES

Appendix I: Consent form

Title of study

Effectiveness of a Family-Centered Support Intervention on Treatment Adherence Among TB Patients in Jinja, Eastern Uganda.

Principal Investigator

Businge Alinaitwe. Contacts. +256 789703890, +254 715859939

Objective of the study

The study aims to evaluate the effect of implementing a family-centered approach in improving adherence to TB treatment.

Procedures

This survey aims to inquire about many aspects of your own identity, overall well-being, and the manner in which you are utilizing the tuberculosis treatment. The study is assessing a patient support method that has the potential to facilitate the appropriate utilization of drugs. Patients will be classified into two categories: the experimental arm and the comparison arm. Participants in the control group will get an initial assessment at the start of the trial, followed by receiving their regular care, and finally, they will be evaluated again after a two-week period. Patients in the experimental group will receive additional support from one or more family members after interacting with the study team, in addition to their regular care. Following a two-week period of supportive involvement, individuals in this group will have a further assessment regarding their medication usage.

Confidentiality

The study team will employ all requisite measures to guarantee the confidentiality of the information you supply. The questionnaire in which you will enter your responses will only be linked to a unique identifier and will not contain any personal information. All paper documents containing personal information will be stored in a secure area and will only be accessible to the research team for the purpose of conducting research.

Voluntary participation

Participating in this study is voluntary and entirely up to you. If you choose not to participate, there will be no repercussions involved. You possess the entitlement to withdraw from the study at any point if you are unwilling to continue participating, without the need to provide any justification to the research team. The type and level of care you are entitled to at this health facility will remain unaffected by your decision.

Discomfort

You will not experience any form of discomfort while taking part in this research and the study will not interfere with your daily routines.

Risks

Your participation in this research does not expose you to any risks. However, when you feel that you are at any risk, immediately inform the research team.

Costs and compensation for participation

Taking part in this study is not associated with any expenses and costs of any nature. There will be no any kind of reimbursement given to you. Any family caregiver who incurs transport expenses related to study procedures will be reimbursed.

Benefits

Participating in this research will assist us in developing a potentially efficacious strategy for enhancing adherence to TB drugs, a crucial step in eradicating the TB epidemic and promoting overall well-being. If you are part of the research group that will be provided assistance from an empowered caregiver, the team will educate you and your family caregiver on the most effective methods to maintain your well-being and properly handle your prescriptions. In addition, we will provide you and your family with an informational pamphlet on tuberculosis and its treatment, which you can refer to at your convenience.

Consenting statement

As a participant in this study, I have thoroughly reviewed the information in this consent form either by reading it myself or having someone read it to me. I acknowledge that my participation in this research is entirely voluntary. The information I provide will be kept confidential and my response will remain anonymous. I reserve the right to discontinue my involvement at any given moment. Voluntarily and unreservedly, I consent to participate in this research without any form of compulsion.

Participant's signature……. Date: dd……mm……yy……..

Researcher's statement

I……..., as the person taking part in the consenting of this participant have provided a comprehensive explanation of the information regarding this research study to the above individual. I am confident that the person has understood the details and has willingly agreed to take part in this research without any coercion.

Researcher's signature……. Date: dd……mm……yy……..

Role in the study……

Appendix II: Questionnaire

STUDY TITLE: Effectiveness of a Family-Centered Support Intervention on Treatment Adherence Among TB Patients in Jinja, Uganda	
BASELINE (PRE-INTERVENTION) ASSESSMENT	
Today's Date	dd…….mm…….yy……
Participant Identifier (PID)	……..
Preferred Language	a. English b. Lusoga
QUESTIONS	**RESPONSES**
SECTION B: SOCIO-DEMOGRAPHY (Ask the patient)	
In which district do you reside?	……
Distance category from home to health facility	a. <=50km b. >50km
How old are you?	……
Marital status	a. Single b. Married
What is your identity in terms of gender	a. Male b. Female
Level of formal schooling	a. No formal schooling b. Completed primary c. Completed high school d. Completed Tertiary

