MASTER OF MEDICINE – PSYCHIATRY

Title

The effects of sexual trauma, intimate partner violence (IPV) and mental health on early versus late antiretroviral therapy (ART) initiation amongst women in South Africa

In partial fulfilment of the requirements for the degree Master of Medicine – Psychiatry

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DECLARATION

I, Charles Gerald Crookes, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

This work has not been reported or published prior to registration for the above-mentioned degree.

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Signed by candidate

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Dr Charles Gerald Crookes

Date: 08/05/2023

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To my supervisors, Professor John Joska and Dr Stephan Rabie, goes much thanks and appreciation for their support in developing this research dissertation.

Gratitude also extended to the teams assisting with data collection and to the participants involved in the study.

Thanks to my parents David and Alvera, who have always supported my dreams.

To my family, Nicole and our children Summer, Cassian, Lincoln and Alaska your love, smiles and laughter make it all worthwhile, thank you.

FORMAT

Publication Ready Manuscript

INSTRUCTION TO AUTHORS

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Aids and Behavior

Journal Instructions

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CONTRIBUTIONS OF AUTHORS

This study was conceptualized and formulated after discussions with Professor John Joska around neuropsychiatry, HIV and mental health. Professor Joska was the principal investigator in this project. The research proposal and protocol were designed and formulated by Dr Charles Crookes with support of the supervisors Professor John Joska and Dr Stephan Rabie. The protocol was reviewed by Dr Adele Marais and Dr Claire Van Der Westhuizen. Dr Charles Crookes was the main author for the manuscript. The authors all assisted with contributions towards the manuscript and data analysis. This manuscript went through the department of psychiatry's research committee for approval prior to submission of this document.

The study acknowledges research contributions from the parent study. The focus of which is to establish interventions that are evidence-based to address the problems of HIV and sexual trauma. The parent study title is:

"A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa".

The parent study aims to evaluate the effectiveness of ImpACT+ (*Improving AIDS Care After Trauma*), an intervention trial, directed at improving individual outcomes and aspects of the HIV care cascade, including viral suppression.

This research acknowledges all the contributions from the parent study. These include all aspects from project initiation to data collection.

STUDY INTENTIONS

The intention of this study is to advance knowledge relating to the prevalence of sexual trauma and IPV in women in Khayelitsha, South Africa. The study seeks to improve mental health and HIV care of women in South Africa and to advance knowledge regarding variables impacting on HIV care.

The data analysis and report form the basis for my Masters in Medicine dissertation in Psychiatry. This in partial fulfilment of the requirements for the degree Master of Medicine in Psychiatry.

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ABBREVIATIONS

ART	Antiretroviral Therapy
IPV	Intimate Partner Violence
PTSD	Post-Traumatic Stress Disorder
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
HAART	Highly Active Antiretroviral Therapy
PHC	Primary Healthcare Centre
ANC	Antenatal Care
GBV	Gender Based Violence
SDI	Same-Day-Initiation
UTT	Universal Test and Treat
RCT	Randomized Controlled Trial
HREC	Human Research Ethics Committee
PLWH	People living with HIV
WLWH	Women living with HIV
PHQ-2	Patient Health Questionnaire – 2
CTS	Conflict Tactics Scale Questionnaire

CD4	CD4 Lymphocyte cell count
ABUSE	Sexual Abuse Questionnaire
MINI	Suicidality Screening Questionnaire
REDCap	Research Electronic Data Capture
SPSS 27	Statistical Package for Social Sciences 27
WHO	World Health Organization

ABSTRACT

Word Count: 499

BACKGROUND

South Africa carries the greatest global burden of HIV and has the largest antiretroviral therapy (ART) program. Women, however, are at greater risk of acquiring HIV, and form the greatest proportion of people living with HIV (PLWH) in the country. Women are also exposed to high rates of intimate partner violence (IPV) and sexual trauma, which may impact on the ability to accept their HIV diagnosis, enter HIV care, and commence ART. This is key to achieving the UNAIDS 95-95-95 goals. Little is known about how sexual trauma may impact this care continuum and ultimately result in a delay in ART initiation. This study sought to explore this gap in care engagement to understand demographic, trauma and mental health variables that may impact on HIV care in South Africa.

OBJECTIVES

This study had two objectives. Firstly, to determine the prevalence of physical and sexual IPV, sexual trauma and mental health symptoms in a sample of women initiating ART at two primary healthcare facilities in Khayelitsha, Cape Town. Secondly, to investigate associations between socio-demographics, sexual trauma and mental health variables on ART initiation times.

METHODS

This study used data from participants screening into a larger RCT of an intervention for

sexual trauma in women living with HIV (WLWH). This study incorporated a cross-sectional data analytic design. Electronically administered surveys collected data on demographics (age and pregnancy status), sexual trauma, physical and sexual IPV, mental health symptoms (depression, PTSD and suicidality). The outcome of interest included firstly the intention to determine the prevalence of trauma experiences and mental health symptoms in this sample of women initiating ART at two primary health care facilities in Khayelitsha. Secondly, to investigate for associations of significance between the demographic, trauma and mental health variables on ART initiation times. Early initiation was defined as ART commencement within 21 days from HIV diagnosis and late was after 21 days from diagnosis.

RESULTS

In total, 170 participants were included in this study. The mean age of participants was 30.65 (SD = 8.7). Most of the participants (80%) were initiated on ART early. Lifetime sexual trauma was reported by 38,2 % (n = 65). More than half the participants reported physical and or sexual IPV (57%; n = 97), more than a third reported depressive symptoms (39,4%; n = 67), half reported PTSD symptoms (50%; n = 85) and acute, high risk, suicidality was noted in (4,7%; n = 9) of the participants. In both univariate and multivariate analysis, no associations between demographic, mental health variables and most notably sexual trauma with ART initiation time were found. Logistic regression also found no association with the variables when compared with early versus late ART initiation.

CONCLUSION

Despite the high prevalence of sexual trauma and lifetime physical and sexual IPV, no

association with delays to ART initiation were found. This study could have been limited by its small sample size and we recommend future studies explore the effects of the variables in broader samples and in other areas of South Africa.

KEYWORDS

Mental Health, HIV, Sexual Trauma, Antiretroviral Therapy, Post Traumatic Stress Disorder, Depression, Suicidality, Intimate Partner Violence, Psychiatry.

CHAPTER 1: BACKGROUND AND LITERATURE REVIEW

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The World Health Organization (WHO) reports that more than 38 million people were infected with HIV in 2019 worldwide [1]. Sub-Saharan Africa accounts for 61% of those newly infected, with South Africa bearing the largest HIV burden both in the region and globally [1]. Approximately 8.2 million people in South Africa are living with HIV [2,3,5] with HIV/AIDS ranking highly as one of the substantial conditions affecting global burden of disease [4,5].

South Africa carries not only the greatest prevalence of HIV but also has the largest antiretroviral therapy (ART) program [5,6]. Antiretrovirals (ARVs) were previously initiated in South Africa according to CD4 level or clinical staging of disease at presentation. In an attempt to eradicate HIV and align with WHO strategic goals, South Africa adopted the WHO Universal Test and Treat (UTT) policy in 2016, resulting in all those who test positive for HIV, being eligible to initiate ART at diagnosis [1]. Moreover, in 2017, this policy was updated with a directive to initiate all HIV positive patients on the day of their diagnosis: also known as same-day-initiation (SDI). UNAIDS (2014) indicates, in their 90-90-90 treatment targets, the importance of improving HIV diagnosis rates, initiating PLWH on treatment early, and the advantages of viral suppression in reducing community HIV transmission rates [7]. These UNAIDS targets were set in an attempt to eradicate HIV by 2020. These targets were subsequently refined to the 95-95-95 treatment goals to eradicate HIV by the year 2030 [5,7]. Extant evidence for UTT and SDI is promising – patients who initiate ART immediately after HIV diagnosis (SDI) were less likely to transmit HIV, had improved viral

suppression, and had lower rates of AIDS-related adverse events compared to patients who deferred ART [8,9].

Despite the improvements with SDI/UTT, ART coverage in South Africa remains below target with uptake of ART, among people living with HIV (PLWH), ranging in sources from 60-92% [5,7,10].

Several individual-level determinants of low rates of uptake have been reported in the literature, including stigma, male gender, difficulties with HIV disclosure [10,11,12]. There are several factors that may modify the health-seeking behaviours of individuals, including resilience, feelings of shame, embarrassment or avoidant denial [13]. There are also systemic factors that impact on initiation to ART including testing for HIV. These individual psychosocial, community and healthcare system factors may affect time to initiation on ART and include physical health, fear of medication side effects, availability of testing sites and clinic infrastructure as well as quality of service delivery at primary healthcare centres [9,12]. Distance from testing sites and financial and economic adversity as well as lack of financial security all influence ability to test for HIV. This incorporates physical distance to testing sites, unemployment, food insecurity as well as transport related costs [12,14]. Lack of information and general education regarding HIV and the importance of early ART seem to also have an impact on entry to HIV care [9,12].

The perinatal period is often a key access point for detecting and initiating pregnant WLWH on ART. Pregnant women often have more regular encounters with health care services and are frequently initiated on treatment early when compared to non-pregnant women [15,16]. It is vital to remember, however, that the greater portion of WLWH are not pregnant. Non-

pregnant women are at higher risk for delays to ART initiation with non-pregnant women being shown to initiate ART at rates comparable to those found in men [15].

WOMEN – SEXUAL TRAUMA AND HIV CARE

Women in South Africa are exposed to high rates of sexual trauma and intimate partner violence (IPV), adding an additional vulnerability to women and their risk for adverse HIV related outcomes [17,18]. In addition to the general barriers that detract from entry to HIV care, women experiencing abuse may potentially have a protracted delay on their initiation to ART.

The World Health Organisation (WHO) estimates 1 in 3 women globally (30%) have been victims, in their lifetime, of either sexual or physical violence from either an intimate partner or from non-partners [5,19]. Statistics South Africa (2020) confirms that women in South Africa face extensive levels of physical and sexual abuse [20]. Women aged 15-49 have been reported to have lifetime IPV rates of around 24%, with IPV rates of 13% in a more recent 12-month period [19]. Studies also suggest that South African women are at greater risk of HIV and form the greatest proportion of PLWH [21]. The prevalence of HIV, in women, has been reported to be higher than that in men, with rates of over 26% described in 15-49-year-old female South Africans [2]. Women face twice the risk of contracting HIV, compared to men, and women and girls represent more than 60% of all new HIV infections in Sub-Saharan Africa [5,22].

Given the significant trauma statistics, reported in South Africa, gender-based violence (GBV) with physical and sexual abuse is of significant concern. Assaults, in 50% of cases were mostly experienced from someone well known or close to the person abused [20]. The level of violence women experienced was higher in those whose education level was lower

[20]. Those with completed primary education levels ranged around 30.7% for physical violence versus those above secondary education with rates at 12.4% [20]. The higher the income the lower the prevalence of violence both physical and sexual [20]. The level of violence women experienced was higher in those whose education level was lower with physical violence rates of 29% and sexual violence rates of 8% [20]. This was significantly reduced in higher wealth categories where less than half the rates of physical and sexual violence are described [20].

