PERCEPTIONS AND ATTITUDES TOWARD PARTICIPATION IN HIV/AIDS CLINICAL TRIALS AMONG ADOLESCENTS AND YOUNG ADULTS LIVING WITH HIV IN A SUBURBAN AREA OF KAMPALA,UGANDA

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ABSTRACT

Background: This study explores the perceptions and attitudes of adolescents and young adults living with HIV (AYALHIV) toward participation in HIV/AIDS clinical trials in a suburban area of Kampala,Uganda. Although clinical trials are essential for advancing HIV treatment, participation rates among adolescents and young adults remain low, particularly in sub-Saharan Africa.

Methods: Using a descriptive qualitative approach, the study involved in-depth interviews (IDI's) and focus group discussions (FGD's) with AYALHIV aged 13-24 years attending the Joint Clinical Research Centre (JCRC) paediatric clinic in Lubowa.

Results: Findings revealed low awareness and knowledge of clinical trials among participants, with most learning about trials through healthcare providers or peers. Major barriers to participation included fear of side effects, practical challenges such as transportation, and concerns about privacy due to HIV-related stigma. However, several facilitators were also identified, such as family and peer support, access to clear information, and a strong sense of altruism among older participants who viewed trial participation as contributing to the broader fight against HIV/AIDS.

Conclusions: The study concludes that while there are significant barriers, addressing logistical issues, improving educational outreach, and emphasizing altruistic motivations could enhance participation.

Recommendations: Doing targeted educational campaigns, increasing logistical support, and community-based initiatives to reduce stigma and promote trial participation among AYALHIV. By understanding and addressing these factors, future HIV clinical trials can become more inclusive, contributing to more effective research and better health outcomes for adolescents and young adults living with HIV.

DECLARATION

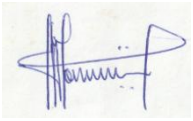
I, Namukwaya Stella Winnie hereby declare that this is my original work, is not plagiarised and has not been submitted to any other institution for any award.

Namukwaya Stella Winnie

Signature:  Date: 06th/02/2025

APPROVAL

This is to certify that the Dissertation titled; "*Perceptions and Attitudes Toward Participation in HIV/AIDS Clinical Trials Among Adolescents and Young Adults Living with HIV in a Suburban Area of Kampala, Uganda*" has been done under my supervision and is now ready for submission.

SUPERVISIOR'S NAME: Dr. Nareeba Peter SIGNATURE: 

DATE: 7th/02/2025

DEDICATION

To my family,

for their unwavering support, patience, and understanding

throughout my journey as a student."

ACKNOWLEDGEMENT

I would like to express my deepest gratitude to all those who have supported me throughout the process of completing this dissertation.

First and foremost, I would like to thank my supervisor, Dr. Nareeba.Peter, for the invaluable guidance, encouragement, and feedback. His expertise and insightful suggestions have been instrumental in shaping this work.

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HIV – Human Immunodeficiency Virus

AIDS - acquired immunodeficiency syndrome

AYA – Adolescents and Young adults

AYALHIV **-** Adolescents and young adults living with HIV/AIDS

ART - Antiretroviral therapy

AZT – Azidothymidine/Zidovudine

HAART- Highly active antiretroviral therapy

NIH-National institute of Health

JCRC-Joint Clinical Research Centre

Operational definitions

AIDS

Acquired immunodeficiency syndrome (AIDS) is a term that applies to the most advanced stages of HIV infection. It is defined by the occurrence of any of the more than 20 life-threatening cancers or "opportunistic infections", so named because they take advantage of a weakened immune system.

Adolescents

The World Health Organisation defines 'adolescents' as individuals in the 10-19 years age group.

Clinical trial

The National institute of Health (NIH) defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes(National Institute of Health, 2024b)

HIV

HIV stands for the Human Immunodeficiency Virus, which is the virus that causes acquired immunodeficiency syndrome or AIDS. HIV attacks the immune system, which gives the body the ability to fight infections (Centre for Disease Prevention and Control, 2008).

Young adults

UNAIDS defines a young person as someone between the ages of 15-24.

CHAPTER ONE

1.0 Introduction

In this chapter, the background to the study and justification as to why it is important to understand the perceptions and attitudes of adolescents and young adults living with HIV(AYALHIV) toward participation in HIV/AIDS clinical trials will be presented. This chapter will begin by highlighting the prevalence of HIV among adolescents and young adults around the world, the role of HIV/AIDS clinical trials in advancing HIV treatment and care and the importance of adolescents and young adults living with HIV taking part in these clinical trials.

1.1 Background to the study

The Human Immunodeficiency Virus (HIV) remains one of the most significant public health and development challenges of the last few decades, with devastating health effects worldwide (World Health Organization, 2019). Discovered in the early 1980s, HIV attacks the body's immune system, specifically targeting the CD4 + T cells, which are important in sustaining the body's immunological response (Sharp & Hahn, 2011). By the end of 2022, an estimated 39 million [33.1million-45.7million] people were living with HIV globally(UNAIDS, 2022).

Advances in HIV research have transformed the disease from a death sentence into a manageable chronic condition(Calabrese et al., 2023). However, adolescents and young adults (AYA) aged 10-24 remain disproportionately affected by HIV/AIDS(HIV/AIDS, 2023; UNAIDS, 2022), with more than half of the new global HIV infections occurring in this age group and up to a third of people living with HIV/AIDS being 25 years or younger (HIV/AIDS, 2023; UNICEF, 2022). In 2022, about

1.65 million [1.18million-2.19 million] adolescents between the ages of 10 and 19 were living with HIV worldwide, and about 1.40 million or 85%, in sub-Saharan Africa.

HIV prevalence among adolescents and young adults is primarily due to perinatally (mother to child) and sexually acquired HIV(Adejumo et al., 2015; Naswa & Marfatia, 2010).The widespread availability and coverage of antiretroviral therapy (ART) has improved the survival of children with perinatal HIV infection to adolescence(Slogrove & Sohn, 2018).New infections continue to be sexually acquired by susceptible adolescents and young adults(Calabrese et al., 2023).

In Uganda, the AIDS commission estimates that 21% of adolescents and young adults between the ages of 15-24 are infected with HIV (Uganda AIDS Commission, 2019-2020).Every week, approximately 570 young women in Uganda between the ages of 15 to 24 contract HIV, highlighting the importance of this age group in new infections in the country (UNAIDS, 2023). According to the Uganda population-based HIV impact assessment, the prevalence of HIV among young adults aged 20 to 24 is almost three times compared to that among those aged 15-19,(Ministry of Health, 2017).

One of the most significant breakthroughs in HIV treatment has been the development of antiretroviral therapy (ART), with clinical trials playing a crucial role in this development process. The National institute of Health (NIH) defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes (National Institute of Health, 2024b).

Clinical trials are essential for advancing HIV treatment and care, providing the scientific foundation for developing new therapies. They ensure that any new treatment reaching the market is safe, effective in managing HIV, and accessible to all who need them(National Institute of Health, 2024a). For instance, the introduction of combination ART (cART) in the mid-1990's was a direct result of rigorous clinical testing (Mani et al., 2012) showing that combining different antiretroviral drugs could suppress the virus to undetectable levels, significantly improving patient outcomes and life expectancy(Mani et al., 2012).

Clinical trials for the drug dolutegravir(DTG),a highly effective integrase inhibitor with a low propensity for developing resistance, that is now widely used in first-line treatment regimens among adults and children, demonstrated its superior efficacy and safety compared to existing treatments(Bollen et al., 2020; Turkova et al., 2021). Recent clinical trials have shown the effectiveness of injectable, long acting Cabotegravir and Rilpivirine antiretroviral therapy (ART) in virologically suppressing HIV among adults(Bares & Scarsi, 2022) and adolescents(Gaur et al., 2024).

In addition to treatment, clinical trials have been crucial in developing preventive measures such as pre-exposure prophylaxis (PrEP). Large-scale clinical trials demonstrated PrEP's effectiveness in lowering HIV transmission risk in high-risk populations, leading to the approval of Truvada(Drallmeier & Meyr, 2022) and Descovy (Blackwell & Castillo, 2021) as PrEP medications. The physiological differences between adolescents, young people, and adults affect how they metabolize drugs(Fernandez et al., 2011), necessitating their participation in specific clinical trials to determine the right dosages, levels of efficacy, and safety

of antiretroviral therapy (ART). In the absence of this data, healthcare professionals are forced to rely on extrapolations from adult research studies, which might not produce the best outcomes.

1.2 Statement of the Problem

Clinical trials are a cornerstone of medical advancement across all clinical subspecialities, including HIV research(DiClemente et al., 2010). They provide critical evidence regarding the efficacy, effectiveness, and safety of interventions, thereby informing clinical practice and improving patient outcomes(Alemayehu et al., 2018; Singh, 2018). In the context of HIV, participation is fundamental for the development of innovative treatments and for enhancing the survival and quality of life of individuals living with the virus(DiClemente et al., 2010).

Despite the increasing availability of HIV clinical trials-including in Uganda-that are investigating novel prevention and treatment approaches, participation rates among adolescents and young adults in sub-Saharan Africa remains disproportionately low(Brown et al., 2015; Landers et al., 2020). This underrepresentation is concerning, as it limits the progress of research and the development of new therapies that are both culturally and age appropriate.