What do you do for a living?	a. Un-employed b. Peasant c. Business d. Skilled technical worker e. Professional worker
How many people live in your household?	…….....
When you are unwell, who usually supports you during your recovery?	a. Spouse b. Child/children c. Sibling d. Friends e. Workmate/employer
In the past two weeks, in what ways has your family helped you? (Select all that apply)	a. No way b. Reminding me to take medicines c. Helping refill prescriptions d. Emotional support e. Encouragement f. TB Information support g. Material support h. Other
If Other, specify	……
In the past 2 weeks, what challenges and fears have you faced while receiving help from your family member(s)? (If a, in Qn.10, skip this question)	a. Stigmatization b. They are always busy c. Caregiver didn't know what to do d. Poor attitude e. Other
If Other, specify	……

LEVEL OF TB TREATMENT ADHERENCE

"Many people find a way of using their TB medication that suits them. This way may differ from the instructions on the label or from what their doctor had said for certain reasons. Here are some statements that people say regarding the use of their TB medication. Please tell me how you have been taking your medication. There are four responses to each of the statements. I will give you the responses and you choose the one that best describes how you've taking your TB medication in the past 2 weeks.

Item	*Never*	*Rarely*	*Sometimes*	*Usually*

In the past 2 weeks, I have forgotten to take my TB medication	*Never*	*Rarely*	*Sometimes*	*Usually*
In the past 2 weeks, taking TB medication has been an important part of my daily activities	*Strongly agree*	*Agree*	*Disagree*	*Strongly disagree*
In the past 2 weeks, when I felt better, I stopped taking my TB medication	*Never*	*Rarely*	*Sometimes*	*Usually*
In the past 2 weeks, when I felt, worse while taking the TB medication, I stopped taking it	*Never*	*Rarely*	*Sometimes*	*Usually*
In the past 2 weeks, I have taken my TB medication only when I felt sick	*Never*	*Rarely*	*Sometimes*	*Usually*
In the past 2 weeks, I have stayed on my TB medication to prevent getting worse	*Strongly agree*	*Agree*	*Disagree*	*Strongly disagree*

LEVEL OF FAMILY SUPPORT

When we are unwell, there are some things we cannot do on our own and sometimes we need a shoulder to lean on. Even taking medication as advised might be challenging without support. Each statement I am going to say below is related to the support you have received from your family. There are four responses to each of the statements. I will give you the responses and you choose the one that best describes how your family people have helped you in the past 2 weeks.

Statements	*Strongly disagree*	*Disagree*	*Agree*	*Strongly agree*
In the past 2 weeks, I have had a special person who is around when I am in need.				
In the past 2 weeks, I have had a special person with whom I can share my sorrows.				
In the past 2 weeks, someone in my family has really tried to help me				
In the past 2 weeks, I have got the help I need from someone in my family.				

In the past 2 weeks, I have had a special person who is a real source of comfort to me.				
In the past 2 weeks, I could talk about my problems with someone in my family				
In the past 2 weeks, there has been a special person in my life who cares about my feelings.				
In the past 2 weeks, there has been someone in my family willing to help me make decisions				

Appendix III: TB Information Brochure

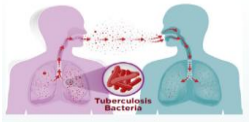
To the Patient and Family Supporter

Tuberculosis disease

Tuberculosis (TB) is a serious disease that can cause a person to become very sick if not treated with medicine.

TB usually affects the lungs, but it sometimes affects other parts of the body such as kidneys and bones

TB germs are spread through air from one person to another and anyone can breathe in the germs to get infected (CDC, 2015)



The TB germs are passed through the air when a person who is sick with TB disease coughs, laughs, sings, or sneezes in the open (CDC, 2015).

REMEMBER;

You cannot get TB germs through;

- Sharing drinking containers or eating utensils
- Saliva shared from kissing
- Shaking someone's hand.
- Sharing food
- Touching bed linens (CDC, 2015)

Tuberculosis medications (CDC, 2015)

Starting medication intake is the single most important way of overcoming TB disease.

The patient will need to take several kinds of pills for at least 6 months according to the care provider's instructions.

Treatment adherence (CDC, 2015)

TB disease can be treated and cured

Always remember that TB germs are very strong and die very slowly.

Even if the patient feels better after a few weeks on the TB medicines, it does not mean all the TB germs are dead.

Treating TB takes several months.