The implication of the high trauma rates, globally and locally, may translate to significant mental health barriers that could impress on initiation times to ART. It is presumed that women exposed to sexual trauma are likely to experience difficulty in accepting their HIV diagnosis [23]. This may further detract from their ability to initiate ART and continue their involvement in HIV care. Those with IPV or sexual trauma are more at risk of HIV, less likely to test for HIV and subsequently have delayed ART initiation times with increased rates of community transmission [23,24]. Women with lifetime exposure to physical or sexual abuse were also 1.5 times more likely to report not using ART [25]. This may have high relevance to HIV care outcomes, in South Africa, as women who are abused may experience more mental health difficulties as a result. Mental health symptoms might create challenges affecting any step of the HIV care cascade [45].

The HIV care cascade encompasses a number of important aspects including testing for HIV, being linked to HIV care, initiation on treatment, retention in care and viral suppression, once on treatment [26]. Much of the HIV care cascade in South Africa has been improved and simplified with UTT and SDI, yet concerning data indicates that only around 65% of South

African women living with HIV (WLWH) are retained in care and less than 66% are virally suppressed [3,5].

These drop-offs in the care cascade present a major barrier in improving care engagement and reducing transmission to others. Many of the factors that are barriers to testing for HIV and engagement in HIV care are also factors that affect adherence and retention in care. Adherence and retention are separate issues that should be considered as they have varying levels of bearing on the HIV care cascade and UNAIDS treatment goals. This may be especially important in the particularly at-risk group of women, exposed to sexual trauma and diagnosed with HIV.

TRAUMA AND MENTAL HEALTH

South African women often have difficulty disclosing their HIV status as this generates a fear of violence. Violence has been shown to have an effect on disclosure rates for individuals with HIV, where some studies reveal non-disclosure prevalence approximating 60% [27]. This may be especially difficult for women dependent on an intimate partner, where non-disclosure relates more to fears of abandonment and fear of partner abuse [28]. This ties in with the financial dependency that some women face in order to have stability and security [14,27,29].

Expanding literature broadens the understanding of a relationship between poverty, co-dependency with male partners and increased rates of gender inequality and intimate partner violence (IPV) [30,31,32,33,34]. This evidence demonstrates clear links between poverty and intimate partner violence (IPV) as well as how IPV perpetuates poverty states. This is further described in the links between male-controlled sexual decision-making power, increased male sexual dominance and sexual risk practices [30]. The levels of dependency and sexual

trauma women face, in areas of South Africa, might explain the higher prevalence of HIV in women and possibly some of the delays to ART [30,35]. In contrast, HIV has at times been described as one of the main factors that forced women to remain in violent relationships [36]. Initiating ART may be reduced as a result of this fear of violence [17,25,28].

Women who experience sexual trauma may face further complex emotions that impact on their entry times to ART. These range from fears of being blamed for having encouraged the abuse [23]. These added to feelings of a loss of trust in relationships [23]. Loss of trust, following sexual abuse, may have parallels that extend further to cognitive avoidance with regards to trusting healthcare systems, care providers and may cause delays to ART initiation. Women exposed to sexual trauma described at times feeling worried about being judged if they disclosed the sexual trauma [23]. Their apprehensions appear to relate mostly to stigma [23]. Stigma related to HIV is already a significant barrier to testing for HIV and initiating treatment, however, the two-fold stigma related to HIV and the disclosure of sexual trauma may compound the delay to ART initiation. These could be particularly significant in those exposed to IPV and or sexual trauma and might be major factors to be aware of in HIV care management in South Africa.

Sexual trauma itself, has been shown to be associated with a range of mental health conditions, such as post-traumatic stress disorder (PTSD), depression and suicidality – conditions that could further delay access to HIV care [23]. Sexual trauma is particularly likely to have an effect on the mental health of those infected with HIV, especially, if the transmission of HIV is as a consequence of the trauma.

Literature from Sub-Saharan Africa, suggests rates of around 1 in 4 PLWH may suffer from depression [37]. Depression is a common concern in those newly diagnosed with HIV and

there is a strong suggestion of a correlations in delays to ART, in those with symptoms of depression [38,39,40,43]. A study in Malawi, noted that the depressive symptom prevalence was 12% for a likely depressive disorder in people living with HIV and suicidality may be a symptom linked to depressive states [43]. Suicidal ideation in patients on ART and those pre-ART found that pre-ART patients were more likely to have higher rates of suicidal ideation [43]. This was significant with 20% indicated for pre-ART vs 11% for those established on ART [43]. Studies exploring the effects of depression on initiation times to ART, found approximately 25% had screened positive for mild to severe depression [37]. Evidence in HIV positive pregnant patients also suggests high prevalence of depression in HIV positive pregnant women [40]. Sexual trauma and IPV are sure to influence mental health and perhaps time to linkage with HIV care.

The literature suggests that HIV positive women with sexual trauma will also likely translate to higher prevalence of PTSD, depression and suicidality in those who experienced physical and or sexual violence [16,23,24]. These are thought to be especially elevated in those who test HIV positive following a sexually traumatic event. Those with PTSD and avoidant behaviours are less likely to engage in self-care and HIV treatment [24]. Mental health and physical health have complex interplays within the individual and may have various bearings on each other. Mental health symptoms such as PTSD have been shown to have associations with immune dysregulation; this even in those adherent to ART [3,7,43]. Mental health and physical health are sure to have associated links that influence one another. Identifying factors that contribute to delayed presentations to HIV care and initiating treatment early is likely to, therefore, improve morbidity and mortality and to reduce health care related economic costs [7].

PTSD could occur where there is a diagnosis of HIV, especially in the context of sexual trauma. A study exploring the rates of PTSD from HIV diagnosis alone, in comparison to those with PTSD from other causes including trauma was performed. This found that PTSD from other causes, including trauma, had higher rates of non-adherence to medication, where HIV diagnosis related PTSD had higher rates of adherence to HIV medications [41]. Mental health states, resulting from these experiences, looks certain to have some impact on the HIV care cascade in general and particularly so on ART related outcomes [26,41,42]. This could contribute to delays in HIV care engagement.

IMPLICATIONS TO HIV CARE IN SOUTH AFRICA - IMPORTANCE OF STUDY

The bi-directional and complex relationships between HIV and mental health may yield crucial evidence that impacts on HIV outcomes in South Africa. The knowledge gap of particular interest, in this study, will explore women who may have been exposed to sexual trauma and who test positive for HIV. Variables, including mental health symptoms, may have relevance as factors that could impress on their presentation times to HIV care. Women, in South Africa, may be at an increased risk of mental health symptoms, given the high dual burden of sexual trauma and HIV that they experience. The effect of adverse mental health could influence resilience and ability to maintain self-care. Mental health is therefore, potentially, a major barrier to initiating HIV care. It is also likely to have an effect on adherence as well as retention in care, in essence, affecting all aspects of the HIV care cascade [26].

The mental health implications may be particularly severe for those who contract HIV as a result of the trauma. The cognitive effects of being HIV positive, following an episode of trauma, seems to distort rational thought and a person's ability to access HIV care early [23].

Accessing clinics for help seems especially difficult for these women. Avoidance is a part of the expression of PTSD symptoms that may explain why people delay initiation to HIV care. When attempting to access an HIV clinic, flashbacks or memories relating to the trauma may trigger avoidant behaviour and further deter these women from accessing care facilities [23].

In order to improve the UNAIDS 95-95-95 treatment goals, this group of women, with potential exposure to trauma and mental health challenges, is important to consider [7,15,22]. This may reveal associations affecting initiation times to ART and could perhaps identify target areas for intervention. This is of relevance as it is likely to have an effect on HIV transmission rates and health outcomes for individuals and communities in South Africa.

Globally there are very few studies that highlight the associations between delays to ART in women, that are HIV positive and exposed to sexual trauma. There are even fewer local data sources on the topic, yet South Africa's HIV burden remains the highest in the world [1,2]. This lack of data, emphasizes the importance of this research.

The outcome of interest in this study includes date of HIV diagnosis in relation to time of initiation on ART. We will further explore variables, socio-demographic data (age and pregnancy status) as well as mental health symptoms (depression, suicidality and PTSD) in women who may have had a lifetime exposure to sexual trauma or IPV (physical or sexual). These variables may highlight associations that could be determinants of early versus late ART initiation.

The findings from this study have high relevance for local populations and could be key in order to improve HIV related outcomes in South Africa.

AIMS – PARENT STUDY

The parent study is evaluating the effectiveness of ImpACT+ (*Improving AIDS Care After Trauma*), an intervention trial, aimed at improving individual outcomes and aspects of the HIV care cascade [26], including viral suppression. This intervention group findings will be contrasted with the control group, not receiving the intervention, to determine significant data. The parent study will screen all women initiating ART at two primary health care facilities in Khayelitsha, South Africa. Namely, Matthew Goniwe (MG) and Town Two (TT) clinics. This screening data collected represents the broader data source for this study.

AIMS – THIS STUDY

This sub-study utilises screening data of participants entering the larger parent RCT to determine any relevant impact on ART initiation times as the outcome of interest for this study. This study seeks to determine the prevalence of sexual trauma, IPV and mental illness in a vulnerable population, and to understand the association between socio-demographics, sexual trauma, IPV and mental health variables on time to initiation of ART. This in women seeking treatment for HIV at the two primary healthcare facilities in Khayelitsha, Cape Town.

OBJECTIVES

1. To determine the prevalence of sexual trauma, physical and sexual IPV and mental health symptoms (depression, suicidality and PTSD) in this population of women initiating ART at two primary healthcare facilities in Khayelitsha, Cape Town.
2. To investigate the associations between socio-demographics (age, pregnancy status), sexual trauma, IPV (physical and sexual) and mental health variables (depression, suicidality and PTSD) on ART initiation times.

HYPOTHESES

1. Older women will initiate ART later than younger women.
2. Women with experiences of sexual trauma, physical or sexual intimate partner violence (IPV) or mental health symptoms (depression, suicidality or PTSD) will initiate ART later than those who have not experienced sexual trauma or IPV and do not have mental health symptoms.

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The effects of sexual trauma, intimate partner violence (IPV) and mental health on early versus late antiretroviral therapy (ART) initiation amongst women in South Africa

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ABSTRACT

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Women in South Africa are disproportionately affected by HIV and sexual violence. An HIV diagnosis and experiences of trauma may have a profound impact on mental health and HIV care engagement. Less is known about the effects of sexual violence, intimate-partner violence (IPV) and mental health symptoms (depression, post-traumatic stress disorder and suicidality) on delays to ART initiation. This was explored in peri-urban clinics in Cape Town as part of a larger randomised controlled trial. ART initiation was dichotomised into early versus late and analysed with respect to the variables above. A total of 170 participants were included, with early ART initiation (<21 days) from diagnosis to initiation in 80% of participants. Sexual trauma was reported by 38,2% of the participants and 57% reported IPV. None of the variables showed a statistically significant effect on early versus late ART initiation. Future research should include structural factors as a possible explanation.

KEYWORDS

Mental Health, HIV/AIDS, Antiretroviral Therapy (ART), Sexual Trauma, South Africa.