While existing literature highlights barriers such as stigma, misinformation, and structural challenges, there is paucity of research that specifically examines the perceptions and attitudes of AYALHIV toward clinical trial participation, particularly within the Ugandan context. As a result, limited understanding exists regarding the motivators, deterrents, and contextual factors that shape their willingness or reluctance to engage in clinical research.

This knowledge gap presents a significant challenge for researchers and policy makers aiming to design and implement inclusive and ethically sound clinical trials that resonate with young people living with HIV.

Therefore, this study explored perceptions and attitudes of AYALHIV in Kampala, Uganda, toward participation in HIV clinical trials. The findings aim to generate insights that can inform the development of more effective recruitment strategies and trial designs tailored to this important population.

1.3 General objective of the study

To explore the perceptions and attitudes of adolescents and young adults living with HIV(AYALHIV) in Kampala, Uganda toward participation in HIV/AIDS clinical trials.

1.4 Specific Objectives

1. To explore how adolescents and young adults living with HIV understand and perceive HIV/AIDS clinical trials.

2. To identify the barriers to participation in HIV/AIDS clinical trials among adolescents and young adults living with HIV.

3. To identify the facilitators that promote participation in HIV/AIDS clinical trials among adolescents and young adults living with HIV.

1.5 Research Questions

1.How do adolescents and young adults living with HIV perceive and understand HIV/AIDS clinical trials?

2.What barriers prevent adolescents and young adults living with HIV from participating in HIV/AIDS clinical trials?

3.What factors facilitate the participation of adolescents and young adults living with HIV in HIV/AIDS clinical trials?

1.6 Justification of the study

Ensuring equitable representation of all affected populations in clinical trials is an ethical imperative and a cornerstone of research integrity. This study upheld the principles of justice and beneficence by examining the factors that limited the participation of adolescents and young adults living with HIV (AYALHIV) in clinical trials. Through identifying these barriers and exploring strategies to address them, the study aimed to promote equitable access and representation for this population in research.

1.7 Significance of the study

The results of this study offered valuable insights to inform the development of targeted interventions and communication strategies to address misconceptions, build trust, and enhance the cultural relevancy and acceptability of HIV/AIDS clinical trials. These results hold practical significance for health care providers, policy makers, and researchers, offering guidance on fostering greater inclusion of adolescents and young adults living with HIV(AYALHIV) in clinical trials and improving health outcomes within this population.

1.8 Scope of the study

1.8.1 Content scope

The study focused on understanding the perceptions and attitudes towards participation in HIV/AIDS clinical trials among AYALHIV aged 13-24 years in Kampala, Uganda. It assessed the knowledge and awareness levels of AYALHIV regarding HIV/AIDS clinical trials, identified key barriers to participation in HIV/AIDS clinical trials as well as the facilitators to participation.

1.8.2 Geographical scope

The study was conducted at the Joint Clinical Research Centre (JCRC), a paediatric HIV treatment and care centre located approximately 10 kms from the capital city Kampala which is an urbanized area with the highest HIV prevalence in the central region (10.4%) (Ministry of Health, Uganda,2019) which provided a critical setting for this research. This paediatric HIV centre has conducted various HIV/AIDS clinical trials and is a primary location for treating and managing paediatric HIV and offered a representative sample for understanding the broader population's attitudes towards participation in HIV/AIDS clinical trials.

1.8.3 Time scope

This study examined the period from December 2024 to January 2025.This timeframe includes the data collection phase, a comprehensive analysis of participant experiences and perceptions during this period.

1.9 Theoretical Framework

This study was guided by the Social Ecological Model (SEM), a theoretical framework that emphasizes the multiple levels of influence on individual health behaviours and outcomes. Developed by Bronfenbrenner (1977) and later adapted

for use in public health by McLeroy et al. (1988), the model has five levels, each representing a different sphere of influence:

1.Individual Level

This is the innermost level and focuses on personal factors that influence behavior such as knowledge, attitudes, beliefs, motivation, biological factors, and personal history.

2.Interpersonal Level

This level considers close relationships that may influence behaviors. These include family, friends, peers, and social networks that provide social identity, support, and role models.

3.Organizational Level

This refers to institutions and organizations (like schools, health facilities, workplaces) that can influence behavior through rules, policies, and structures.

4.Community Level

This involves relationships among organizations and institutions within defined boundaries. It includes community norms, standards, and collective social networks that affect access to resources and support systems.

5.Societal (or Policy) Level

This is the outermost level and includes broader societal factors like national policies, laws, cultural norms, economic systems, and social justice that shape the environment in which all other levels operate.

1.10 Conceptual Framework

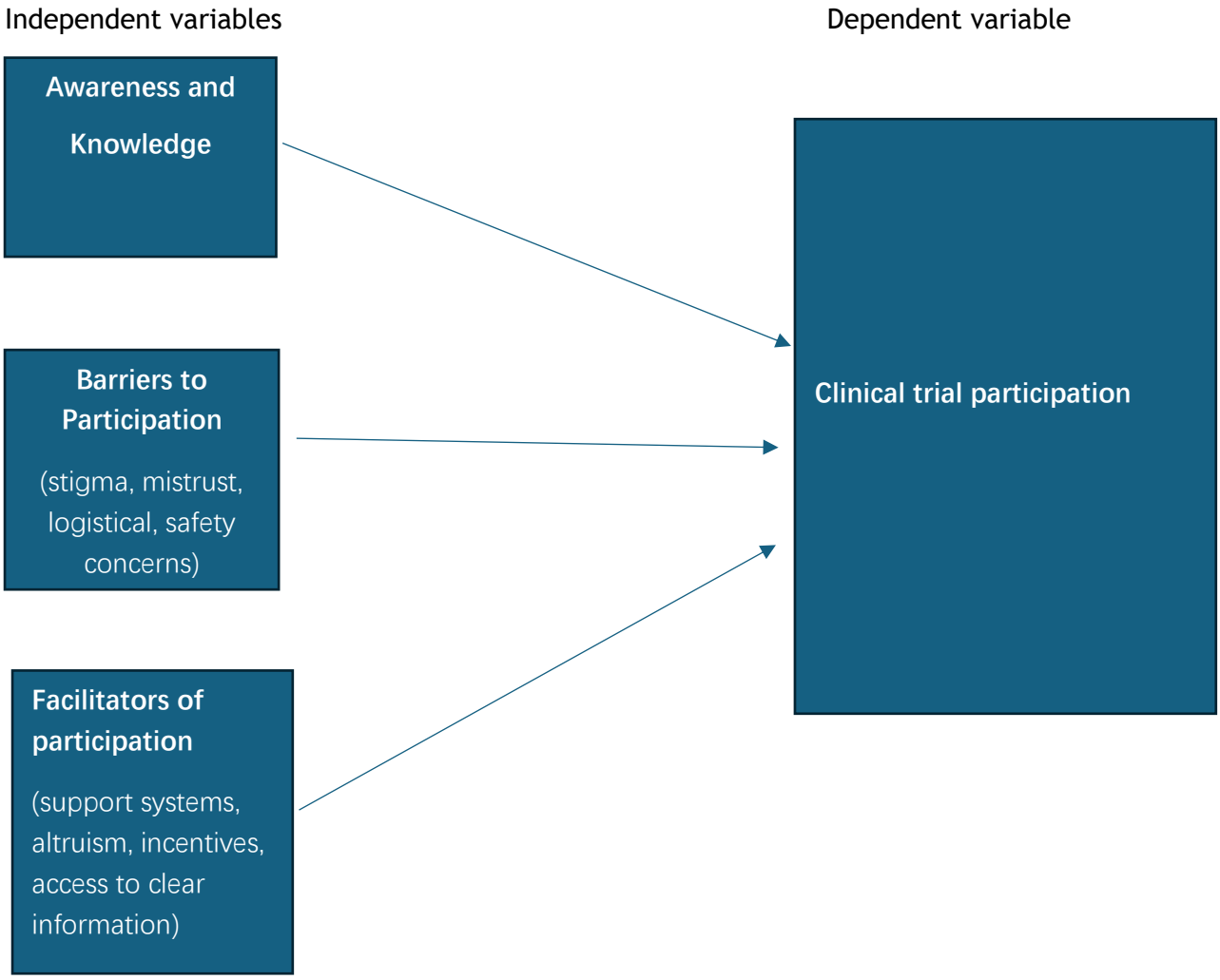

Figure 1: Conceptual framework

The Social Ecological Model (SEM) informed the development of the conceptual framework by providing a structured,multi-level lens through which to examine the perceptions and attitudes of AYALHIV toward participation in HIV clinical trials. The conceptual framework illustrates the relationships between key factors that influence clinical trial participation among adolescents and young adults living with HIV. It focuses on the interplay between independent variables, including awareness and knowledge, barriers to participation, and facilitators of

participation, and their effect on the dependent variable, which is clinical trial participation.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter synthesizes the available literature on HIV/AIDS clinical trials, with a focus on historical milestones, types of clinical trials and knowledge of clinical trials among adolescents. Additionally, it examines the barriers and facilitators influencing participation among adolescents and young adults living with HIV (AYALHIV). The review was structured around the objectives of the study, aiming to provide a comprehensive understanding of the factors influencing AYALHIV's decision-making in this context.

2.2 Overview of clinical trials in HIV/AIDS research

Over the past decade, the number of HIV clinical trials (CT) in Africa has increased(Chu et al., 2015) and these trials have played a crucial role in the advancement for knowledge regarding HIV and its prevention, treatment, and management since the early 1980's, when the virus was first discovered(Mbuagbaw et al., 2022).These trials have been instrumental in the development of life-saving antiretroviral therapy (ART), have advanced approaches for HIV prevention, and more recently, have guided research into possible cures(Mbuagbaw et al., 2022). This section provides an overview of the evolution and current landscape of HIV clinical trials, emphasizing both their significant contributions to public health and ongoing challenges in the field.