Staying on medicine the way care providers are advising is known as being adherent and is the only way to cure TB.

What happens when medicines are not swallowed well?

If the patient stops taking medicines for TB disease early or does not take them the right way (CDC, 2015);

- It can be harder or not possible to cure TB.
- He/she can become sick again
- He/she can stay sick for a longer time.
- The medicines can stop working, meaning the patient will need to take different medicines that have more side effects.
- The new medicines may not be available or may even be more expensive making the family spend a lot of money.
- Even the new medicines may not work well as the first type of medicine to cure the TB.
- In the end, the patient can pass TB germs on to others.

Like all medicines, the medicine you take to cure TB infection can have side effects. People react differently to medicines and many people take their medicines without any problems.

If the patient thinks think he/she is having any reaction to treatment, call care provider right away.

Some side effects may include (CDC, 2015);

- Dizziness when sitting, standing or lying down.
- Less appetite, or no appetite for food.
- Stomach upset, nausea, or vomiting.
- Pain in your lower chest or heartburn.

- Flu-like symptoms with or without fever.
- Severe tiredness or weakness.
- Fevers or chills.
- Severe diarrhea or light-colored stools (poop).
- Brown, tea-colored, or cola-colored urine.
- Skin or whites appearing yellow.
- Skin rash or itching.
- Bruises, or red and purple spots on your skin that you cannot explain.
- Nosebleeds, or bleeding from your gums or around your teeth.
- Shortness of breath.
- Pain or tingling in your hands, arms and legs.

To You the Patient

Taking medicine each day can be difficult. Remind yourself you are staying on your treatment plan to kill all the TB germs.

Remember that you have done other tough things in your life and you can do this too (CDC, 2015)!

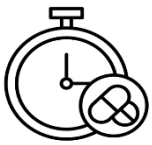
- Take your medicine as your doctor says.
- You must complete the treatment unless your doctor tells you to stop taking the medication.
- Always follow your care provider's instructions. Ask questions if you don't understand.

In a few weeks of treatment for TB disease, you will need to (CDC, 2015)*;*

- Put all tissues in a trash bag. Close the bag until you can throw it away.
- Keep windows open in your home, if possible, until your doctor says you cannot pass TB germs to others.
- Your doctor may ask you to wear a special mask at home, so you don't put TB germs into the air.
- If you are not wearing a mask, you should cover your mouth and nose with a tissue when you cough, laugh, or sneeze.