INTRODUCTION

Women and girls in Sub-Saharan Africa make up 63% of all new HIV infections in 2021 according to UNAIDS with more than 38 million people globally living with HIV [1,5]. Sub-Saharan Africa remains the epicentre of the epidemic being home to an estimated 8.2 million people infected with HIV, this representing the highest HIV rates in the world [1,2,3,5]. In an attempt to eradicate HIV, the joint United Nations Programme on HIV/AIDS (UNAIDS) advocated for HIV treatment targets [7]. These encompassed the 90-90-90 treatment goals to combat HIV [7]: specifically, that 90% of people should know their HIV status, 90% of those infected should receive treatment and 90% should achieve viral suppression on treatment [7]. These targets, set for the year 2020, were never reached and have subsequently been refined to the 95-95-95 treatment goals to eradicate HIV by the year 2030 [7].

Despite the high prevalence HIV rates seen in South Africa, uptake to ART remains below target ranging between 60-92% [5,7,10]. In addition, around 65% of South African women with HIV (WLWH) are retained in care and of those, less than 66% achieve viral suppression on treatment [3,5]. These figures represent a major risk to HIV transmissibility and control of the epidemic. To understand how to close these gaps, investigation into the barriers to HIV care is required. These include all aspects of the HIV care cascade including, testing for HIV, initiation on treatment, retention in care and viral suppression on treatment [1,26].

Despite the implementation of policies to improve uptake to ART, many barriers to ART initiation remain, including, male gender, HIV disclosure fears, substance use and an awareness of HIV risks and transmissibility [10,11,12,15,25].

Health care system structural factors are also likely to influence HIV care. These include access to health facilities, ART services, distance from treatment sites, availability of information regarding HIV, medical expertise and availability of ART [10,11,12].

In an attempt to improve uptake to ART and align with WHO strategic goals, South Africa adopted the WHO Universal Test and Treat (UTT) policy in 2016, resulting in all those who test positive for HIV, being eligible to initiate ART at the time of diagnosis [1,10,14]. Moreover, in 2017, this policy was updated with a directive to initiate all HIV positive patients on the day of their diagnosis: also known as same-day-initiation (SDI).

Extant evidence suggests improved outcomes for PLWH in reducing HIV viral load and subsequently transmissibility of the virus under the implemented UTT/SDI policies [7]. Further to this, lower rates of AIDS related adverse events are recorded under the new policies when compared to those who initiate late [8,9].

There is evidence to support SDI/UTT policies, yet there is also overwhelming evidence indicating that women may be at particular risk of HIV infection. South African women are reported to be at twice the risk of contracting HIV compared to men [22], they are also at greater risk of HIV and form the largest proportion of PLWH [21]. South African women aged 15-24 are twice as likely to be living with HIV when compared to men [5].

In addition to this, one in three women globally, according to WHO and UNAIDS research, have been the victim of either sexual and or physical violence [5,19]. Intimate partner violence (IPV) is also commonly described by many South African women. Rates of IPV around 13% are reported in the last 12-month period in South Africa, and women aged 15-49 report lifetime IPV rates of around 24% [19,20]. Women with physical and or sexual IPV are described as being one and a half times more likely to contract HIV [5].

In contrast, HIV has been described at times as being one of the main factors that forced women to remain in violent relationships [36]. Poverty states including financial uncertainty, lower levels of education and food insecurity are some of the compounders that foster dependency on the support of another [20,30]. This may include dependency on a violent partner [36]. This places a high vulnerability risk on women and is a significant concern in some areas of South Africa.

A major barrier to HIV care may, therefore, include the fact that women in South Africa endure significant sexual and physical trauma. This coupled with the effects of the HIV epidemic may have an effect on their mental health. Mental health is perhaps a major, and often overlooked, important barrier that is liable to play a significant role on entry to HIV care in South Africa [23,24,70].

Evidence supports the notion that the dual epidemics of HIV and trauma adversely affect mental health and contribute to disruptions in ART initiation [20,77]. This may include symptoms of depression, suicidality and post-traumatic stress disorder (PTSD). Sexual trauma and mental health symptoms are expected to diminish a person's ability to accept a diagnosis of HIV [23]. This especially important in those women who develop HIV as a result of the sexual trauma. Loss of trust, following sexual abuse, may have parallels that extend further to cognitive avoidance with regards to trusting healthcare systems, care providers and may cause delays to ART initiation [23].

Determining the pertinent links between mental health, trauma and HIV initiation and retention in care may be fundamental in improving HIV outcomes in South Africa.

Limited research in low and middle-income countries has been done to determine any relevant associations between sexual trauma, mental health symptoms and ART initiation in women, a gap that this study sought to explore.

METHODS

STUDY DESIGN

The study utilised a cross-sectional analytic design. A secondary analysis of data was performed. Screening data was obtained from a larger parent randomized controlled trial (RCT). Improving AIDS care after trauma (ImpACT +), a coping intervention for women with sexual abuse and HIV [77].

STUDY SETTING

This study was conducted in Khayelitsha, a peri-urban community on the outskirts of Cape Town, South Africa. Khayelitsha is described as a largely immigrant community [44]. Certain areas in Khayelitsha have substantial socio-economic challenges. Poverty is apparent with high levels of unemployment, limited resources with areas of informal housing [44]. An increasing population growth is observed, in part, due to ongoing immigration mostly from the Eastern Cape province to Cape Town [44]. It is becoming one of the fastest growing informal settlements in South Africa, and is currently the second largest informal settlement in the country [44]. The study takes place within two primary healthcare centres (PHC) in the Khayelitsha area.

STUDY POPULATION

The study population comprised of women, diagnosed with HIV, who were initiating ART for the first time at two primary healthcare facilities in Khayelitsha in the Western Cape Province in South Africa.

SAMPLING AND SAMPLING PROCEDURE

Prospective participants for the main study were identified during their intake visit at the HIV clinic, ART initiation appointment, or antenatal care (ANC) and referred for screening. The screening process involved collecting basic demographic data. It also included seven questions about IPV and sexual trauma, two questions about depression, and seven questions about traumatic stress symptoms [45,46,47,48]. All patients screened were also assessed for suicide risk before seeking informed consent in the parent study [43]. The voluntary screening for sexual trauma and traumatic stress was offered to all women attending a first appointment at the HIV treatment clinic or who were diagnosed with HIV at an ANC appointment.

INCLUSION AND EXCLUSION CRITERIA

To be included in this study, participants were HIV positive and recently initiated on ART (< 4 months). In addition, participants were required to be female, 18 years or older, isiXhosa and/or English speaking, and receiving HIV care at one of the two study clinics. Participants were excluded from the parent study if not able to provide informed consent, were visibly intoxicated, or unable to communicate in isiXhosa or English.

STUDY MEASURES

DEMOGRAPHICS

Demographics including age and pregnancy status were captured.

HIV DIAGNOSIS DATE AND ART START DATE

Date of diagnosis with HIV and date of initiation on ART were determined via self-report and medical record abstraction. Participants considered as initiating treatment early were those initiated before 21 days from date of diagnosis to initiation on ART. Those delayed more than 21 days were considered to be late initiators. The definition of early versus late initiation to ART was informed by clinical process and initiation times frequently encountered at community ART clinics in South Africa. ART initiation may require medical practitioners to review results or manage medical co-morbidities that prevent concurrent initiation on treatment. There may at times require repeat HIV testing in diagnostic uncertainty. This allowed those testing positive for HIV a clinically informed timeframe to conclude for ART initiation to commence. Early versus late initiators were therefore defined with this clinically informed discriminator being incorporated. This would allow adequate time for clinical process to conclude and for patients to be initiated on ART, should there be any outstanding clinical process preventing SDI on ART.

TRAUMA VARIABLES - PHYSICAL AND SEXUAL IPV

IPV physical abuse was measured using the Revised Conflict Tactics Scale (CTS) [45]. Sexual Abuse - measured using the sexual coercion subscales of the CTS (ABUSE) [46]. The CTS and ABUSE screens for suggestions of lifetime physical and sexual abuse. Descriptions are either of it “ever happening” or “never happening” to the participant. The time period is recorded during childhood (< 12 years), adolescence (13-17 years) or adulthood (18 and older) [45,46]. Those that had experienced treats of physical violence as well as threats of sexual abuse were included. It also incorporated those that had been beaten, kicked or had a weapon used against them (knife, gun or bottle). Sexual trauma included being touched in a

sexual way or being forced to touch someone in a sexual way against their will. These were all included in this study. Physical IPV and or sexual abuse was included, regardless of when it had occurred in their lifetime.

MENTAL HEALTH VARIABLES – DEPRESSION – PTSD – SUICIDALITY

Depression was measured using the Patient Health Questionnaire-2 (PHQ-2) [48]. The PHQ-2 is a two-item measure that assesses depression on a four-point Likert scale [48]. This is rated on a severity scale of 0-3 (zero being the least severe or "not at all" and 3 being the most severe or "nearly every day"). The measures include a screening for depressed mood and anhedonia. A rating of 0-3 is recorded for each to give a total of 0-6 points. Participants have depression symptoms at a rating of 1 and above. A cut off score of 3 or above indicated likely for screened major depressive disorder.

PTSD symptoms were measured using the Breslau Short Screening Scale for PTSD (PTSD) [47]. This was done if the participant answered yes for any of the CTS or ABUSE questions suggesting trauma exposure. PTSD screening was then done to determine presence of any suggestion of symptoms. Relevance was reported for any value between 1 and 7 screening positive on the PTSD scale.

Suicidality was screened for using The Mini International Neuropsychiatric Interview (MINI) for Suicidality Disorders Studies [43]. Six questions were asked related to suicidality and participants were scored as being, low (1-5 points), moderate (6-9 points) or high risk (10 or more points) for suicidality. Participants were referred for further assessment when indicated to be high risk for suicidality. Those in the high-risk group were regarded as suicidal in this analysis.

These measures have been demonstrated to have good reliability and validity and are used in South African research.

DATA MANAGEMENT AND ANALYSIS

All data were anonymised, and screening ID numbers were utilized to remove personal identifiers. The anonymised data was safeguarded with password protected spreadsheets in REDCap. Statistical analysis was performed using SPSS 27.

At first, we explored the parametric assumptions of normality for all relevant variables and found the variable "days from diagnosis of HIV to initiation on ART" to be skewed. As such, a more sensitive linear model could not be performed and these data were dichotomized into early (< 21 days) versus late (> 21 days) initiators on ART. All subsequent variables met the parametric assumptions of normality. To meet objective 1, we ran descriptive and frequency analyses to determine the prevalence of sexual trauma, IPV and mental health outcomes. Thereafter, to meet objective 2, we ran a binary logistic analysis with early versus late initiation to ART as the dependent variables. The demographic data (age, pregnancy status) as well as the trauma factors (sexual abuse, IPV) and mental health symptoms (depression, suicidality and PTSD) were compared for relevance, as the independent variables for this study. Hosmer and Lemeshow Test was used, in the final model, to test the null hypothesis and model fit. Variance was explained by using Nagelkerke R^2 value. The three groups; total participants, early initiators on ART and late initiators to ART are described, including their relative means, standard deviations (SD), number (n) and percentages (%). The *p*-value is reported for the univariate analysis (chi-square test for categorical variables). Significance for the overall model was set at $\alpha = .05$.