2.2.1 Historical milestones of HIV clinical trials

The early phase of HIV research was propelled by the pressing need to develop treatments for infection due to the deadly virus that was spreading quickly. The first significant breakthrough came in 1987 with the approval of zidovudine, also known as azidothymidine (AZT), the first drug proven to prevent the replication of HIV in humans(Fischl et al., 1987). This was based on clinical trials that demonstrated that AZT could delay HIV progression in people that were infected with the virus(Fischl et al., 1987). This success paved the way for subsequent clinical trials that aimed at improving treatment strategies, eventually leading to the development of combination therapy, which was later termed as highly active antiretroviral therapy (HAART). HAART transformed the treatment of HIV by significantly reducing viral loads and delaying the onset of AIDS(Hammer et al., 1996).

2.2.2 Types of HIV clinical trials

HIV/AIDS clinical trials cover a broad range of studies, each focusing on distinct aspects of managing the virus:

1. Antiretroviral therapy trials:

These trials focus on the development and optimization of ART regimens(Darbyshire, 2003). Early trials showed the efficacy of single-drug therapies like AZT(Fischl et al., 1987), while subsequent research showed that combination therapies were more effective(Deathe, 1996), current trials continue to assess novel antiretroviral medications, fixed-dose combinations, and long-acting injectable formulations, with the aim of reducing drug resistance and improving patient adherence.

2.Vaccine trials:

These trials aim to stimulate the immune system to identify and fight HIV(Graham, 2002). Despite decades of extensive research, an effective HIV vaccine is yet to be developed. Although early-phase trials have demonstrated the potential of various vaccine candidates, achieving broad and durable protection against the virus has proven to be difficult(Kim et al., 2021). Amongst the reasons for no success is the genetic variability of HIV. However, current clinical trials continue to explore novel strategies, like vaccines called mosaics that aim to stimulate the immune system against several HIV strains(Kim et al., 2021).

3.Cure research trials:

Cure research is a cutting-edge field and evolving area in HIV clinical trials, that focuses on strategies to eradicate HIV from the body or attain long-term remission without ART(Kuo et al., 2019). Even though a complete cure is still unattainable, these trials explore diverse approaches and have been important in giving insights into the causes of HIV persistence and potential pathways to eradication(Kuo et al., 2019).

4.**Prevention trials:**

Prevention trials have been crucial in developing strategies for the reduction of HIV transmission(Gray & Wawer, 2007). Clinical trials have demonstrated that Pre-exposure prophylaxis (PrEP), a daily oral medication, can lower HIV infection risk in high-risk populations by more than 90%(Grant et al., 2010).Microbicides(Zhernov & Khaitov, 2019), injectable PrEP (Grinsztejn et al., 2023)and HIV neutralizing antibodies are among the other preventative measures that are currently being researched.

In conclusion, clinical trials continue to be the driving force behind the progress in HIV research. The ongoing commitment to innovation in this field offers hope for even more significant breakthroughs in the future, potentially leading to the ultimate goals of an effective HIV vaccine and a functional cure.

2.3 Knowledge and awareness of clinical trials among adolescents and young adults.

Awareness and understanding of clinical trials are crucial for increasing participation, especially among groups that are frequently underrepresented in research, such as adolescents and young adults living with HIV(Unicef, 2017; UNICEF, 2021). However, there is still a lack of general knowledge about clinical trials, particularly among marginalised and vulnerable populations(Anderson et al., 2018) which might hinder participant recruitment and slow the advancement of medical research.

Research has consistently shown that the general public, including adolescents and young adults, lacks adequate knowledge about clinical trials(Anderson et al., 2018). Many people are unaware of what clinical trials entail, their purpose, or how to participate in them(Anderson et al., 2018; Santelli et al., 2003). This lack of awareness is even more pronounced among younger individuals and those from minority backgrounds, who are less likely to be informed about the opportunities and benefits associated with clinical trial participation(Nalubega & Evans, 2015).

Several factors contribute to the low levels of awareness about clinical trials. Firstly, there is a general lack of education on clinical research in schools and community settings, which means that young people are not exposed to information about trials unless they or someone they know is affected by a

condition that requires participation in a trial(Frances Ndyetukira et al., 2019). Additionally, the complexity of medical research terminology and the way clinical trials are often communicated to the public can be a barrier to understanding, especially for those with lower health literacy(Wendler, 2006). Media coverage of clinical trials is also limited, often focusing only on the results of high-profile studies rather than on the process and importance of participation(Castelnuovo et al., 2014). This can result in a narrow perception of what clinical trials are, reinforcing misconceptions that trials are risky or only for those with no other treatment options available.

Improving awareness of clinical trials is essential for several reasons. Firstly, greater awareness can lead to increased participation, which is necessary for the success of trials(Nodora et al., 2010). Diverse participation ensures that research findings are applicable to a broader population, including different age groups, ethnicities, and genders. This is particularly important in HIV research, where the disease affects diverse populations with varying needs and responses to treatment. Secondly, informed individuals are better equipped to make decisions about their health and are more likely to consider participating in a clinical trial if they understand the potential benefits and risks(Parker et al., 2021). Educating young people about clinical trials can also empower them to become advocates for research within their communities, further enhancing recruitment efforts(Parker et al., 2021).

In conclusion, the inclusion of adolescents and young adults in HIV clinical trials is indispensable for developing age-appropriate treatments and prevention

strategies. It ensures that this vulnerable group benefits from medical advances and contributes to the broader goal of ending the HIV epidemic.

2.4 Barriers to participation in clinical trials among adolescents and young adults living with HIV.

Participation in clinical trials is vital for advancing HIV research and developing effective treatments, particularly for adolescents and young adults living with HIV. However, this population faces several barriers that limit their involvement in clinical research. These barriers are multifaceted, encompassing psychosocial, structural, and systemic challenges that must be addressed to increase AYALHIV participation in clinical trials.

Psychosocial Barriers

One of the primary psychosocial barriers is the stigma associated with HIV(Newman et al., 2006). Adolescents and young adults often fear discrimination and social isolation if their HIV status is disclosed through trial participation(Newman et al., 2006). This stigma can be particularly pronounced in younger populations who may still be grappling with their diagnosis and are more vulnerable to peer pressure and societal judgment(Nyblade et al., 2011). Moreover, the psychological burden of living with HIV, including anxiety and depression, can further diminish motivation to participate in clinical research.

Mistrust of the medical system also contributes to low participation rates(Newman et al., 2006). Historical abuses in medical research, particularly documented in the Tuskegee syphilis study(Sengupta et al., 2000; Shavers et al., 2000; Thomas & Quinn, 1991), have fostered a deep-seated mistrust in the healthcare system

among many communities. Further more, the emergence of HIV and HIV/AIDS related trials created suspicion among African Americans towards AIDS related public health policy which has been identified as a barrier to participation in research by adults and adolescents(Newman et al., 2006). This mistrust is often passed down through generations and can deter AYALHIV from engaging in clinical trials, which are sometimes perceived as risky or exploitative.

Structural Barriers

Logistical issues, such as transportation and time commitments(DiClemente et al., 2010; Nodora et al., 2010), present significant structural barriers to AYA participation in clinical trials. Many adolescents and young adults may lack access to reliable transportation, making it difficult to attend regular study visits(DiClemente et al., 2010). Additionally, school or work commitments may conflict with trial schedules, leading to difficulties in maintaining participation(DiClemente et al., 2010; Nodora et al., 2010). These challenges are often exacerbated in low-income populations, where financial constraints further limit the feasibility of trial involvement(DiClemente et al., 2010).

The complexity of clinical trial protocols can also be a deterrent(Ssali et al., 2015). Clinical trials often involve lengthy consent forms, frequent monitoring, and invasive procedures that may be intimidating or overwhelming for younger participants(Santelli et al., 2003; Ssali et al., 2015). The lack of adolescent-friendly trial designs that consider the unique needs and concerns of this age group contributes to their underrepresentation in research(Ssali et al., 2015).

Systemic Barriers

Systemic barriers, including a lack of targeted outreach and recruitment efforts, further impede AYALHIV participation in clinical trials(Ross et al., 1999). Many clinical trials do not specifically target or recruit adolescents and young adults, leading to their exclusion from potentially beneficial research. This lack of focus on AYALHIV in trial design and recruitment strategies perpetuates their underrepresentation in clinical studies(Ross et al., 1999).

Moreover, the legal and ethical complexities surrounding consent for minors present another systemic challenge(Ott et al., 2018). In many regions, adolescents under the age of 18 cannot consent to participate in clinical trials without parental or guardian approval (ascent). This requirement can discourage participation, particularly for those who may not wish to disclose their HIV status to their family. The fear of breaching confidentiality is a significant deterrent for many adolescents, further limiting their involvement in research(Ott et al., 2018).

Addressing Barriers to Participation

To overcome these barriers, it is essential to develop strategies that address the unique needs and concerns of AYALHIV. This includes creating more adolescent-friendly trial designs, improving outreach and education efforts, and addressing the logistical and systemic challenges that hinder participation(Alpert et al., 2023; Nipp et al., 2019). Reducing stigma and building trust within communities, particularly through culturally sensitive and inclusive approaches, is also crucial(Alpert et al., 2023; Nipp et al., 2019). Legal and ethical frameworks must be adapted to balance the need for parental consent with the protection of adolescent autonomy and confidentiality(Nipp et al., 2019).