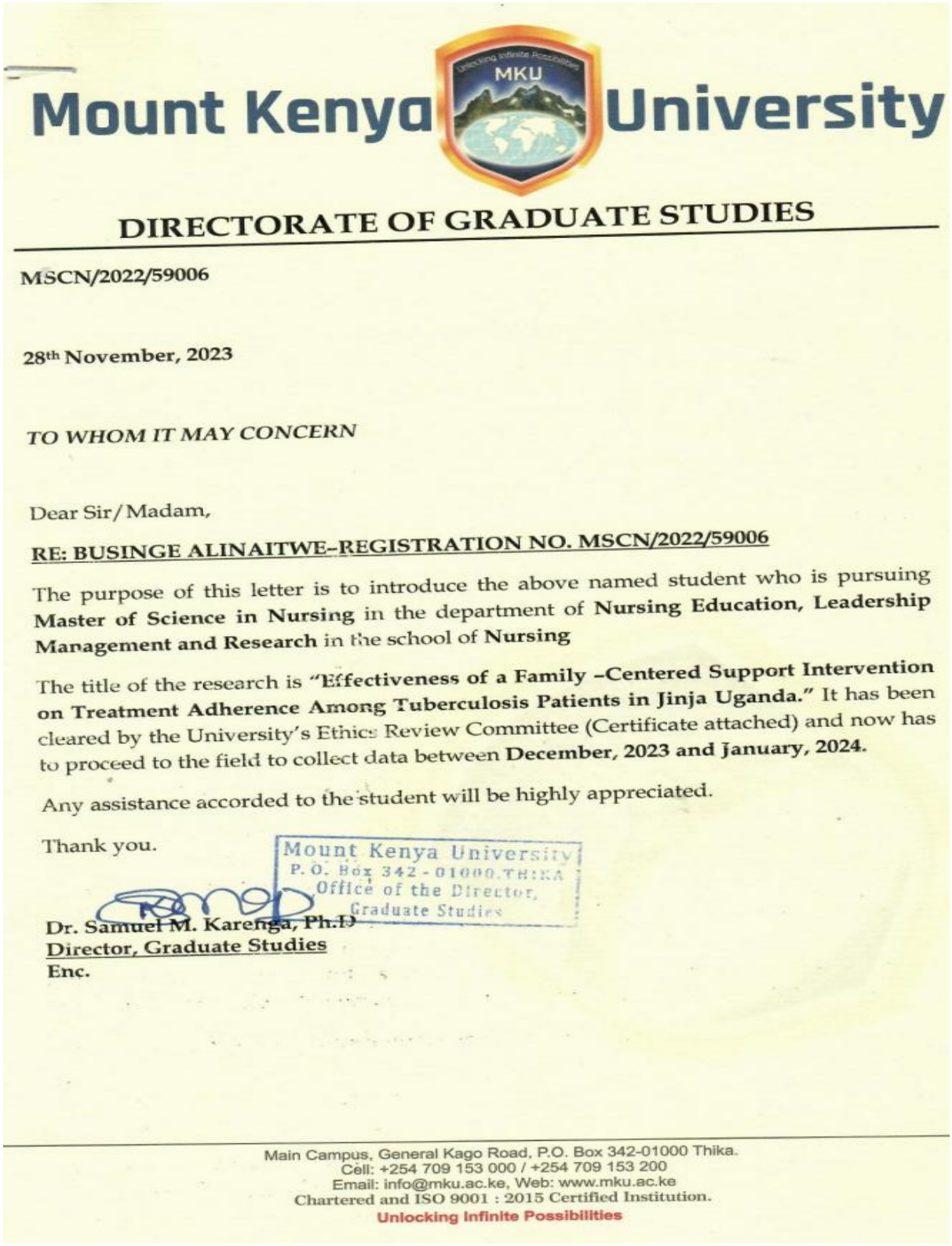
To you the family treatment supporter (CDC, 2015)

Most patients fail to take their medicines well because they are not well supported by people around them. Others forget, have difficulty accessing medicines, have side effects or feel too weak.
Remember; improper taking of TB medicines can affect the rest of the family.
Your role as the family member is to;



- Ensure the patient takes the medicine at the same time every day.
- Reminding the patient to take their medicines
- Keeping the medicines in a place where the patient will readily access it
- Reminding the patient to go for their medication refills and any other appointment with the care provider.
- Assisting the patient in refilling their medicines.
- Providing the patient with encouragement.
- Helping him/her with any other chores when he feels weak to perform them.
- Reporting side effects to the primary care providers and helping the patient fetch adjunct drugs for side effects.
- Avoid any form of stigmatization and discrimination of the patient
- Some people do not understand how TB is spread or how it is treated. It may be helpful to share these facts about TB with your family.

Appendix IV: Graduate Studies Introduction Letter



Mount Kenya University

DIRECTORATE OF GRADUATE STUDIES

MSCN/2022/59006

28th November, 2023

TO WHOM IT MAY CONCERN

Dear Sir/Madam,

RE: BUSINGE ALINAITWE–REGISTRATION NO. MSCN/2022/59006

The purpose of this letter is to introduce the above named student who is pursuing **Master of Science in Nursing** in the department of **Nursing Education, Leadership Management and Research** in the school of **Nursing**

The title of the research is **"Effectiveness of a Family –Centered Support Intervention on Treatment Adherence Among Tuberculosis Patients in Jinja Uganda."** It has been cleared by the University's Ethics Review Committee (Certificate attached) and now has to proceed to the field to collect data between **December, 2023 and January, 2024.**

Any assistance accorded to the student will be highly appreciated.

Thank you.