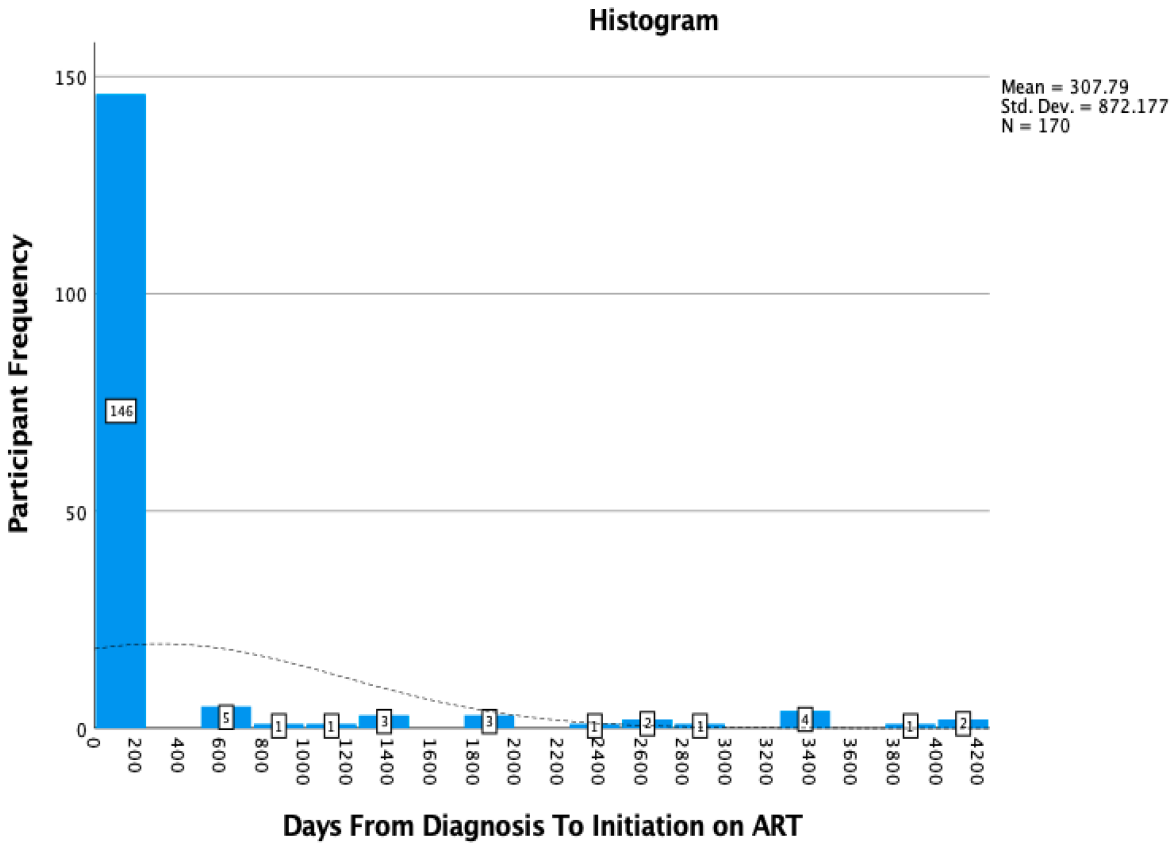
ETHICAL CONSIDERATIONS

This study complied with the principles of the latest Declaration of Helsinki. Ethics approval, to conduct this study, was obtained from the Faculty of Health Sciences, University of Cape Town (UCT) with HREC number 658/2021. All participants provided written informed consent and were informed of the right to withdraw from the study, at any time without consequence, during the data collection phase of the parent RTC. Data was anonymised and safeguarded with password protected spreadsheets in REDCap. This study comprised a secondary analysis of the anonymous screening data. Confidential medical records were not accessed during this study. No additional data collection or patient interviews were conducted during this study.

RESULTS

In total 170 participants, were included in this study. The mean age of the sample was 30.65 (SD 8.7), ranging between 18 and 60 years of age. The mean number of days from diagnosis to initiation on treatment was 307.79 days. However, this was not representative of the broader sample, with the median and mode both showing a value of 1, inter quartile range (IQR) 10 (25-35). This indicating initiation on ART, in the majority of cases, was within 1 day from date of diagnosis. This equates to early initiation on ART rates of 80% (n =136) and SDI rates of 67,1% (n=114). A few participants took more than 10 years to initiate treatment n=3 (1,8%). The longest time for a participant to initiate ART was 4209 days from date of diagnosis with HIV. Late initiators on ART equated to 20% (n=34) since date of diagnosis to ART initiation.

FIGURE 1: Participant Frequency - Days from Diagnosis to Initiation on ART



Note: Participant frequency is compared to indicate those that initiated ART and how many days from diagnosis of HIV until initiation on ART. These numbers represent the initiation on ART trend of the participants

Many of the participants described sexual trauma experiences 38,2% (n=65); in addition, IPV descriptions were reported in more than half the sample at 57%. Participants met PHQ-2 criteria for symptoms of screened major depression in 39,4% (n=67) of cases. High risk suicidality symptoms were reported by 4,7% (n= 9). PTSD symptoms were reported in half the sample at 50,0%. There were no significant differences noted between early versus late initiators with respect to demographic or clinical outcomes.

The participant characteristics and descriptive statistics are presented in Table 1.

TABLE 1: Characteristics of Participants

	Total Participants n %	Early Initiators on ART n %	Late Initiators on ART n %	*p*-value
Total Participants	170 (100%)	136 (80,0%)	34 (20,0%)	.566
Age	Mean 30,65 SD 8,7	Mean 30,37 SD 9,04	Mean 31,79 SD 7,33	.102
Pregnancy Status	31 (18,2%)	24 (17,6%)	7 (20,6%)	.726
Sexual Trauma	65 (38,2%)	51 (37,5%)	14 (41,2%)	.135
Physical and Sexual IPV	97 (57,1%)	77 (56,6%)	20 (58,8%)	.890
Depression	67 (39,4%)	54 (39,7%)	13 (38,2%)	.524
Suicidality	9 (4,7%)	7 (5,1%)	2 (5,9%)	.337
PTSD	85 (50%)	65 (47,8%)	20 (58,8 %)	.212

Note: Total participants - represents the total sample studied and the relative number (n) and percentage (%) for the descriptive statistics. Early initiators - represents the participants initiated on ART early (<21 days) and the respective number (n) and percentages (%) according to that sub-group. Late initiators - represents the participants initiated on ART late (>21 days) and the respective number and percentages according to that sub-group. The p-value is reported for the univariate analysis (chi-square test for categorical variables) with dependent variable early versus late ART initiation with independent variables (age, pregnancy status, sexual trauma, IPV, depression, suicidality and PTSD).

Logistic regression assessed the association between socio-demographic, trauma and mental health variables in predicting early versus late ART initiation. The final model was not statistically significant (p = .482) when compared to the null hypothesis ($X^2(8) = 7.518$, $p > 0.05$). It explained 2.8% of the variance, but was not significant. The model correctly predicted 79.9% of early versus late ART initiation.

Specifically, the results demonstrated that neither age (p = .343) nor pregnancy (p = .773) was associated with ART initiation status (i.e., early versus late). Moreover, sexual trauma (p = .682), showed no association with ART initiation status, nor did intimate partner violence (IPV) (p = .506). Finally, the screened mental health symptoms, depression (p = .728), suicidality (p = .661) and PTSD (p =.178), were not found to be significant predictors of ART initiation status.

The relevant findings from the logistic regression are presented in Table 2.

TABLE 2: Logistic Regression Analysis

	B	df	*p*-value	Odds Ratio (OR)	95% Confidence Intervals (CI)
Age	.021	1	.343	1.022	.978 – 1.068
Pregnancy Status	-.118	1	.773	.889	.398 – 1.984
Sexual Trauma	.202	1	.682	1.223	.467 – 3.204
Physical and Sexual IPV	.318	1	.506	1.375	.538 – 3.512
Depression	.141	1	.728	1.152	.518 – 2.560
Suicidality	.365	1	.661	1.441	.282 – 7.367
PTSD	-.757	1	.178	.469	.156 – 1.411

Note: Logistic regression analysis. Dependent variable early versus late initiation on ART compared with the independent variables (age, pregnancy status, sexual trauma, IPV, depression, suicidality and PTSD) for associations of significance.

DISCUSSION

Trauma experiences and mental health symptoms were highly prevalent, in our study, among women initiating ART in Khayelitsha, Cape Town. Sexual trauma and IPV prevalence were reported at (> 30% and > 50% respectively).

Women globally experience sexual violence rates of around 6% with IPV reported at approximately 30% [5,19,20]. This is comparable to those figures reported by South African women [5,19,20]. The frequency of trauma in this sample from Khayelitsha, however, is significantly elevated when compared to both global and local estimates of trauma. Extant literature confirms that trauma and mental health prevalence is elevated in the community of Khayelitsha. A similar study found sexual trauma reports of 51% [78]. Women in Khayelitsha are clearly exposed to elevated levels of sexual trauma and these risks are likely to impact on their mental health and HIV care engagement [78].

In addition, South Africa is confronted with diverse socioeconomic challenges and many women in communities such as Khayelitsha, struggle with poverty and financial dependency [14,27,29,44]. Dependency on violent partners and experiences of violence are likely to increase HIV transmission [23,25]. Much of this study data was also collected during the global Covid-19 pandemic. During times of lockdown, the risks to mental health and rates of trauma were reported to have increased [76]. Trauma and violence likely account for some of the explanation for the prominent prevalence of HIV in South African women. Extant literature supports the notion that women are at higher risk of HIV in South Africa and are more likely to contract HIV, especially where there is a history of violence [21,23]. Recent studies further suggest that ART outcomes may be affected as a result of the fear of violence from partners [17,25,28].

Trauma and its impact on the mental health of individuals may include expressions of depression, suicidality and PTSD. As a result, women may be at risk of adverse coping that may impact their engagement with HIV care [66,77]. Hyperarousal, avoidance and other mental health symptoms adversely affect HIV care, particularly for vulnerable groups including women with HIV [66,76,77]. Despite the high prevalence of mental health symptoms reported in our study, none of the variables were shown to have an effect on ART initiation times. This may be related to structural factors.

No association with delayed ART for pregnant women or for elderly participants was shown in our study. Pregnant women usually initiate ART early when compared to non-pregnant women [15,16]. This was not confirmed in our study and may be related to the small number of pregnant participants in the sample. The HIV epidemic has become one where there are many that have advancing age who are now testing for HIV [75]. Those at advancing age may struggle more with stigma and delays to ART [75]. Stigma has been an ongoing concern that could affect mental health and presents a major barrier to ART initiation [66,75]. Under the SDI/UTT policies, and with mental health and psychosocial support for those experiencing trauma, there has been a suggestion that stigma may be reduced to improve ART related outcomes [54,55,66,77].