In conclusion, addressing the barriers to participation in clinical trials among adolescents and young adults living with HIV is essential for ensuring that this population benefits from advances in HIV treatment and prevention. By recognizing and mitigating these challenges, researchers can foster greater inclusion of AYALHIV in clinical research, ultimately contributing to more effective and equitable healthcare outcomes.

2.5 Facilitators of participation in HIV/AIDS clinical trials among adolescents and young adults living with HIV.

While numerous barriers hinder participation in clinical trials among adolescents and young adults living with HIV, several facilitators can enhance their involvement. Understanding and leveraging these facilitators is crucial for designing and implementing clinical trials that are more accessible and appealing to this demographic. Facilitators include fostering trust and relationships, tailoring communication strategies, providing logistical support, and ensuring that trials are perceived as relevant and beneficial.

Building Trust and Strong Relationships

One of the most significant facilitators of participation in clinical trials is the establishment of trust between participants and the research team(Hall et al., 2001). Trust is especially critical in populations that may be wary of medical institutions due to historical abuses or previous negative experiences(Hall et al., 2001).Variables in the literature that are mentioned as barriers to participant trust in clinical research include insufficient information regarding research studies, unethical behaviour on the part of the research team, and safety

concerns(Ceballos et al., 2014; Cortés et al., 2017; Erves et al., 2017; Scharff et al., 2010). Building trust can be achieved through consistent and transparent communication, culturally sensitive practices, and the involvement of community leaders or peers who can vouch for the trial's integrity(Hall et al., 2001).

Additionally, developing strong relationships between AYALHIV and healthcare providers can encourage trial participation. Adolescents and young adults are more likely to engage in clinical research if they feel supported and understood by their healthcare team(Hurd et al., 2017). This relationship can be fostered through personalized care, regular follow-ups, and providing a safe space for AYALHIV to express their concerns and ask questions(Hurd et al., 2017) .

Tailored Communication and Education Strategies

Effective communication is key to facilitating AYALHIV participation in clinical trials. Tailoring communication strategies to meet the needs of this age group can significantly improve their willingness to participate(Williams & Kolb, 2022). For instance, using age-appropriate language, incorporating digital platforms, and leveraging social media can make information about clinical trials more accessible and relatable to young people(Williams & Kolb, 2022).

Educational interventions that increase awareness and understanding of clinical trials are also important facilitators(Cowdery et al., 2019). Providing clear and concise information about the purpose of the trial, potential risks and benefits, and the importance of research in advancing HIV treatment can empower AYALHIV to make informed decisions about participation(Cowdery et al., 2019).

Additionally, involving AYALHIV in the design and dissemination of educational materials can enhance their relevance and impact(Cowdery et al., 2019).

Providing Logistical Support

Addressing logistical barriers can facilitate greater participation in clinical trials among AYALHIV(Cowdery et al., 2019). Providing transportation assistance, flexible scheduling, and financial incentives are practical solutions that can make trial participation more feasible for young people(Cowdery et al., 2019). For example, offering stipends to cover transportation costs or scheduling study visits around school or work commitments can significantly reduce the burden of participation.

Furthermore, simplifying trial protocols to minimize the time and effort required for participation can make trials more appealing to AYALHIV(Gayet-Ageron et al., 2020). This might include reducing the frequency of study visits, allowing for virtual or remote participation, and ensuring that trial procedures are as non-invasive as possible(Gayet-Ageron et al., 2020).

Highlighting the Relevance and Benefits of Participation

AYALHIV are more likely to participate in clinical trials if they perceive the research as relevant to their lives and if they believe it will lead to tangible benefits(Anastasi et al., 2024). Emphasizing the potential personal and societal impact of their participation can motivate AYALHIV to engage in clinical research. For instance, explaining how the trial could lead to better treatments for HIV or improve the quality of life for themselves and others in their community can be powerful motivators(Anastasi et al., 2024).

Additionally, involving AYALHIV in the research process, such as through youth advisory boards or peer-led initiatives, can increase their sense of ownership and engagement with the trial(Mandoh et al., 2023). When AYALHIV see themselves as active contributors to research rather than passive subjects, they are more likely to participate and remain committed to the study(Mandoh et al., 2023).

Community and Peer Support

Finally, the involvement of communities and peer support networks can play a significant role in facilitating AYALHIV participation in clinical trials. Communities through leaders can engage with young people living with HIV can help bridge the gap between researchers and potential participants by providing education, resources, and support(Kwizera et al., 2020). Similarly, peer support groups can offer encouragement and reduce the fear and stigma associated with trial participation(Kwizera et al., 2020).

In conclusion, enhancing AYALHIV participation in HIV clinical trials requires a multifaceted approach that addresses both the barriers and facilitators specific to this population. By building trust, tailoring communication strategies, providing logistical support, and highlighting the relevance and benefits of participation, researchers can create more inclusive and effective clinical trials that better serve the needs of adolescents and young adults living with HIV.

2.6 Summary

Clinical trials have been pivotal in advancing HIV research, leading to breakthroughs such as the development of antiretroviral therapy (ART) and potential HIV vaccines and cures. Despite their significance, there is a lack of or

low awareness and understanding of clinical trials, particularly among adolescents and young adults living with HIV (AYALHIV), which hampers recruitment. Factors like stigma, mistrust in the healthcare system, and lack of education contribute to low participation rates. Barriers also include logistical challenges such as transportation, conflicting schedules, and complex trial protocols, as well as legal and ethical issues related to consent.

Facilitators of participation include building trust, tailoring communication strategies to younger audiences, offering logistical support, and ensuring that trials are seen as relevant and beneficial. Trust-building with healthcare providers, clear communication, and involving AYALHIV in the research process can enhance participation. Additionally, providing community and peer support networks can help reduce stigma and encourage engagement. Addressing these barriers and facilitators is essential for improving AYALHIV participation in clinical trials, ultimately contributing to better treatments and prevention strategies for this population.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

In this chapter, the methods, and materials that were used in the study including study design, study population, and study setting, sampling, data collection methods, recruitment procedure, data analysis, and ethical consideration were outlined.

3.2 Study Design

This study used a descriptive qualitative design, which is well-suited for capturing and describing the lived experiences of adolescents and young adults living with HIV(AYALHIV) regarding HIV/AIDS clinical trial participation. This design allowed for an in-depth exploration of the complex social, psychological, and contextual factors that influence their decisions and attitudes towards clinical trials. By utilizing methods such as in-depth interviews and focus groups, the study gathered rich, detailed narratives that provided a comprehensive understanding of participants' experiences, meanings, and perspectives.

3.3 Study setting

The study was conducted at the Paediatric HIV clinic of the Joint Clinical Research Centre (JCRC) in Lubowa, a suburb located approximately 10 kilometres from Kampala, the capital city of Uganda. Established in 1991 in response to the peak of the HIV epidemic, JCRC provides comprehensive HIV care and treatment services, including specialized support for children and adolescents living with HIV. It is also a centre that has conducted various HIV/AIDS clinical trials. Patients at this centre

are drawn from different areas across the Kampala metropolitan region and its surrounding areas.

3.4 Study population

The participants of the study were adolescents and young adults enrolled on antiretroviral therapy (ART), aware of their HIV status, and receiving HIV care at JCRC paediatric clinic. The target population included individuals aged 13-24, comprising both those who had previously participated in an HIV/AIDS clinical trial as well as those who had not.

Inclusion criteria:

- Adolescents and young adults aged 13-24 who had been diagnosed with HIV and were aware of their HIV status.
- Willing and able to provide informed consent or assent for minors

Exclusion criteria

- Individuals outside the specific age range
- Those who are unable to provide informed consent or assent
- Those with severe cognitive impairments that may hinder the interview process.

During the recruitment process, a few potential participants were unable to participate due to their guardians' busy work schedules, which prevented them from attending in-person sessions to provide informed consent. Additionally, some adolescents were unavailable due to being in school during the recruitment period. Despite these challenges, all participants who received guardian consent and assented themselves fully participated in the in-depth interviews or focus group

discussions. The non-response rate was low, and the composition and diversity of the study sample were not significantly affected.

3.5 Sampling technique

Purposive sampling was employed to select 20 adolescents and young adults living with HIV, aged 13 to 24 years, for this study. The sample was stratified by age, gender, and previous participation in a clinical trial to ensure diversity and capture a range of perspectives. These strata were chosen to explore potential differences in experiences and attitudes that may be influenced by these factors.

According to(Braun & Clarke, 2016), qualitative research studies typically require a minimum of 12 participants to reach data saturation. Based on this guideline and study's focus on diverse subgroups, a sample size of 20 was deemed sufficient for the qualitative analysis. This size allowed for the rich exploration of the research question while remaining manageable within the study's scope.

3.6 Data collection methods

Data was collected using 10 semi-structured in-depth interviews (IDIs) and 2 focus group discussions (FGDs) to provide a comprehensive understanding of participants' experiences and perspectives.

Semi-structured interviews were conducted in a private setting to ensure confidentiality. An interview guide with open-ended questions explored participants 'knowledge, attitudes, and beliefs about clinical trials, their health care experiences, and factors influencing their decision to participate. The guide was developed to cover these topics comprehensively and was piloted to ensure clarity and relevance.