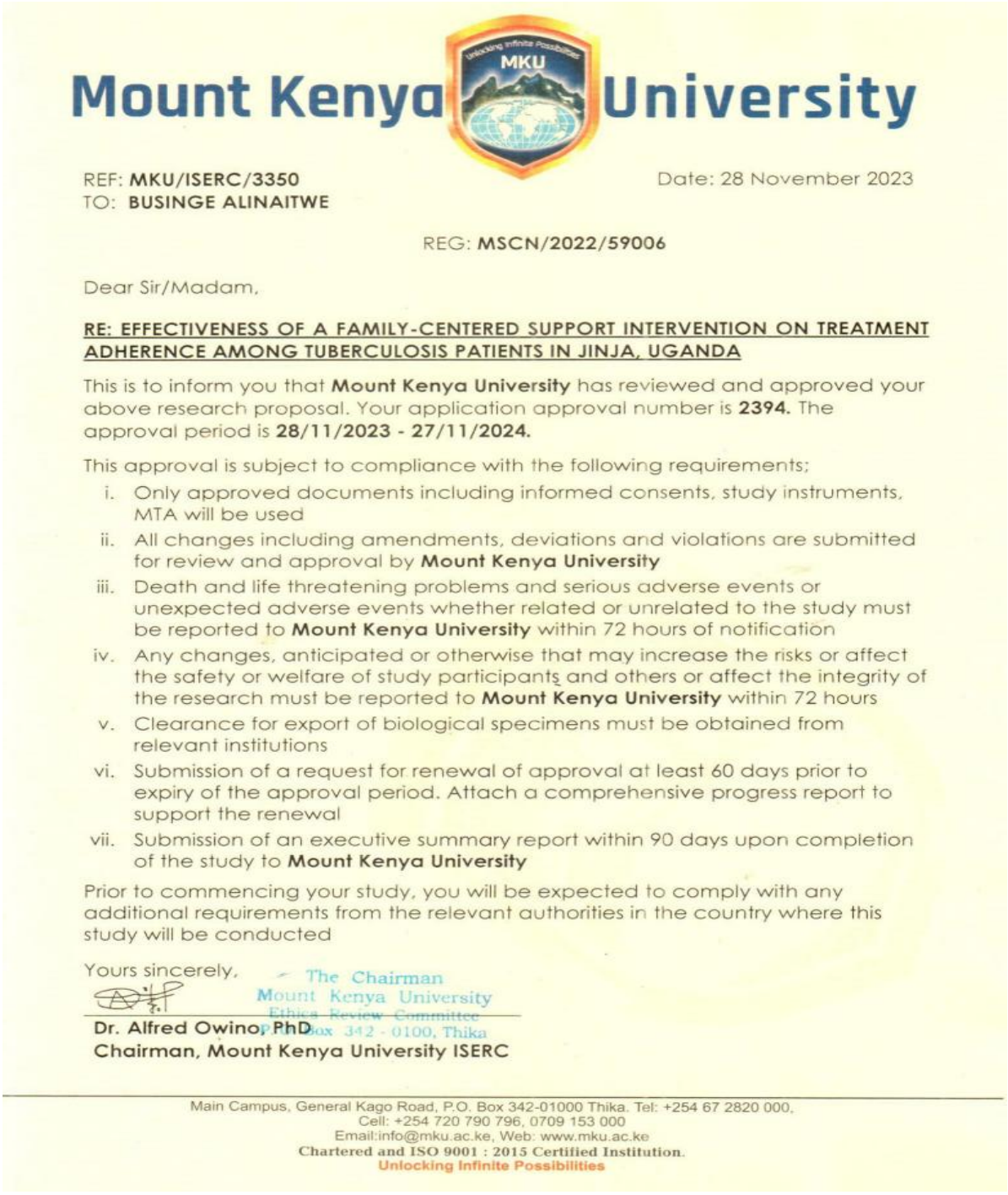
Mount Kenya University
P. O. Box 342 - 01000 THIKA
Office of the Director,
Graduate Studies

Dr. Samuel M. Karenga, Ph.D
Director, Graduate Studies
Enc.