Reports of depression, suicidality and PTSD were highly prevalent in our study. More than a third of the women (>30%) described symptoms suggestive of screened major depression. These rates are elevated when compared to extant literature, which suggests any depression rates, including mild to severe depression, of around 12-25% in those living with HIV [37,38]. A previous study across similar settings, in South Africa, found major depression rates of only around 11% [74]. Most participants in our study scored low to moderate risk for

suicide at 23%. Less than 5%, of the total sample, were determined to be a high suicide risk. These rates of suicidal ideation seem to correlate with existing literature, indicating around 20% of PLWH experience suicidal ideation pre-ART initiation [62]. This may be related to the HIV diagnosis itself, mental health factors as well as the impact of trauma. Suicidal expression, in these participants, is likely to be multifactorial. PTSD symptoms were reported in half the participants. When compared to extant literature these rates are substantially elevated [72]. Local estimated lifetime PTSD rates, in South Africa, are around 2-3% [73]. This is higher in those newly diagnosed with HIV in South Africa, with PTSD prevalence reported at around 5-8% [72]. The rates of PTSD in this sample, of only women in Khayelitsha, are at least ten-fold higher than most local estimates in South Africa. Neither depression, suicidality nor PTSD were, however, found to be associated with delayed ART. These findings are in contrast to extant literature which indicates an association between mental health symptoms and adverse HIV care related outcomes [38].

The significant prevalence of mental health symptoms, detected at our screening ART clinics in Khayelitsha, highlights the value in advocating for an integration of HIV and mental health care services. This may be particularly crucial in low-and-middle-income countries such as South Africa. The available literature suggests that the interacting and bi-directional links between HIV and mental health are substantial. HIV diagnosis influences individual mental health and mental health symptoms likewise also affect linkage and retention in HIV care [29,37,61,66,74]. Improving advocacy for mental health and counselling systems could show improved HIV care related effects [56,61,66,70,74]. The benefits of therefore integrating mental health and HIV care may have important connections that could further optimize patient outcomes and their HIV care engagement [49,64,71,77].

Advancing literature, on the benefit of UTT/SDI, indicates an improvement in our capacity to combat the HIV/AIDS pandemic. This especially significant when contrasted with previous initiation policies and patient outcomes [1,7,8,9]. Adequate resources, structures and leadership to ensure effective UTT/SDI implementation is important to improve universal standards of care for all local communities [58]. Mental health screening and integrated services may support improved determination of 'readiness to treatment'. This may be particularly useful to improve HIV care targets [7,64]. Studies suggest complex integrated social dynamics may impact the HIV statistics and UNAIDS treatment goals, including initiation, adherence and retention in care [7,53,54,63,67]. Numerous authors therefore advocate for a more comprehensive screening assessment process and selection criteria prior to initiation on treatment under the SDI/UTT policies [49,50,51,52,57,59,60,65,68]. Mental health screening and interventions incorporated with HIV services may improve HIV care in community clinics such as those in our study from Khayelitsha [66,77].

While the intention to detect associations of relevance to HIV initiation was not realized, in this sample, there are many important findings worthy of consideration. Firstly, the rigorous implementation of SDI and UTT within South Africa may account for some of the reason that the variables did not demonstrate significance with delays in ART initiation being observed. Secondly, the actual low number of people who initiated ART late may be an additional reason that no statistically relevant association was detected with the variables considered in this study.

Despite the trauma and mental health challenges noted in these participants, many initiated ART within a day of diagnosis under the effected SDI policies [1,7,69,72]. 67% initiated as SDI while 80% started ART early at less than 21 days from date of diagnosis. Those that

initiated late (>21 days) still representing one fifth (20%) of the original number. These figures still fall short of the UNAIDS targets [7].

The links between mental health and HIV care may need to be further strengthened if we are to achieve improved HIV care in South Africa. A redirection of efforts to reduce trauma, advocate for the rights of women and improve HIV and mental health care in this community seems essential.

This study identifies that woman with HIV and trauma share complex interactions that could have an impact on both their HIV care and mental health. Approaches to integrate mental health and HIV care are likely to improve outcomes for those women accessing care at these community clinics in Khayelitsha, South Africa.

LIMITATIONS

The study only includes participants 18 years and older. The study also only looks at data from those women who actually access HIV care at one of the study clinics. Women and girls age 15-19 represent the majority of new HIV infections in Sub-Saharan Africa [5]. They account for almost two thirds of all new HIV infections [5]. A similar analysis conducted on those younger than 18 may find other data of significance.

This analysis only looks at participants in the peri-urban Khayelitsha area and may not be representative of other areas in South Africa. Other factors that influence initiation of ART, such as co-morbidities, Covid 19 pandemic related difficulties in accessing clinic care and service-related complications like medication stockouts, may have limited patient access to HIV care and are not considered in this study. Initiation on ART as well as adherence to treatment, viral suppression and retention in care are separate areas that should be considered

individually. A further limitation to this study is that a linear model may have added value but the choice of analysis was influenced by the distribution of the outcome variable.

RECOMMENDATIONS

Advance mental health and HIV awareness and advocacy through research. Explore relevance in the integration of mental health and HIV care in clinical practice.

Continue to collect data and perform studies of this nature in order to optimize mental health and HIV care for women in South Africa.

CONCLUSION

Sexual trauma is common in this population of women with greater than expected reports of incidents of trauma. Despite the high expression of sexual trauma and mental health symptoms, no significant correlations were found in this study that clearly demonstrated an association with delayed ART initiation.

Enhanced screening for trauma and mental health symptoms, at clinics in South Africa, seems crucial. Community health centres, in Khayelitsha, should explore ways to improve their screening and integration of mental health and HIV care. This support, to vulnerable women, is expected to improve outcomes for both mental health and HIV care in South Africa.

ACKNOWLEDGEMENTS

Thanks to the teams assisting with data collection and to the participants involved in the study.

APPENDICES

APPENDIX 1: Screening Instrument

Confidential

Screening Instrument

Study ID	_____
Date of survey	_____
Interviewer	◯ Nokuphumla ◯ Lindokuhle ◯ Neliswa ◯ Thulani ◯ Nomakaziwe ◯ Sybil ◯ Stephan ◯ Esona-Sethu
Clinic	◯ Matthew Goniwe ◯ Town Two
Referral Source	◯ ARV nurse ◯ ARV Counselors ◯ Antenatal Care ◯ Certified nurse practitioner (CNP) ◯ Doctor ◯ Reception ◯ General nurse (vitals) ◯ Wellness ◯ Readiness ◯ Other
Other Referral Source	_____ (If other referral source, please specify)

Introduction

Before beginning, say to participant:

Ndiyabulela ngokuba uvume ukuphendula imibuzo yoluvavanyo ezakuthi isibonakalisele ukuba unokwazi ukuthatha inxaxheba koluphando. Ndizakubuza imibuzo malunga nobomi bakho kunye namava akho. Ukhumbule, oluphando lunomdla wokukwazi malunga nempilo yengqondo yabantu abane HIV. Sizakuthetha ngezinto ezibuthathaka, eminye imibuzo izakubalula kuneminye. Kubalulekile ukuphendula imibuzo yonke ngokukhululekileyo kwaye ungathatha ixesha lakho lokucinga kakuhle ukuze undinike impendulo yakho. Ukuba ngaba unemibuzo odinga ndiyicacise, unako ukundicela ndicacise. Ukuba ufika endaweni onqwenela ukungaphenduli kuyo okanye ufuna uyeka oluvavanyo, unako ukukhetha oko siyeke. Akukho mpendulo ilungileyo nenga lunganga kwaye yonke into ondixelela yona sizakuyigcina iyimfinhlo. Ingaba ikhona imibuzo onayo phambi kokuba siqale?

Thank you for agreeing to complete this short survey that will tell us if you are eligible to take part in this study. I will be asking you some questions about your life and your experiences. As a reminder, this study is interested in the mental health of people living with HIV. We will

be discussing some sensitive topics, and some questions might be easier to answer than others. It is very important that you answer all questions openly, and you can take as much time as you need to think carefully and choose your answer. If you have any questions or would like me to clarify anything while we go through the questions, please let me know. If at any point you would prefer to not answer a question or want to stop the survey, please let me know. There are no right or wrong answers and all the information that you give me will be kept completely private and confidential. I will begin with some general questions about yourself. Do you have any questions before we begin?

Mingaphi iminyaka yakho? How old are you?	_____
Ingaba ukhulelwe? Are you currently pregnant?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Mhlawumbi (Maybe) ◯ Andazi (I don't know) ◯ Ndiyala ukuphendula (Decline to answer)
Ufunyaniswe kunini ukuba unentsholongwane iHIV? When were you diagnosed with HIV?	_____ (Enter DATE of HIV diagnosis.)
Ingaba uthatha unyango lwentsholongwane iHIV (ARV's)? Are you currently prescribed antiretroviral (ARV) treatment ARVs?	◯ No (Hayi) ◯ Ewe (Yes)
Ingaba sowuxelelwe ukuba uzakuqala unyango lwentsholongwane iHIV (ARV's)? Have you been told you will be starting ARVs?	◯ No (Hayi) STOP ◯ Ewe (Yes)
Xa uthekelela inokuba uzakuqala nini ukuthatha iipilisi (ARVs) zentsholongwane iHIV? Approximately when do you think you will be starting ARVs?	_____ (Enter the number of weeks.)
Ukuba sele uzinikiwe, sele uqalile ukuzisebenzisa? If you're prescribed, have you started taking them?	◯ No (Hayi) ◯ Ewe (Yes)
Lixesha elingakanani uthatha iARVs zakho (bhala nge veki) How long have you been taking your ARVs (in weeks)?	_____ (Enter the number of weeks.)
Additional notes about participant (if needed):	_____

Ngoku ndizakubuza ngemvakalelo zakhe othe wanazo kutsha nje. Kwiiveki ezimbini ezidlulileyo, kukangakanani uziva ngezindlela zilandelayo?

Now I'll ask you about some feelings you might have had recently. Over the past two weeks, how often have you felt in the following ways?

Ukuba nomdla omncinci okanye ukungakonwabeli ukwenza izinto?

Little interest or pleasure in doing things

- ◯ Zange kwaphela (Not at all)
- ◯ Ngeentsuku ezithile (Several days)
- ◯ Iintsuku ezingaphezulu kwesiqhelo (More than half the days)
- ◯ Phantse zonke iintsuku (Nearly every day)
- ◯ Ndiyala ukuphendula (Decline to answer)

Ukuziva umzimba wakho uphantsi, uphantsi koxinzelelo olumandla okanye ungenathemba?

Feeling down, depressed, or hopeless

- ◯ Zange kwaphela (Not at all)
- ◯ Ngeentsuku ezithile (Several days)
- ◯ Iintsuku ezingaphezulu kwesiqhelo (More than half the days)
- ◯ Phantse zonke iintsuku (Nearly every day)
- ◯ Ndiyala ukuphendula (Decline to answer)

Le mibuzo ilandelayo inokuba nzinyana ukuphendula kodwa unokuthatha ithuba olidingayo ukuphendula. Ukhumbule ukuba yonke into ondixelela yona izakugcinwa iyimfihlo ikhuselekile.