In addition to the in-depth interviews (IDIs), two focus group discussions (FGDs) were conducted, each comprising five participants. One FGD included female adolescents and young adults living with HIV (ALYAHIV) aged 13–15 years, while the other involved male participants of the same age group. These FGDs explored group dynamics and shared experiences, helping to identify common themes and contrasting perspectives. All interviews and focus groups were audio-recorded with participants consent and transcribed verbatim. Field notes were taken during and after the interviews to capture non-verbal cues and contextual details. These notes were analysed alongside the interview and focus group data to provide a richer understanding of the findings.

In this study, younger participants were engaged through focus group discussions (FGDs), while older participants took part in in-depth interviews (IDIs). This decision was based on preliminary observations from previous studies (Gibson, F. 2007) indicating that younger participants were less articulate and forthcoming in one-on-one interviews but communicated more effectively in group settings.

3.7 Quality control

To enhance the reliability, credibility, and trustworthiness of the study, the following methods were employed:

Triangulation: Used multiple data collection methods, including in-depth interviews (IDIs) and focus group discussions (FGDs), to cross-check and validate findings from different perspectives.

Peer Debriefing: Engaged with research peers for feedback and to identify potential biases or gaps in the analysis.

Member Checking: Presented findings to participants for feedback, allowing them to confirm the accuracy and resonance of the results.

Reflexivity: Continuously reflected on my role, biases, and influence on the research process, maintaining a reflective journal throughout the study.

These strategies were applied to ensure the study's rigor and to confirm the accuracy and validity of the findings.

3.8 Data analysis

Thematic analysis was used to identify, analyse, and report patterns(themes) within the qualitative data. The analysis process involved familiarization with the data, generating initial codes, searching for themes, reviewing the themes, defining and naming the themes. A codebook was developed from the initial readings of the transcripts. Two independent coders analysed the data to enhance reliability and NVivo 14 software was used for organizing and coding the qualitative data.

3.9 Ethical considerations

The study sought ethical approval from the Uganda Christian University Research and Ethics committee in Uganda. The study also sought administrative approval from JCRC where the study was conducted.

Informed consent was obtained from all participants aged 18 and above. For participants under 18, both assent and parental or guardian consent was secured. Participants were provided with clear information about the study's purpose, procedures, potential risks, and benefits, as well as their right to withdraw at any time without consequences. This information was conveyed through written

consent forms and verbal explanations, tailored to be age-appropriate and comprehensible.

To ensure confidentiality, all data was anonymised, with identifiable information removed from transcripts. Data was securely stored in password-protected and encrypted files, with access limited to the research team.

3.10 Limitations of the study

This study's findings are not representative due to the small, non random sample size, which makes findings not generalizable to all adolescents living with HIV.

3.11 Dissemination plans

The findings will be submitted for publication in peer-reviewed journals specializing in HIV, adolescent health, or public health. Potential target journals include The Lancet HIV, AIDS and Behavior, and Journal of Adolescent Health.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter presents the findings of the in-depth interviews (IDIs) and Focus group discussions (FGD's) conducted with adolescents and young adults living with HIV in a suburban area of Kampala, Uganda. The analysis explores participants' knowledge and awareness of HIV/AIDS clinical trials, attitudes toward participation, barriers and facilitators, and personal experiences with clinical trials. The themes identified are based on the responses collected from the IDI's and FGD's, with a focus on how perceptions and attitudes influence clinical trial participation among young people living with HIV.

4.1 Socio demographic characteristics of study participants

A total of 20 adolescents and young adults living with HIV (AYALHIV) were interviewed for this study, including 10 in-depth interviews (IDI's) and two focus group discussions (FGD's). Of the 20 participants, 10 were female and 10 were male, spanning different age groups from 13 to 24 years. All participants were perinatally infected with HIV (mother-to-child transmission), with most having been diagnosed during childhood or early adolescence and were receiving HIV treatment.

All participants had attained at least a primary level of education, while a smaller number were attending or had completed secondary or tertiary education. Six participants were employed in part-time jobs, while the rest were either still in school or unemployed. Additionally, the majority (12) of AYALHIV (Adolescents and

Young Adults Living with HIV) were participating in a randomized, open-label, two-arm HIV/AIDS clinical trial on long-acting injectable ART (LATA) at JCRC, while 8 had no prior clinical trial experience. Table 1 describes the socio demographic characteristics of the study participants.

Table 1: AYALHIV socio demographic characteristics

Characteristics		
	IDIs	**FGDs**
Mean age	18.8	14.6
Age range	16 - 24	13 -15
Age group		
13-15	0	10
16-24	10	0
Education level		
None	0	0
Primary	6	7
Secondary	3	2
Post-Secondary/Vocational	1	1
Gender		
Male	5	5
Female	5	5
Mode of HIV infection		
Perinatal/vertical (Mother-to-child)	10	10
Behavioural/horizontal	0	0
Other	0	0
Participation in an HIV/AIDS clinical trial		
Yes	7	5
No	3	5
Aware of their HIV/AIDS positive status		
Yes	10	10
No	0	0

4.2 Knowledge and Awareness of HIV/AIDS Clinical Trials

4.2.1 Awareness and sources of information

Most (15/20) participants had a basic awareness of HIV/AIDS clinical trials, although the depth of their knowledge varied. Health care providers were the primary source of information, typically when participants were invited to join a clinical trial as one 19-year-old male explained:

“I *first heard about the trial when the doctor called my parent to ask if I could join*”.(Participant 004,19-year-old Male, IDI)

Others learned about trials informally from friends or peers involved in clinical research, though their understanding of the processes remained limited. For instance, a 16-year-old-female noted:

"*I heard about the trials from my friend who told me about the HIV injection treatment she was getting in a certain study*."(Participant 010,16-year-old female, IDI)

4.2.2 Understanding of the purpose of clinical trials

While participants generally understood that the purpose of clinical trials was to test new treatments for HIV, their understanding was often vague, as one participant explained:

“I *think they want to find new ways to treat HIV so that it is easier for us to manage the disease”* (Participant 001,16-year-old male, IDI).

Some could not distinguish between their routine HIV treatment and clinical trials. One participant mentioned:

“I didn’t really understand that trials were different from my regular treatment” (Participant 003,19-year-old female, IDI).

Although there was a basic level of awareness, the technical details and phases of trials were not well understood by most participants.

4.3 Attitudes Toward HIV/AIDS Clinical Trials

4.3.1 Positive Attitudes and optimism

Several (12/20) participants expressed a positive outlook toward participation in clinical trials, viewing them as opportunities to access new and potentially better treatments. Many expressed hope that new treatments tested in these trials could lead to improved health outcomes and possibly contribute to finding a cure for HIV. A 13-year-old female participant shared her optimism about their involvement in a trial, stating:

"*I joined the trial because I have hope that they will find a cure for HIV since they have come up with this (long-acting) injection.*"(Participant 015,13-year-old female, FGD)

4.3.2 Concerns about safety and trust

Despite the general positivity, some participants expressed concerns about the safety of the experimental or clinical trial treatments, particularly the possibility of side effects. Participants shared fears about unknown reactions to the trial medications, especially those who had limited experience with the injections or new medications as one participant stated:

"*I was worried about how the injections would affect me. The first one was very painful*" (Participant 002,19-year-old-female, IDI).

This concern was more pronounced among those who had previously experienced unpleasant side effects from their regular HIV treatment.

Additionally, few participants expressed a degree of mistrust toward the research process, particularly when they lacked a clear understanding about what the trial involved like the regular blood tests. For example, one participant shared:

"I *didn't really understand why they needed to take blood so often, and that made me uneasy*" (Participant 005,16-year-old-female, IDI).

This suggests that the lack of detailed comprehension can lead to apprehension and decreased willingness to participate.

4.3.3 Concerns about privacy

Participants were also concerned about privacy, particularly in relation to HIV stigma in their communities. A 14-year-old explained:

"I *didn't want people to know that I'm part of the clinical trial. They might start asking why I'm always going to the clinic since the trial requires us to attend the clinic every 8 weeks.*" (Participant 014,14-year-old-male, FGD)

Privacy concerns were particularly significant among younger participants still in school, where stigma could impact their social interactions. Similarly, those who were employed feared being fired if their HIV status were disclosed.

4.4. Barriers to participation in HIV/AIDS clinical trials

4.4.1 Fear of side effects

One of the most cited barriers was the fear of side effects from clinical trial (experimental) drugs. Some participants experienced physical pain, that sometimes even disrupted normal routines during their participation in the trial, particularly from the long-acting injectable ART as a participant remarked:

"*The first time I got the injection; I felt pain for almost a week. It was so painful that I was limping, but after a while, I got used to it*" (Participant 007,19-year-old-male, IDI).

This fear of pain was also a deterrent for participants who had never received injections as part of their HIV treatment.

4.4.2 Logistical challenges

Several participants mentioned that logistical issues, such as transportation to the clinic or time commitment to attend scheduled trial clinic visits, were significant barriers to participation. Although the clinical trial provided reimbursement for transport, clinic visits disrupted school or work schedules for some of the participants as one commented:

"It's hard to leave school and come to the clinic, especially when the teachers ask questions about why I am going to the hospital all the time"(Participant 002,19-year-old-female,IDI).

4.4.3 Social stigma and fear of disclosure

The fear of being exposed as persons living with HIV also emerged as a barrier for many participants, particularly adolescents who were concerned about the reactions of their peers. A 13-year-old participant shared her anxiety:

"if someone at school finds out that I have HIV, they will talk about it, and that's scary."