Main Campus, General Kago Road, P.O. Box 342-01000 Thika.
Cell: +254 709 153 000 / +254 709 153 200
Email: info@mku.ac.ke, Web: www.mku.ac.ke
Chartered and ISO 9001 : 2015 Certified Institution.
Unlocking Infinite Possibilities

Figure 6. Graduate Studies Introduction Letter

Appendix V: MKU Ethics clearance



Mount Kenya University

REF: **MKU/ISERC/3350**
TO: **BUSINGE ALINAITWE**

Date: 28 November 2023

REG: **MSCN/2022/59006**

Dear Sir/Madam,

RE: EFFECTIVENESS OF A FAMILY-CENTERED SUPPORT INTERVENTION ON TREATMENT ADHERENCE AMONG TUBERCULOSIS PATIENTS IN JINJA, UGANDA

This is to inform you that **Mount Kenya University** has reviewed and approved your above research proposal. Your application approval number is **2394.** The approval period is **28/11/2023 - 27/11/2024.**

This approval is subject to compliance with the following requirements;

i. Only approved documents including informed consents, study instruments, MTA will be used
ii. All changes including amendments, deviations and violations are submitted for review and approval by **Mount Kenya University**
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to **Mount Kenya University** within 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affect the safety or welfare of study participants and others or affect the integrity of the research must be reported to **Mount Kenya University** within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal
vii. Submission of an executive summary report within 90 days upon completion of the study to **Mount Kenya University**

Prior to commencing your study, you will be expected to comply with any additional requirements from the relevant authorities in the country where this study will be conducted

Yours sincerely,

The Chairman
Mount Kenya University
Ethics Review Committee
P.O. Box 342 - 0100, Thika

Dr. Alfred Owino, PhD
Chairman, Mount Kenya University ISERC

Main Campus, General Kago Road, P.O. Box 342-01000 Thika. Tel: +254 67 2820 000,
Cell: +254 720 790 796, 0709 153 000
Email:info@mku.ac.ke, Web: www.mku.ac.ke
Chartered and ISO 9001 : 2015 Certified Institution.
Unlocking Infinite Possibilities

Figure 7. Mount Kenya University Ethics clearance

Appendix VI: Uganda Ethics Clearance

Telephones: **General Line:** 039-3280584
041-4671162

E-mail: mrrhrec@gmail.com

MINISTRY OF HEALTH
MBALE REGIONAL HOSPITAL
P.O. BOX 921
Mbale – Uganda

THE REPUBLIC OF UGANDA

In any correspondence on this
Subject, please quote: MRRHREC-OUT- 011/2020 **Date:**

MRHREC ACCREDITED BY THE UNCST, REGISTRATION NUMBER UG-REC-011

06/12/2023

To: Businge Alinaitwe

Mount Kenya University
0789703890

Type: Initial Review

Re: MRRH-2023-358: Effectiveness of a Family-Centered Support Intervention on Treatment Adherence Among Tuberculosis Patients in Jinja, Uganda

I am pleased to inform you that the Mbale Regional Referral Hospital REC, through expedited review held on **06/12/2023** approved the above referenced study.
Approval of the research is for the period of **06/12/2023** to **06/12/2024.**

As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

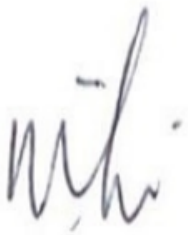
1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the REC for re-review and approval **prior** to the activation of the changes.
3. Reports of unanticipated problems involving risks to participants or any new information which could change the risk benefit: ratio must be submitted to the REC.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by participants and/or witnesses should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Continuing review application must be submitted to the REC **eight weeks** prior to the expiration date of **06/12/2024** in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. You are required to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

The following is the list of all documents approved in this application by Mbale Regional Referral Hospital REC:

Figure 8. Mbale Regional Referral Hospital Ethics Clearance

No.	Document Title	Language	Version Number	Version Date
1	Translated consent if applicable to your study	Lusoga	2	2023-12-04
2	Data collection tools	Luganda	1	2023-12-04
3	Translated consent if applicable to your study	Luganda	1	2023-12-04
4	Investigator Brochure	Luganda	1	2023-12-04
5	Informed Consent forms	English	2	2023-12-04
6	Protocol	English	2	2023-12-04
7	CVs of the investigators	English	1	2023-10-15
8	Investigator Brochure	English	1	2023-11-10

Yours Sincerely



Francis Okello
For: Mbale Regional Referral Hospital REC

Figure 9. Mbale Regional Referral Hospital Ethics Clearance

Appendix VII: Jinja District Local Government Clearance

JINJA DISTRICT LOCAL GOVERNMENT

Telephone: 0434 - 243914
Fax: 256 - 043 – 121267
E.mail:ddhs.jinja@health.go.ug

THE REPUBLIC OF UGANDA

Office of the Chief Administrative Officer
Health Department
P.O. Box 1551,
Jinja