The following questions might be difficult to answer but you may take as much time as you need to answer. I would like to remind you that the information you give me will be kept private and confidential.

Okulandelayo, ndizakubuza malunga nobundlobongela kunye nomonzakalo othe wawufumana ngenxa yomyeni wakho, iqabane okanye umntu owabelana naye ngokwesondo. Nceda ucinge ngelixa ebomini bakho apho wawukhe wehlelwa koku ngethuba wawusekufikiseni (13-17) okanye ebudaleni (18 ukuza kutsho ngoku).

Ebomi bakho, ingaba iqabane lakho langoku okanye lakudala belikhe:

Next, I am going to ask you about any past experiences of physical violence and trauma you might have had with a husband, boyfriend, or other sexual partner. Please think about time(s) in your life when you may have experienced this, whether it be as an adolescent (13 – 17) or as an adult (18 until now). In your lifetime, has a previous or current partner ever:

Lakugrogrisa ngokukubetha okanye likujule ngento?

Threatened to hit or throw something at you?

- ◯ No (Hayi)
- ◯ Ewe (Yes)
- ◯ Ndiyala ukuphendula (Decline to answer)

Kwenzeka nini oku? When did it happen?	☐ Ekufikiseni (Adolescence) ☐ Ebudaleni (Adulthood) ☐ Ndiyala ukuphendula (Decline to answer) (Enter when abuse happened)
Lakubetha, lakukhaba okanye lakungquba? Beat, kicked, or hit you?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Kwenzeka nini oku? When did it happen? (Mark all that apply)	☐ Ekufikiseni (Adolescence) ☐ Ebudaleni (Adulthood) ☐ Ndiyala ukuphendula (Decline to answer) (Enter when abuse happened)
Lasebenzisa imela okanye umpu kuwe, lakujula okanye lakuhlaba ngebhotile? Used a knife, gun, or bottle on you?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Kwenzeka nini oku? When did it happen?	☐ Ekufikiseni (Adolescence) ☐ Ebudaleni (Adulthood) ☐ Ndiyala ukuphendula (Decline to answer) (Enter when abuse happened)

Ngoku ndizakukubuza imibuzo ethile malunga nezinto ohlangene nazo ezidibaniselene nesondo ekungenzeka ukuba wanyanzeliswa kuzo ungazifuni. Ebomini bakho, zakhe zenzeka ezizinto zilandelayo kuwe?

I will now ask you about sexual experiences you may have had that were forced or unwanted. In your lifetime, have any of the following things happened to you?

Note to RA: If necessary, include clarification about the difference between known and acquaintance.

Ngexesha ungumntwana okanye ekufikiseni, ingaba kukho nabani na owakhe wakubamba-bamba ngokwesondo okanye wafuna ukuba umbamba-bambe ngokwesondo ngokungekho kwimvume yakho? As a child or adolescent, did anyone ever touch you in a sexual way or make you touch them in a sexual way against your will?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Kwenzeka nini oku? When did it happen?	☐ Ebuntwaneni (Childhood) ☐ Ekufikiseni (Adolescence) ☐ Ndiyala ukuphendula (Decline to answer)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Ilungu losapho (Family) ☐ Ayilolungu losapho (Non family) ☐ Ndiyala ukuphendula (Decline to answer) (In childhood)

Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ ilungu losapho (Family) ☐ iqabane (Partner) ☐ ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)
Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)
Ngexesha umdala, ingaba kukho nabani na owakhe wakubamba-bamba ngokwesondo okanye wafuna ukuba umbamba-bambe ngokwesondo ngokungekho kwimvume yakho nakubeni uyithethe yacaca okanye wenze kwacaca ukuba ubungafuni enze loo nto? As an adult, did anyone ever touch you in a sexual way or make you touch them in a sexual way against your will, when you made it clear through words or actions that you did not want to, or when you were afraid to say no?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Iqabane (Partner) ☐ Ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adulthood)
Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer)
Ingaba kukho umntu owakhe wakugrogrisa ngokukuvisa ubuhlungu ngaphandleni kokuba wenze into ngesondo naye? Has anyone ever threatened to hurt you unless you did something sexual with them?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Kwenzeka nini oku? When did it happen?	☐ Ebuntwaneni (Childhood) ☐ Ekufikiseni (Adolescence) ☐ Ebudaleni (Adulthood) ☐ Ndiyala ukuphendula (Decline to answer)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Ilungu losapho (Family) ☐ Ayilolungu losapho (Non family) ☐ Ndiyala ukuphendula (Decline to answer) (In childhood)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Ilungu losapho (Family) ☐ Iqabane (Partner) ☐ Ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)

Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Iqabane (Partner) ☐ Ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adulthood)
Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer) (In adulthood)
Ingaba kukho umntu owakhe wakunyanzela (ngokwasemzimbeni, ngokwasemoyeni okanye ngesixhobo) ukuba uzibandakanye ngesondo naye ngokungekho kwimvume yakho? Has anyone ever forced you (physically, emotionally, or with a weapon) to have sexual intercourse or other sexual activities against your will?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Kwenzeka nini oku? When did it happen?	☐ Ebuntwaneni (Childhood) ☐ Ekufikiseni (Adolescence) ☐ Ebudaleni (Adulthood) ☐ Ndiyala ukuphendula (Decline to answer)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Ilungu losapho (Family) ☐ Ayilolungu losapho (Non family) ☐ Ndiyala ukuphendula (Decline to answer) (In childhood)
Yayingubani lo mntu/abo bantu? (jonga konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Ilungu losapho (Family) ☐ Iqabane (Partner) ☐ Ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)
Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer) (In adolescence)
Yayingubani lo mntu/abo bantu? (khetha konke okungenayo) What was the identity of the person(s)? (Check all that apply)	☐ Iqabane (Partner) ☐ Ayiloqabane (Non-partner) ☐ Ndiyala ukuphendula (Decline to answer) (In adulthood)

Ukuba ayiloqabane ingaba: If non-partner:	☐ Uyamazi (Known) ☐ Ngumntu omaziyo kodwa ongengomhlobo osondeleyo kuwe (Acquaintance) ☐ Awumazi (Stranger) ☐ Ndiyala ukuphendula (Decline to answer) (In adulthood)

Inclusion criteria for sexual abuse

Sexual abuse eligibility calculation:

_____
(1 = meets criteria, 0 = does not meet criteria)

NOTE: This set of questions should be asked ONLY if a woman has answered yes to at least ONE question from above questions (ABUSE).

Ngoku ndizakufundela uluhlu lobunzima abathi abantu ngamanye amaxesha babuve obunxulumene nemeko ezonzakalisa ngaphakathi ebomini babo, njengokuhlukunyezwa okanye ubundlobongela. Nceda uphendule ukuba ingaba ubufumene na obu bunzima okanye ubunxulumene neemeko ezonzakalisa ngaphakathi kwinyanga edlulileyo:

I am now going to read a list of problems that people sometimes have in response to stressful or traumatic experiences such as abuse or acts of violence. Please listen to each one carefully and consider whether it applies to you. In the past month, how much have you been bothered by each of these problems because of a traumatic experience you have had:

Ubukhe wazikhwebula ekuthini ukhunjuzwe ngezehlo ezithile, oku ukwenze ngokuthi uhlalele kude kwiindawo ezithile, abantu okanye imisebenzi ethile? Did you avoid being reminded of this experience by staying away from certain places, people or activities?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Ubukhe waphelelwa ngumdla kwimisebenzi ebikhe yabaluleka kuwe okanye wayonwabela? Did you lose interest in activities that were once important or enjoyable?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Uqale ukufumanisa ukuba uyinkomo edla yodwa okanye uthe qelele ebantwini? Did you begin to feel more isolated or distant from other people?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Ufumanise kunzima ukuba nothando kubanye abantu? Did you find it hard to have love or affection for other people?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)

Uqale ukuziva ngokungathi akukho sidingo sokuba uqingqe ngekamva lakho? Did you begin to feel that there was no point in planning for the future?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Emva koku kuziva unje, uzifumene uneengxaki ezininzi zokungalali okanye ukulala kakhulu? After this experience were you having more trouble than usual falling asleep or staying asleep?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)
Uzifumane usexhaleni okanye usothuswa lula nayingxolo eqhelekileyo okanye imigushuzo? Did you become jumpy or easily startled by ordinary noises or movements?	◯ Hayi (No) ◯ Ewe (Yes) ◯ Ndiyala ukuphendula (Decline to answer)

Inclusion criteria for trauma

1 = meets criteria

0 = does not meet criteria

Trauma eligibility calculation: _____

Suicidality Screening

NOTE: Ask EVERY participant the suicidality screening questions.

Okokugqibela ndingathanda ukukubuza ngezimvo neengcinga obuke wanazo kutsha nje malunga nobomi bakho. Kulenyanga idlulileyo ubuke wanamava wezi zinto zilandelayo:

Lastly, I would like to ask you about feelings and thoughts you might have recently had about your life. In the last month, have you experienced any of the following:

Wacinga ukuba ngekungcono ukuba ubunokufa okanye unqwenele ukuba ubufile? Think that you would be better off dead or wish you were dead?	◯ Hayi (No) ◯ Ewe (Yes)
Wafuna ukuzonzakalisa? Want to harm yourself?	◯ Hayi (No) ◯ Ewe (Yes)

Wacinga ngokuzibulala? Think about suicide?	◯ Hayi (No) ◯ Ewe (Yes)
Wanecebo lokuzibulala? Have a suicide plan?	◯ Hayi (No) ◯ Ewe (Yes)
Wazama ukuzibulala? Attempt suicide?	◯ Hayi (No) ◯ Ewe (Yes)
Ebomini bakho wakhe wazama ukuzibulala? In your lifetime, did you ever make a suicide attempt?	◯ Hayi (No) ◯ Ewe (Yes)
Suicide assessment calculation:	_____
Indicate suicide risk level based on above calculation:	◯ Zero: 0 points ◯ Low: 1-5 points ◯ Moderate: 6-9 points ◯ High: 10 or more points

If Low: INCLUDE

Ndixhalabile malunga nolwazi ondabele lona, Ndingathanda ukukunika uluhlu lwenombolo zomnxeba onokuzitsalela, xa ungandiga uncedo oluthe vetshe. Ingaba kulungile oku kuwe?

I am slightly concerned about the information you have shared with me. I would like to give you a list of numbers you can call, should you require additional support. Is that okay with you?

If Moderate: INCLUDE and refer to study coordinator

Ndixhalabile malunga nolwazi ondabele lona, ndingathanda ukukuthatha ndikuse ku Clinical Co-coordinator ukuze nixoxe malunga nolulwazi undabele lona. Oku kuquka ukuthetha malunga nokudluliswa kwakho apho uyakufumana khona uncendo oluthe vetshe. Ingaba oku kulungile kuwe?

I am concerned about the information you have shared with me. I would like to take you to our Clinical Study Coordinator to discuss the information you have shared with me. This will include talking about a potential referral for additional support. Is that okay with you?

If High: EXCLUDE from study, refer participant to study coordinator, and document clearly.