This fear was compounded by the fact that trial participation often required attending clinic visits, which would raise suspicion among peers and family members.

4.5 Facilitators of participation in HIV/AIDS clinical trials

4.5.1 Family and peer support

Family and peer support played a crucial role in influencing participants' decisions to participate in clinical trials. Participants who discussed the clinical trials with their parents or siblings reported feeling more confident in their decision to participate. A participant explained:

"My parents supported me in joining the trial, and that gave me the confidence to go ahead with it"(12-year-old male).

4.5.2 Access to Information and Counseling

Participants highlighted the importance of receiving more comprehensive information about clinical trials, including details about the risks and benefits of participation. As one participant put it:

"If they explained better what the trial is about and how it can help, I think more young people like me would join"(16-year-old-male).

Participants expressed that clear, transparent communication would make them feel more confident about participating in trials.

4.5.3 Incentives and Financial Support

Several participants mentioned that financial incentives, such as transport refunds or compensation for time spent attending the clinic, would encourage participation. A participant shared:

"The transport refund is really helpful; it makes it easier to come for the injections"(19-year-old-female).

4.5.4 Altruism and sense of hope

Some participants viewed clinical trials as a source of hope for the future. This hope was tied both to the potential discovery of a cure and to contributing to the broader fight against HIV/AIDS, which motivated them to participate. One male participant, aged 19, expressed this sentiment saying:

"I feel like being in this trial is helping researchers find a cure, and this will be helpful for others like me(living with HIV).

This altruistic perspective was particularly evident among older participants who were more aware of the impact of research.

4.6 Conclusion of findings

Overall, the study found that adolescents and young adults living with HIV in suburban Kampala have varying levels of awareness and understanding of HIV/AIDS clinical trials. While many participants viewed trials as opportunities to access better treatments and contribute to finding a cure, concerns about safety, side effects, and logistical barriers deterred participation. Improved communication, transparent information, and logistical support could facilitate greater involvement in future trials.

CHAPTER FIVE

Discussion and Recommendations

5.0 Introduction:

The findings of this study highlight important insights regarding the perceptions and attitudes of adolescents and young adults living with HIV (AYALHIV) toward participation in HIV/AIDS clinical trials in suburban Kampala. This discussion integrates these findings with existing literature on the topic, providing a broader context and offering potential explanations for the observed trends.

Awareness and Knowledge of HIV/AIDS Clinical Trials

The study found that while a majority of participants were aware of clinical trials, their understanding was often limited or superficial. Participants primarily learned about clinical trials only when approached by healthcare providers to participate, and some relied on peers. This aligns with previous research that emphasizes the lack of information available to young people regarding clinical trials (Anderson et al., 2018).

Similarly, Brown et al. (2025) highlighted that adolescents often lack exposure to information about clinical research unless they are directly invited to participate. Additionally, some participants confused clinical trial participation with routine HIV care, suggesting a significant gap in understanding research concepts. This supports Nalubega and Evans (2015), who emphasized that poor comprehension of research processes can act as a barrier to participation. Such misconceptions may stem from inadequate or unclear communication from healthcare providers, as well as low health literacy levels among AYALHIV. As Castelnuovo et al. (2014)

noted, simplifying research information and utilizing multimedia tools can help bridge the information gap and make clinical research more accessible to young populations.

Educational strategies tailored to adolescents are thus crucial. These should include age-appropriate, culturally sensitive communication delivered through trusted sources, including peers, community health workers, and social media platforms. According to Frances Ndyetukira et al. (2019), community-based health education campaigns have proven effective in raising awareness and correcting misconceptions about research participation in sub-Saharan Africa.

Barriers to Participation

Several barriers to participation in HIV/AIDS clinical trials were identified, including fear of side effects, logistical challenges, and concerns about privacy due to stigma. The fear of side effects was particularly pronounced, especially regarding injectable treatments, and reflects findings in other studies where young participants express concerns about unknown adverse reactions (Ssali et al., 2015). This shows that uncertainty about risk of harm significantly influences decisions to participate in clinical research.

The logistical barriers, such as transportation issues and time commitments, mirror challenges highlighted in studies conducted in other low-income settings (DiClemente et al., 2010), suggesting the need for context-specific interventions, such as providing transportation support of offering flexible trial schedules to accommodate participants' needs.

Furthermore, stigma associated with HIV, which leads to fear of disclosure, remains a significant barrier, especially for adolescents who face social and peer pressure, as seen in Newman et al. (2006) and Nyblade et al. (2011). Stigma underscores the importance of confidentiality and sensitivity in the design and communication of clinical trials.

Facilitators of Participation

Despite these barriers, the study identified key facilitators that could encourage participation in clinical trials. Family and peer support played a crucial role, with participants more likely to join trials if they had a strong support network. This finding is consistent with previous research emphasizing the importance of trust and support systems in facilitating trial participation (Hall et al., 2001). Additionally, the provision of clear, transparent information about trials was seen as essential, supporting findings from other studies that suggest that effective communication can empower young people to make informed decisions (Cowdery et al., 2019).

Altruism and a sense of contributing to the broader fight against HIV/AIDS were also powerful motivators, especially among older participants. This mirrors previous literature where participants view clinical trials as an opportunity to contribute to finding a cure and helping their community (Anastasi et al., 2024). Lastly, the provision of logistical support, such as transportation reimbursement, was highlighted as a facilitator, emphasizing the importance of addressing practical barriers to participation (Cowdery et al., 2019).

Recommendations

Based on the findings of this study, several recommendations can be made to enhance participation of AYALHIV in clinical trials:

1. Health care providers and researchers should implement comprehensive education campaigns aimed at adolescents and young adults to improve their awareness and understanding of HIV/AIDS clinical trials. These campaigns should provide clear, accessible information on the differences between clinical trials and regular HIV treatment, the purpose of trials, and the potential benefits of participating. By enhancing education, participants will be better equipped to make informed decisions about their involvement, reducing misconceptions and ensuring that they understand the processes involved in clinical trials.

2. Researchers and health care providers must prioritize transparent communication regarding the safety of experimental treatments in HIV/AIDS clinical trials. It is important that pre-trial counselling includes clear explanations of the potential risks, side effects, and benefits associated with trial participation. Transparent communication can build trust between participants and researchers, alleviate concerns about safety, and reduce fears related to the unknown, thereby encouraging more adolescents and young adults to participate in trials.

3.Confidentiality and privacy protections should be strengthened in clinical trials to safeguard participants' identities, particularly in communities where HIV-related stigma is prevalent. Clinical research institutions should offer discrete trial participation options for adolescents, especially those who may fear the social consequences of being identified as living with HIV. Ensuring participants' privacy can mitigate the stigma associated with HIV and encourage wider participation,

particularly among younger individuals who are more vulnerable to societal judgment.

4.To address logistical barriers, policy makers and clinical research institutions should continue offering support such as transportation reimbursement and flexible clinic scheduling to accommodate the schedules of adolescents and young adults, especially those who are in school or employed. Additionally, providing compensation for time spent attending clinical trial visits would help ease the financial burden of participation. These efforts can help reduce the practical challenges associated with trial participation, making it easier for adolescents and young adults to engage in clinical research.

5. Family and peer support plays a crucial role in facilitating adolescent and young adult participation in clinical trials. Health care providers, researchers, and family support programs should actively involve families and peers in the recruitment and decision-making process. Informational sessions for families, along with the encouragement of peer support networks, can help provide the emotional and practical support needed to increase participants' confidence and willingness to join clinical trials. By fostering a supportive environment, more young people may feel empowered to take part in HIV/AIDS research.

Conclusion

The study provides valuable insights into the perceptions and attitudes of AYALHIV toward HIV/AIDS clinical trials. While several barriers exist, such as fear of side effects, logistical challenges, and stigma, there are also significant facilitators, including family support, altruism, and the provision of logistical assistance. By

addressing these barriers and leveraging the facilitators, it is possible to enhance participation rates among this critical population, ultimately contributing to more inclusive and effective HIV research.

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APPENDICES

APPENDIX 1

Participant information sheet for a study on the Perceptions and attitudes toward HIV/AIDS clinical trial participation among adolescents and young adults living with HIV in a suburban area of Kampala, Uganda.

We invite you to take part in a research study to understand the perceptions and attitudes of adolescents and young adults living with HIV toward clinical trial participation. This study is a research project of Namukwaya Stella, a Master of Public health student, school of midwifery, nursing and public health, Uganda Christian University.

Purpose of the study

The study aims to:

1. Assess the level of awareness and knowledge about HIV/AIDS clinical trials among adolescents and young people living with HIV.

2. Identify the barriers to participation in these trials

3. Explore the facilitators that encourage participation in these trials.

Study procedures

You are invited to participate in this study because you are receiving HIV/AIDS treatment and care from JCRC and may have participated in an HIV/AIDS clinical trial there. If you agree to participate in this study, you will be asked to:

- Take part in a one-time, one on one in-depth interview or focus group discussion.

- The interview will last approximately 60 minutes
- It will be audio recorded and transcribed verbatim

Benefits

While there may not be direct benefits to you for participating, the information you provide will contribute to a better understanding of how to increase clinical trial participation among young people living with HIV/AIDS.

Risks

The study poses minimal risk. However, some questions may be sensitive or personal. You are free not to respond to any questions or to stop the interview at any point without any consequence.