5th January, 2024

OUR REF: MED/220/1

YOU REF:

Businge Alinaitwe
The Principal Investigator
Msc. Fellow, Mount Kenya University
P.O Box 342-01000, General Kago Road, Thika Town -Kenya

Dear Sir,

RE: ADMINISTRATIVE CLEARANCE TO CONDUCT ASTUDY IN JINJA ON EFFECTIVENES OF A FAMILY-CENTERED SUPPORT INTERVENTION ON TREATMENT ADHERENCE AMONG TUBERCULOSIS PATIENTS.

Reference is made to yours dated 4th January, 2024 and Mout Kenya University Introductory letter dated 28th November, 2023, Ref MSCN/2022/59006, requesting administrative clearance to conduct a study on "**Effectiveness of a Family-Centered Support Intervention on Treatment Adherence Among Tuberculosis Patients in Jinja**

This is to inform you that your request to obtain administrative clearance from the district health office to conduct this study in the health facilities of Buwenge General Hospital and Buwenge HC IV has been granted as IRB clearances have been presented to DHO office. In Charges and Tuberculosis focal point persons are requested to support you in any way possible.

We request that you share with our office the research report as soon as the study is completed

ASS. DISTRICT HEALTH OFFICER (ENVIRONMENTAL HEALTH)
05 JAN 2024
JINJA DISTRICT LOCAL GOVERNMENT

Sincerely,

Were Edward
For District Health Officer- Jinja district

Copy to: In Charges Buwenge General Hospital and Buwenge HC IV

Copy to: File

Figure 10. Jinja District Local Government Clearance

Appendix VIII: Approval from Uganda National Council of Science and Technology

Uganda National Council for Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

Our Ref: HS3583ES **2 January 2024**

Businge Alinaitwe
Jinja Regional Referral Hospital
Jinja

Re: Research Approval: **Effectiveness of a Family-Centered Support Intervention on Treatment Adherence Among Tuberculosis Patients in Jinja, Uganda**

I am pleased to inform you that on **02/01/2024**, the Uganda National Council for Science and Technology (UNCST) approved the above referenced research project. The Approval of the research project is for the period of **02/01/2024** to **02/01/2025**.

Your research registration number with the UNCST is **HS3583ES**. Please, cite this number in all your future correspondences with UNCST in respect of the above research project. As the Principal Investigator of the research project, you are responsible for fulfilling the following requirements of approval:

1. Keeping all co-investigators informed of the status of the research.
2. Submitting all changes, amendments, and addenda to the research protocol or the consent form (where applicable) to the designated Research Ethics Committee (REC) or Lead Agency for re-review and approval **prior** to the activation of the changes. UNCST must be notified of the approved changes within five working days.
3. For clinical trials, all serious adverse events must be reported promptly to the designated local REC for review with copies to the National Drug Authority and a notification to the UNCST.
4. Unanticipated problems involving risks to research participants or other must be reported promptly to the UNCST. New information that becomes available which could change the risk/benefit ratio must be submitted promptly for UNCST notification after review by the REC.
5. Only approved study procedures are to be implemented. The UNCST may conduct impromptu audits of all study records.
6. An annual progress report and approval letter of continuation from the REC must be submitted electronically to UNCST. Failure to do so may result in termination of the research project.

Figure 11. Approval from Uganda National Council of Science and Technology

Please note that this approval includes all study related tools submitted as part of the application as shown below:

No.	Document Title	Language	Version Number	Version Date
1	Data collection tools	Luganda	1	04 December 2023
2	Informed Consent forms	English	2	04 December 2023
3	Data Collection tool	English	1	10 November 2023
4	Consent form	Luganda	2	04 December 2023
5	Project Proposal	English	2	
6	Approval Letter	English		
7	Administrative Clearance	English		
7	Luganda Consent form	Luganda	2	30 December 2023
8	Lusoga Consent form	Lusoga	2	30 December 2023
9	COVID-19 risk management plan	English	1	20 December 2023