Ndixhalabile malunga nolwazi ondabele lona, ndingathanda ukukuthatha ndikuse ku Clinical Co-coordinator ukuze nixoxe malunga nolulwazi undabele lona. Oku kuquka ukuthetha malunga nokudluliswa kwakho apho uyakufumana khona uncendo oluthe vetshe. Ingaba oku kulungile kuwe?

I am concerned about the information you have shared with me. I would like to take you to our Clinical Study Coordinator to discuss the information you have shared with me. This will include talking about a potential referral for additional support. Is that okay with you?

Eligibility and Scheduling

Eligibility calculation

_____
(1 = eligible, 0 = not eligible)

If 0, NOT eligible

If 1, Eligible

Confirm eligibility:
◯ Yes
◯ No
(Enter whether participant was eligible or not.)

If a participant is NOT eligible:

Enkosi ngokuthatha ixesha lakho uphendule lemibuzo. Kodwa ngokweziphumo ze screener, awukulungelanga ukuthatha inxaxheba koluphando. Nceda uqhubeke ukuzimasa amadinga akho eclinic okhathalelo lwe HIV.

Thank you for taking time to answer these questions but according to the screener results, you are not eligible to take part in this study. Please continue to attend your clinic appointments for your HIV care and treatment.

If a participant is ELIGIBLE:

Enkosi ngokuthatha ixesha ukuphendula le mibuzo. Ukulungele ukuthatha inxaxheba koluphando kodwa ngemvume yakho, singathanda ukufikelela kwiingxelo zakho zempilo (medical record) ukungqininisa iminyaka yakho kunye nomhla wakho owaqala ngawo ukufumana ipilisi (ARVs) zakho ukuze siqukumbele ungenelelo lwakho. Ukuba ukulungele ukuthatha inxaxheba, sizakunxulumelana nawe ngomnxeba ukuba uze kutyelelo lwakho lokuqala. (Note: Read Oral Consent Part B)

Thank you for taking time to answer these questions. You meet criteria to take part in this study but with your permission, we need to access your medical record to confirm your age and date of ARV initiation before we can finalize your eligibility. If you are eligible, we will contact you to come in for your first study visit. (Note: Read Oral Consent Part B)

Reason not eligible (check all that apply):
☐ No history of sexual abuse
☐ No trauma symptoms
☐ High risk for suicidality
☐ Other

OTHER reason not eligible:

_____

Scheduled for baseline?
◯ Yes
◯ No

Reason not scheduled for baseline (check all that apply):
☐ Not eligible
☐ Not interested in enrollment
☐ Other

OTHER reason not scheduled:

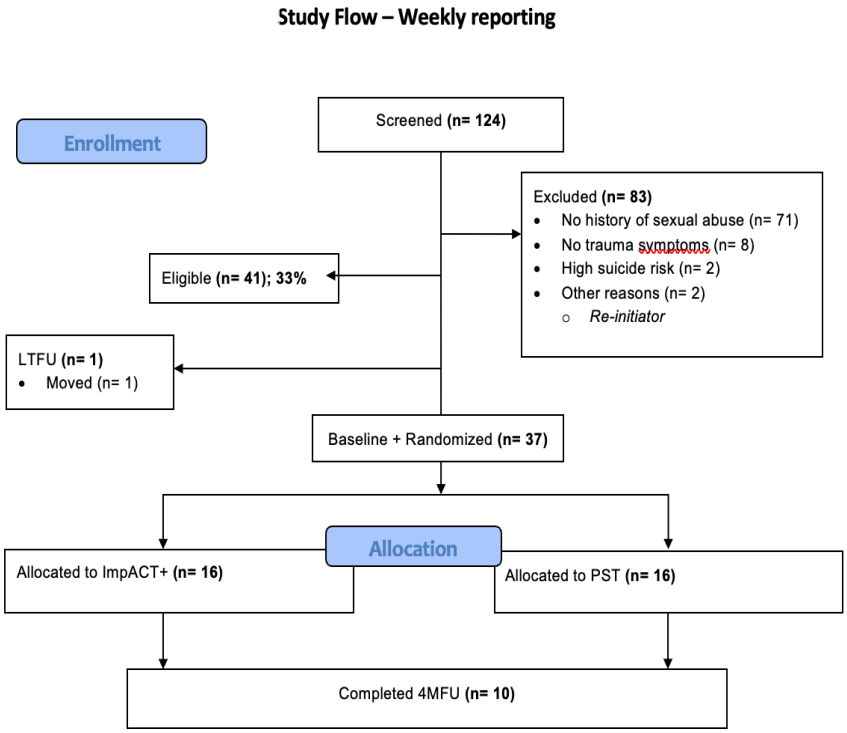
_____

Confirm ARV status and age from medical record.
☐ ART
☐ Age

Medical Record Checklist

Participant Screening ID	_____
Date of medical record access (Today)	_____
Is the participant 18 years of age or older?	◯ No ◯ Yes ◯ Unknown
Has the participant started ART?	◯ No ◯ Yes ◯ Unknown
Date of ART initiation	_____
Date of scheduled baseline	_____
Weeks between ART initiation and scheduled baseline [CALCULATED]	_____
ART Eligibility [CALCULATED]: 0 = NOT ELIGIBLE 1 = ELIGIBLE	_____
Participant eligibility [CALCULATED] 0 = NOT ELIGIBLE 1 = ELIGIBLE	_____
Eligible?	◯ 0 - NOT ELIGIBLE ◯ 1 - ELIGIBLE
Reschedule baseline!	

Parent Study – Data Collection Flow – Weekly Reporting Example



APPENDIX 2: Study Measures Incorporated In The Screening Instrument

Demographic Data

1.1. Demographics

DEM1	How old are you?	____ (if under age 18, STOP)
DEM2	Are you currently pregnant?	1. Yes 0. No
DEM3	When were you diagnosed with HIV?	Month_____, Year_____
DEM4	Are you currently prescribed antiretroviral (ARV) treatment or have you previously taken ARVs?	1. Yes 0. No (SKIP TO DEM 6)
DEM5	If you have started, how long have you been taking your ARVs?	
DEM6	Have you been told you will be starting ARVs?	1. Yes 0. No (STOP)
DEM7	When do you think you will be starting ARVs? (Number of weeks/months)	

Patient Health Questionnaire-2 (PHQ-2)

1.3 Patient Health Questionnaire-2 (PHQ-2)

	Depression screening : PHQ-2 Over the past two weeks, how often have you been bothered by any of the following problems?	
PHQ2_1	1. Little interest or pleasure in doing things	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day
PHQ2_2	2. Feeling down, depressed, or hopeless	0 = Not at all 1 = Several days 2 = More than half the days 3 = Nearly every day

IPV Physical Abuse: Revised Conflict Tactics Scale (CTS)

1.3. IPV Physical Abuse: Revised Conflict Tactics Scale (CTS)

	Question	Ever	If Yes: When did it happen? (Check all that apply)
CTS1	Threatened to hit or throw something at you?	1. Yes 0. No	1. Adolescence 2. Adulthood
CTS2	Beat, kicked or hit you?	1. Yes 0. No	1. Adolescence 2. Adulthood
CTS3	Used a knife, gun, or bottle on you?	1. Yes 0. No	1. Adolescence 2. Adulthood

Sexual Abuse (ABUSE)

1.4. Sexual Abuse (ABUSE)

	Question	Response Options	If Yes: When did it happen? (Check all that apply)	If Yes: What was the identity of the person(s)? (Check all that apply)
ABUSE1A	A. As a child or adolescent, did anyone ever touch you in a sexual way or make you touch them in a sexual way against your will?	1. Yes 0. No	1. Childhood	1. Family 2. Non-Family
			2. Adolescence	1. Family 3. Partner 4. Non-Partner *If non-partner:* a. Known b. Acquaintance c. Stranger
ABUSE1B	B. As an adult, did anyone ever touch you in a sexual way or make you touch them in a sexual way against your will, when you made it clear through words or actions that you did not want to, or when you were afraid to say no?	1. Yes 0. No	3. Adulthood	1. Family 3. Partner 4. Non-Partner *If non-partner:* a. Known b. Acquaintance c. Stranger
Interviewer should remind participants to think about their experiences across their lifetime (childhood, adolescence, adulthood).				
ABUSE2	Has anyone ever threatened to hurt you unless you did something sexual with them?	1. Yes 0. No	1. Childhood	1. Family 2. Non-Family
			2. Adolescence	1. Family 3. Partner 4. Non-Partner *If non-partner:* a. Known b. Acquaintance c. Stranger
			3. Adulthood	1. Family 3. Partner 4. Non-Partner *If non-partner:* a. Known

Traumatic Symptoms Screener: Breslau Short Screening Scale for PTSD (PTSD)

1.5. Traumatic Symptoms Screener: Breslau Short Screening Scale for PTSD

	Question	Response Options
PTSD1	Did you avoid being reminded of this experience by staying away from certain places, people or activities?	1. Yes 0. No
PTSD2	Did you lose interest in activities that were once important or enjoyable?	1. Yes 0. No
PTSD3	Did you begin to feel more isolated or distant from other people?	1. Yes 0. No
PTSD4	Did you find it hard to have love or affection for other people?	1. Yes 0. No
PTSD5	Did you begin to feel that there was no point in planning for the future?	1. Yes 0. No
PTSD6	After this experience were you having more trouble than usual falling asleep or staying asleep?	1. Yes 0. No
PTSD7	Did you become jumpy or easily startled by ordinary noises or movements?	1. Yes 0. No

Suicidality Screening (MINI)

1.6. Suicidality Screening (MINI)

	Question	Response Options
MINI1	Think that you would be better off dead or wish you were dead?	1. Yes 0. No
MINI2	Want to harm yourself?	1. Yes 0. No
MINI3	Think about suicide?	1. Yes 0. No
MINI4	Have a suicide plan?	1. Yes 0. No
MINI5	Attempt suicide?	1. Yes 0. No
MINI6	In your lifetime, did you ever make a suicide attempt?	1. Yes 0. No

EXCLUDE FROM STUDY IF HIGH RISK, DEFINED AS NEEDING IMMEDIATE OR SAME DAY REFERRAL

- **ADD THE TOTAL NUMBER OF POINTS FOR THE ANSWERS CHECKED 'YES' AND SPECIFY THE LEVEL OF SUICIDE RISK**

1 point if B1 is Yes: B1 is Ewe (Yes)
2 points if B2 is Yes: B2 is Ewe (Yes)
6 points if B3 is Yes: B3 is Ewe (Yes)
10 points if B4 is Yes: B4 is Ewe (Yes)
10 points if B5 is Yes: B5 is Ewe (Yes)
4 points if B6 is Yes: B6 is Ewe (Yes)

Low: 1-5 points
Moderate: 6-9 points
High: 10 or more points

- **If Moderate: INCLUDE and refer to psychologist at clinic**
- **If HIGH:**
  - immediate referral to primary care physician to be seen on same day
  - phone study psychologist
  - complete referral form
  - accompany participant to the doctor's office
  - exclude from study
  - document clearly