Privacy and confidentiality

We will keep your study records private and confidential. The only people who will be allowed to see these records are: The research team, including the Principal Investigator and those involved with the study. I may publish what I have learnt from this study. However, I will not include your name. I will not publish anything that would let people know who you are. This study does not require you to provide your name as part of the interview. All information will be stored securely and only accessible to the research team. Audio recordings will be deleted after transcription.

Voluntary Participation / Withdrawal

Your participation is entirely voluntary. Whether or not you choose to participate will not affect your treatment or any care that you are receiving at JCRC. If you

have any questions, concerns, or complaints about this study, please contact the researcher.

APPENDIX 2

In-depth interview guide for adolescents and young adults living with HIV- English

Title: Perceptions and attitudes toward HIV/AIDS clinical trial participation among adolescents and young adults living with HIV in a suburban area of Kampala, Uganda.

Demographic Information

1. Could you please tell me a little about yourself?
    - Age
    - Gender
    - Level of education
    - Employment status (if applicable)
    - How long have you been living with HIV?

Knowledge and Awareness of HIV/AIDS Clinical Trials

2.Have you ever heard about HIV/AIDS clinical trials?

- If yes, can you tell me what you know about clinical trials?
- Where did you first hear about clinical trials?

3.Can you explain what you think the purpose of HIV/AIDS clinical trials is?

4.Have you ever been approached or invited to participate in an HIV/AIDS clinical trial?

- If yes, what information were you given about the trial?
- How did you feel when you were asked to participate?

Attitudes Toward HIV/AIDS Clinical Trials

5.What are your general thoughts or feelings about participating in an HIV/AIDS clinical trial?

6.Do you think clinical trials are important for people living with HIV? Why or why not?

7.How do you feel about being a participant in a clinical trial that might test new treatments for HIV?

8.What concerns, if any, do you have about participating in a clinical trial?

- Safety concerns?
- Privacy concerns?
- Trust in the medical team or the research process?

9.What factors would make you more willing or less willing to participate in a clinical trial?

10.What do your family or friends think about clinical trials? Have they influenced your attitude toward participation?

Barriers to Participation

11.In your opinion, what are the main reasons why young people living with HIV might not want to participate in clinical trials?

12.Have you ever refused to participate in a clinical trial? If yes, can you explain why?

13.Do you think there are any cultural or social factors that make it difficult for people in your community to participate in clinical trials?

14.Are there any logistical challenges (e.g., transportation, time commitment, distance from trial sites) that might prevent participation in clinical trials?

15.How do you feel about the communication between healthcare providers and patients regarding clinical trials?

Facilitators of Participation

16.What would encourage you or other young people living with HIV to participate in clinical trials?

- Access to information?
- Financial or other incentives?
- Reassurance about safety or privacy?

17.If you were given more information about the benefits of clinical trials, would that make you more likely to participate?

18. Are there any specific changes that you think would increase participation in clinical trials among young people living with HIV?

19.Do you think having peer support groups or discussions with other people living with HIV would make it easier to decide about participating in a clinical trial?

Personal Experiences with Clinical Trials (If Applicable)

20.Have you ever participated in an HIV/AIDS clinical trial?

- If yes, can you tell me about your experience?
- What were the positive aspects of your participation?
- Were there any challenges you faced during the trial?

21. What did you learn from your experience in the trial?

22.Would you recommend participation in clinical trials to others living with HIV? Why or why not?

Recommendations for Improving Clinical Trial Participation

23.What do you think healthcare providers or researchers can do to improve young people's willingness to participate in clinical trials?

24.How can clinical trials be made more accessible or attractive to young people living with HIV?

25. Is there anything else you would like to share about how to improve participation in HIV/AIDS clinical trials?

APPENDIX 3

Focus group discussion guide for adolescents and young adults living with HIV-English

Title: Perceptions and attitudes toward HIV/AIDS clinical trial participation among adolescents and young adults living with HIV in a suburban area of Kampala, Uganda.

Opening Discussion – General Introduction

Let's start by going around the group. Could each of you tell us your name or a nickname you'd like us to use and share something about yourself?

Age

How long have you been living with HIV?

Have you ever heard about or been involved in an HIV/AIDS clinical trial?

Knowledge and Awareness of HIV/AIDS Clinical Trials

2.What have you heard about HIV/AIDS clinical trials?

Where did you first hear about them?

Can you describe what you think happens in a clinical trial?

3.How well do you think young people in your community understand what HIV/AIDS clinical trials are?

Do you feel like there is enough information available to young people about clinical trials?

4.For those who know about clinical trials, what are the sources of this information?

Health care providers?

Media (radio, TV, social media)?

Friends or family?

Attitudes Toward HIV/AIDS Clinical Trials

5.What are your general thoughts or feelings about participating in a clinical trial for HIV/AIDS?

Does the idea of participating in a clinical trial make you feel nervous or excited? Why?

6.Do you think clinical trials are important for young people living with HIV?

Why or why not?

7.What would make someone want to participate in a trial?

8.What are some of the concerns or fears you have about participating in an HIV/AIDS clinical trial?

- Concerns about safety or side effects?
- Trust in the healthcare providers running the trial?
- Privacy or confidentiality concerns?

9.How do your friends or family feel about clinical trials?

- Have they ever shared any opinions or advice with you about participating?

Barriers to Participation

10.What are the reasons why young people like yourselves may choose *not* to participate in a clinical trial?

- Fear of side effects or unknown risks?
- Lack of trust in doctors or researchers?
- Concerns about confidentiality or stigma?

11.Do you think there are any challenges in your daily life that would make participating in a clinical trial difficult?

- Time commitment or busy schedules?
- Distance to trial centres or transportation issues?
- Concerns about missing work or school?

12.Are there cultural or social beliefs in your community that might discourage participation in clinical trials?

- How do cultural beliefs about medicine, treatment, or health affect participation?

Facilitators of Participation

13.What could encourage you to participate in an HIV/AIDS clinical trial?

Better access to information or clear explanations?

Financial compensation or other incentives (e.g., transportation or meals)?

Assurance of safety and privacy?

14.If you were more informed about the benefits of clinical trials, would you be more willing to participate?

- What kind of information would you need to feel more comfortable?

15.Do you think having a peer or support group to talk about clinical trials with would encourage more young people to participate?

- How important is hearing about other people's experiences in your decision-making?

Experiences with Clinical Trials (If Applicable)

16.For those who have participated in a clinical trial before, can you share your experience?

- What was positive about it?
- Were there any challenges or difficulties?

17.For those who haven't participated, would you consider joining a clinical trial in the future?

- What would make you more likely to participate?
- What would hold you back?

Recommendations for Improving Participation

18.What do you think could be done to make more young people like yourselves interested in participating in clinical trials?

- What kind of support or resources would be helpful?
- How could healthcare providers improve the way they talk about clinical trials?

19.What role do you think the government, health institutions, or community leaders should play in encouraging participation in clinical trials?

- Should there be more education and awareness campaigns?

Closing Questions and Wrap-Up

20.Is there anything else you would like to share about your thoughts or experiences with HIV/AIDS clinical trials?

21.If you had the chance to speak directly to researchers, what would you tell them about how to make clinical trials better for young people living with HIV?

APPENDIX 4

UCU REC Approval letter

UGANDA CHRISTIAN UNIVERSITY
A Centre of Excellence in the Heart of Africa

Office of the Vice Chancellor
Research Ethics Committee UG-026

03rd December, 2024

STELLA NAMUKWAYA
Uganda Christian University
0701197717
Email: winniemukwaya@yahoo.co.uk

UG-REC-026 APPROVAL NOTICE

To: Stella Namukwaya, Principal Investigator

Re: UCU-REC Application titled: *Perceptions And Attitudes Toward Participation In HIV/AIDS Clinical Trials Among Adolescents And Young Adults Living With HIV In A Suburban Area Of Kampala, Uganda.*

Application Number: **UCUREC-2024-1120**

Version: 4.1

UGANDA CHRISTIAN UNIVERSITY APPROVED UNTIL 03 DEC 2025 RESEARCH ETHICS COMMITTEE

Type: [ ] **INITIAL REVIEW**
[ ] Protocol Amendment
[ ] Letter of Amendment (Loa)
[ ] Continuing Review
[ ] Material Transfer Agreement
[ ] Other, Specify:

I am pleased to inform you that the **UG-REC-026;** UCUREC approved the above referenced application.

Approval of the research is for the period from **03rd December, 2024**, to 03rd **December, 2025**
This research is considered minimal risk category.
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 additions 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. The REC application number assigned to the research should be cited in any correspondence.

Research and Ethics
P.O. Box 4, Mukono, Uganda, Plot 67-173, Bishop Tucker Road, Mukono Hill
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UCUREC is accredited by Uganda National Council for Science & Technology, FDA, and National Institutes for Health of the United States of America

3. Reports of unanticipated problems involving risks to participants or other must be submitted to the REC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for REC review.

4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects 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. Regulations require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the REC eight weeks prior to the above expiration date of 03rd December, 2025 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, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. Your research details have been shared with the Executive secretary of Uganda National Council for Science and Technology (UNCST) and you are **not** required to get clearance since you are a Master's Degree research. Refer to UNCST Research registration and clearance Policy and guidelines (July 2016) in Uganda section 6(e).

The following is the list of all documents approved in this application by **UG-REC _026:**

	Document Title	Language	Version	Version Date
1.	Protocol	English	1.0	2024-11-15
2	Focus Group Discussion Guide	English	1.0	2024-11-15
3	Informed Consent Form	English	1.0	2024-11-15
4	Interview Guide	English	1.0	2024-11-15
5	Assent forms	English	1.0	2024-11-15
6	Risk Mitigation Plan	English	1.0	2024-11-15

Signed and Stamped

.....