Yours sincerely,

Hellen Opolot
For: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

LOCATION/CORRESPONDENCE

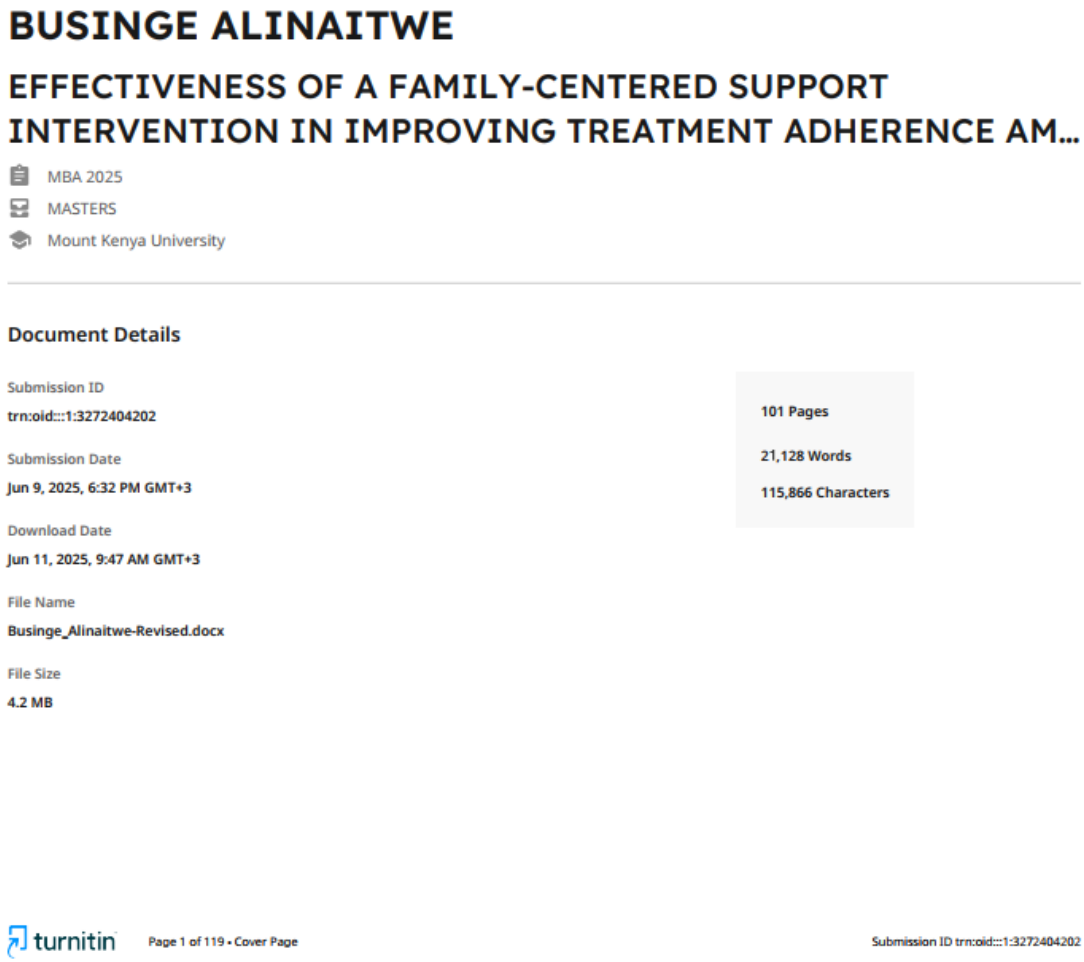
Plot 6 Kimera Road, Ntinda
P.O. Box 6884
KAMPALA, UGANDA

COMMUNICATION

TEL: (256) 414 705500
FAX: (256) 414-234579
EMAIL: info@uncst.go.ug
WEBSITE: http://www.uncst.go.ug

Figure 12. Approval from Uganda National Council of Science and Technology

Appendix IX: Similarity Index



BUSINGE ALINAITWE

EFFECTIVENESS OF A FAMILY-CENTERED SUPPORT INTERVENTION IN IMPROVING TREATMENT ADHERENCE AM...

MBA 2025

MASTERS

Mount Kenya University

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Figure 13. Similarity Index

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Appendix X: A map showing the location of study sites

Figure 14. A map showing the location of study sites