Prof. Peter Waiswa.
UCUREC Chairperson,
pwaiswa@musph.ac.ug

UGANDA CHRISTIAN UNIVERSITY APPROVED 03 DEC 2025 RESEARCH ETHICS COMMITTEE

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UCUREC is accredited by Uganda National Council for Science & Technology, FDA, and National Institutes for Health of the United States of America

APPENDIX 5

Work Plan / Timeline

Activities	**October**	**November**	**December**	**January**
Proposal Development	■	■		
Approvals		■		
Data collection			■	
Data analysis			■	■
Results presentation / dissemination				■

APPENDIX 6

Budget

Budget Item	**Unit cost (Shs)**	**Amount (Shs)**	**Justification**
Data collection: Material and Supplies:			
1 ream of Papers	50,000	50.000	Research instruments, consents, & information sheet
Pens, batteries	50,000	50,000	Pens for writing and batteries for the audio-recorder
Audio-digital recorder	350,000	350,000	Recorder for capturing audios from the participants
Research assistants (RA)	450,000	900,000	2-research assistants' allowance for one month
Training of RA	50,000	100,000	2-days training; refreshments and transport refund
Travel costs	20, 000	300,000	Travel cost to the site for at least one month
Compensation fee	10000	300000	Participant's compensation for taking part in the study
Data analysis:			
Consultation services	500,000	500,000	Qualitative expert consultation regarding analysis
Report writing			
Dissertation reports	50,000	100,000	Two books; for the library and department
Publication			
Dissemination	300,000	300,000	Conference hall booking and refreshments
Miscellaneous	250,000	250,000	for any other unexpected expenses
GRAND TOTAL			**UGX: 3,500,000**

UGANDA CHRISTIAN UNIVERSITY

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DISSERTATION CORRECTION COMPLIANCE REPORT BY THE CANDIDATE (POST VIVA FORM)

Date: 11/04/2025

Name of Candidate: Namukwaya Stella Winnie **Reg. No:** RJ22M21011

Title of Dissertation:

PERCEPTIONS AND ATTITUDES TOWARD PARTICIPATION IN HIV/AIDS CLINICAL TRIALS AMONG ADOLESCENTS AND YOUNG ADULTS LIVING WITH HIV IN A SUBURBAN AREA OF KAMPALA, UGANDA.

SN	COMMENTS BY EXTERNAL EXAMINER	ACTION TAKEN	INDICATOR
1	INCLUDE THE APPROPRIATE LITERATURE ON PAGE 8 OF REPORT. The appropriate literature should have been, "Ministry of Health, Uganda. Uganda Population-based HIV Impact Assessment (UPHIA) 2016-2017: Final Report. Kampala: Ministry of Health; July 2019".	The appropriate literature recommended — Ministry of Health, Uganda. Uganda Population-based HIV Impact Assessment (UPHIA) 2016–2017: Final Report. Kampala: Ministry of Health; July 2019 — has been included on page 8 of the report, in the section discussing national HIV statistics.	The citation has been inserted both in-text as (Ministry of Health, Uganda, 2019) and added to the reference list in APA format. Page 8
2	REVIEW CITATIONS OF LITERATURE	I reviewed all citations in the literature review section to ensure accuracy, relevance, and consistency with the required referencing style (APA 7th edition).	Updated and correctly formatted citations are reflected throughout the literature review section. Pages 34-38
3	DESCRIBE THE COMPOSITION OF THE FOCUS GROUP DISCUSSIONS	The composition of the focus group discussions was described, including the number of participants in each group, their gender, age range, and HIV status.	A clear description of the focus group composition is now included in the Methodology section, under the subsection "Data collection methods." Page 17
4	INCLUDE ANY ISSUES RELATED TO NON-RESPONSE OR PARTICIPATION IN THE STUDY	The issues related to non-response and participation have been addressed by describing the reasons for non-	A description of non-response and participation issues, along with the non-response rate, has been

		participation, including guardians' busy schedules and participants being in school during recruitment. The non-response rate and its impact on the study sample were also discussed.	added to the Study Population section of the Methodology. Pages 15 and 16
5	DESCRIBE DISSEMINATION PLANS	The dissemination plan has been described and focuses on publishing the study's findings in peer-reviewed journals. The target journals for submission have been identified.	A dissemination plan for publishing the study's findings in peer-reviewed journals has been added to the dissertation. Page 9
6	EXPLAIN RATIONALE FOR HAVING YOUNGER PARTICIPANTS IN FGD's AND OLDER ONES IN THE IDI's IN THE METHODS SECTION	Rationale for selecting FGDs for younger participants and IDIs for older participants was added to the methods section, highlighting differences in communication preferences and comfort levels. A supporting citation from Gibson (2007) was included to justify this methodological decision.	The revised methods section includes a clear explanation that younger participants were more expressive in FGDs, while older participants were better suited for IDIs due to their ability to articulate personal experiences in one-on-one settings. This rationale is supported by a citation from Gibson (2007). Page 17
7	ADD TO THE DISCUSSION SECTION WHERE BRIEF AND ENSURE THAT ALL FINDINGS ARE DISCUSSED	The discussion section has been revised to provide a more comprehensive analysis of the study findings.	An expanded discussion section that includes detailed interpretation of all study findings, supported by relevant

			literature and linked to the study objectives

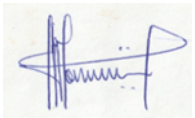
SN	COMMENTS BY INTERNAL EXAMINER	ACTION TAKEN	INDICATOR
1	THE OBJECTIVES ARE NOT WELL ALIGNED WITH THE RESEARCH DESIGN APPLIED.	I rephrased the specific objective 1 to ensure that it aligns with the qualitative nature of the study. The previous wording suggested a quantitative approach, and this was revised to reflect an exploratory focus consistent with qualitative research	The rephrased specific objective is now clearly qualitative, using wording that aligns with the study's qualitative methodology. Page 6
2	THE KNOWLEDGE GAP IS NOT CLEARLY SPELT OUT	The Statement of the Problem was revised to clearly articulate the knowledge gap by explicitly stating that there is a paucity of research on the perceptions and attitudes of Adolescents and Young Adults Living with HIV (AYALHIV) in Uganda toward participation in HIV clinical trials. The revised text also clarifies that existing studies focus mainly on general barriers such as stigma and misinformation, with limited attention to AYALHIV's specific perspectives and contextual influences in Uganda.	The revised Statement of the Problem now includes a clearly defined knowledge gap that justifies the need for the study. Pages 4 and 5

3	THE QUOTES NEED TO BE CODED FOR EASY IDENTIFICATION & ENSURE TO EXHAUST THE FINDINGS FOR EACH QUESTION	The quotes have been coded for easy identification and findings for each question have been exhausted	Quotes now clearly show the participant who said what, with their age, gender and whether it was in the FGD or IDI. Pages 21 to 27
4	EXPLORE MORE RELATED LITERATURE FOR EACH THEME TO HAVE A BALANCED DISCUSSION	The discussion section has been revised to include additional scholarly literature relevant to each theme.	Each theme in the discussion section now includes multiple references to related literature
5	RECOMMENDATIONS ARE NOT DIRECTED TO ANY SPECIFIC OFFICE/POSITION	The recommendations have been revised to ensure that each one is clearly directed to the appropriate office, position, or stakeholder group. This includes addressing recommendations to health care providers, researchers, policy makers, clinical research institutions, and other relevant parties involved in HIV/AIDS clinical trials.	The recommendations are directed to specific offices or positions: health care providers, researchers, clinical research institutions, policy makers, and family support programs. Pages 31 and 32

SN	**COMMENTS BY VIVA VOCE PANNEL**	**ACTION TAKEN**	**INDICATOR**
1	INCLUDE QUALITATIVE QUALITY CONTROL MEASURES	I added a section on qualitative quality control, to the dissertation outlining strategies such as triangulation, peer debriefing, member checking, and reflexivity. These measures were incorporated to enhance the study's credibility,	A dedicated section on qualitative quality control has been added. Pages 17 and 18

		dependability, and trustworthiness, ensuring rigor in the data collection and analysis	
2	ALIGN OBJECTIVES WITH THE STUDY METHOD	I rephrased the specific objective 1 to align with qualitative research methods used in the study, ensuring a focus on exploring perceptions and understanding rather than quantifying data.	Specific objective 1 has been rephrased to reflect qualitative approach. Page 6
3	REALIGN RECOMMENDATIONS WITH FINDINGS	I carefully reviewed the findings of the study and ensured that each recommendation directly addressed the key barriers, facilitators, and perceptions identified in the data. I adjusted the recommendations to reflect the specific concerns and needs highlighted by participants, such as the need for clearer communication, better logistical support, and addressing privacy concerns.	The recommendations are now more closely tied to the study's findings, with clear links to the specific issues raised by participants. Pages 31 and 32
4	INCLUDE A THEORETICAL FRAMEWORK TO GUIDE THE STUDY	The Social Ecological Model (SEM) was included as the theoretical framework guiding the study. A detailed explanation of the model was added, along with a narrative describing how it informed the development of the conceptual framework.	Theoretical framework section updated to include the Social Ecological Model. Pages 9 and 10

Namukwaya Stella Winnie — **Candidate's Name** — **Signature**



Dr. Nareeba Peter — **Supervisor's Name** — **Signature**