APPENDIX 3: Data Extraction Tables and Figures

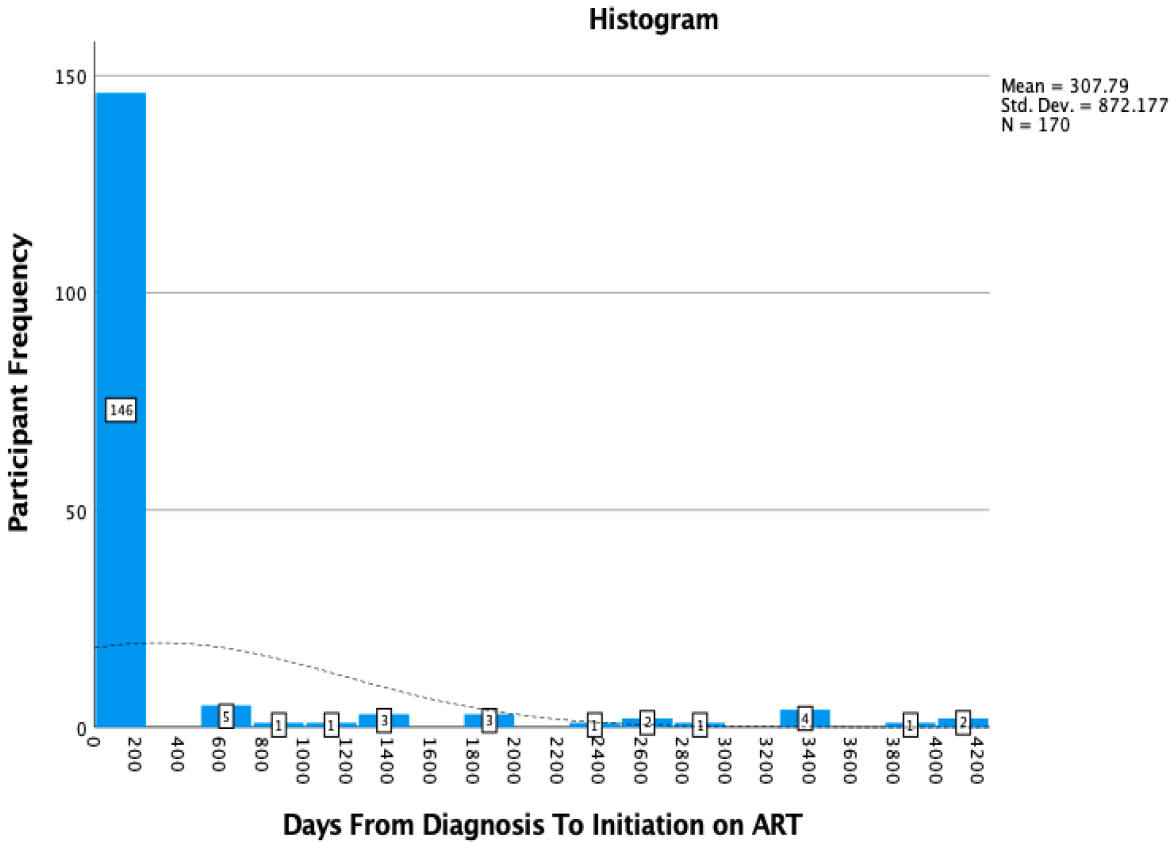
TABLE 1: Characteristics of Participants

	Total Participants n%	Early Initiators on ART n %	Late Initiators on ART n %	*p*-value
Total Participants	170 (100%)	136 (80,0%)	34 (20,0%)	.566
Age	Mean 30,65 SD 8,7	Mean 30,37 SD 9,04	Mean 31,79 SD 7,33	.102
Pregnancy Status	31 (18,2%)	24 (17,6%)	7 (20,6%)	.726
Sexual Trauma	65 (38,2%)	51 (37,5%)	14 (41,2%)	.135
Physical and Sexual IPV	97 (57,1%)	77 (56,6%)	20 (58,8%)	.890
Depression	67 (39,4%)	54 (39,7%)	13 (38,2%)	.524
Suicidality	9 (4,7%)	7 (5,1%)	2 (5,9%)	.337
PTSD	85 (50%)	65 (47,8%)	20 (58,8 %)	.212

TABLE 2: Logistic Regression Analysis

	B	df	*p*-value	Odds Ratio (OR)	95% Confidence Intervals (CI)
Age	.021	1	.343	1.022	.978 – 1.068
Pregnancy Status	-.118	1	.773	.889	.398 – 1.984
Sexual Trauma	.202	1	.682	1.223	.467 – 3.204
Physical and Sexual IPV	.318	1	.506	1.375	.538 – 3.512
Depression	.141	1	.728	1.152	.518 – 2.560
Suicidality	.365	1	.661	1.441	.282 – 7.367
PTSD	-.757	1	.178	.469	.156 – 1.411

FIGURE 1 – Participants Frequency – Days from Diagnosis to Initiation on ART



APPENDIX 4: Literature Search Strategy

Database	MESH	keywords
PubMed	HIV [MeSH] OR HIV Infections [MeSH]	HIV OR human immune deficiency syndrome OR acquired immune deficiency syndrome OR immunodeficiency syndrome OR AIDS virus
	AND	
	Antiretroviral Therapy, Highly Active [MeSH] OR Anti-Retroviral Agents [MeSH]	Antiretroviral OR anti-retroviral OR antiviral OR anti-HIV agents OR Antiretroviral therapy OR ART OR highly active antiretroviral therapy OR HAART OR ARV
	AND	
	Time-To-Treatment [MeSH] OR Drug Administration Schedule [MeSH] OR Time Factors [MeSH]	early OR immediate OR delayed OR timing OR time to treatment OR care cascade
	AND	
	"Stress Disorders, Post-Traumatic"[Mesh] OR "Intimate Partner Violence"[Mesh] OR "Sexual Trauma"[Mesh] OR "Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh] OR "Suicide"[Mesh] OR "Suicide, Attempted"[Mesh]	Sexual trauma OR Sexual Abuse Trauma OR Intimate partner violence OR IPV OR Intimate Partner Abuse OR spousal abuse OR Post traumatic stress disorder OR Post-Traumatic Stress Disorder OR PTSD OR suicide OR attempted suicide Suicidality OR Depression OR Depressive Symptoms OR Unipolar Depression OR Major Depressive Disorder
		Access OR barriers OR challenges
Filter|: Southern Africa	TW	Southern Africa OR South Africa OR Botswana OR Namibia OR Zimbabwe OR Mozambique OR Angola OR Eswatini OR Lesotho OR Malawi OR Zambia
	53	Search: **((((((((("Time-to-Treatment"[Mesh]) OR ("Drug Administration Schedule"[Mesh])) OR ("Time**

		Factors"[Mesh])) OR (early OR immediate OR delayed OR timing OR time to treatment)) OR (care cascade)) AND (((("Antiretroviral Therapy, Highly Active"[Mesh]) OR ("Anti-Retroviral Agents"[Mesh])) OR (Antiretroviral OR anti-retroviral OR antiviral OR anti-HIV agents OR Antiretroviral therapy OR ART OR highly active antiretroviral therapy OR HAART OR ARV))) AND ((HIV OR human immune deficiency syndrome OR acquired immune deficiency syndrome OR immunodeficiency syndrome OR AIDS virus) OR ("HIV"[Mesh] OR "HIV Infections"[Mesh]))) AND (Southern Africa[Text Word] OR South Africa[Text Word] OR Botswana[Text Word] OR Namibia[Text Word] OR Zimbabwe[Text Word] OR Mozambique[Text Word] OR Angola[Text Word] OR Eswatini[Text Word] OR Lesotho[Text Word] OR Malawi[Text Word] OR Zambia[Text Word])) AND (((((("Stress Disorders, Post-Traumatic"[Mesh]) OR ("Intimate Partner Violence"[Mesh])) OR ("Sexual Trauma"[Mesh])) OR ("Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh])) OR ("Suicide"[Mesh])) OR ("Suicide, Attempted"[Mesh])) OR (Sexual trauma OR Sexual Abuse Trauma OR Intimate partner violence OR IPV OR Intimate Partner Abuse OR spousal abuse OR Post traumatic stress disorder OR

		Post-Traumatic Stress Disorder OR PTSD OR suicide OR attempted suicide OR Suicidality OR Depression OR Depressive Symptoms OR Unipolar Depression OR Major Depressive Disorder)) Sort by: **Most Recent**
	163	Search: **((Access OR barriers OR challenges) AND (((((("Time-to-Treatment"[Mesh]) OR ("Drug Administration Schedule"[Mesh])) OR ("Time Factors"[Mesh])) OR (early OR immediate OR delayed OR timing OR time to treatment)) OR (care cascade)) AND ((("Antiretroviral Therapy, Highly Active"[Mesh]) OR ("Anti-Retroviral Agents"[Mesh])) OR (Antiretroviral OR anti-retroviral OR antiviral OR anti-HIV agents OR Antiretroviral therapy OR ART OR highly active antiretroviral therapy OR HAART OR ARV))) AND ((HIV OR human immune deficiency syndrome OR acquired immune deficiency syndrome OR immunodeficiency syndrome OR AIDS virus) OR ("HIV"[Mesh] OR "HIV Infections"[Mesh]))))) AND (((((("Stress Disorders, Post-Traumatic"[Mesh]) OR ("Intimate Partner Violence"[Mesh])) OR ("Sexual Trauma"[Mesh])) OR ("Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh])) OR ("Suicide"[Mesh])) OR ("Suicide, Attempted"[Mesh])) OR (Sexual trauma OR Sexual Abuse Trauma OR Intimate**

		partner violence OR IPV OR Intimate Partner Abuse OR spousal abuse OR Post traumatic stress disorder OR Post-Traumatic Stress Disorder OR PTSD OR suicide OR attempted suicide OR Suicidality OR Depression OR Depressive Symptoms OR Unipolar Depression OR Major Depressive Disorder)) Sort by: **Most Recent**
	853	Search: **((Access OR barriers OR challenges) AND (((((("Time-to-Treatment"[Mesh]) OR ("Drug Administration Schedule"[Mesh])) OR ("Time Factors"[Mesh])) OR (early OR immediate OR delayed OR timing OR time to treatment)) OR (care cascade)) AND ((("Antiretroviral Therapy, Highly Active"[Mesh]) OR ("Anti-Retroviral Agents"[Mesh])) OR (Antiretroviral OR anti-retroviral OR antiviral OR anti-HIV agents OR Antiretroviral therapy OR ART OR highly active antiretroviral therapy OR HAART OR ARV))) AND ((HIV OR human immune deficiency syndrome OR acquired immune deficiency syndrome OR immunodeficiency syndrome OR AIDS virus) OR ("HIV"[Mesh] OR "HIV Infections"[Mesh]))))) AND (Southern Africa[Text Word] OR South Africa[Text Word] OR Botswana[Text Word] OR Namibia[Text Word] OR Zimbabwe[Text Word] OR Mozambique[Text Word] OR Angola[Text Word] OR Eswatini[Text Word] OR Lesotho[Text Word] OR Malawi[Text Word] OR**

		Zambia[Text Word]) Sort by: **Most Recentt**
	19	Search: **(((Access OR barriers OR challenges) AND (((((("Time-to-Treatment"[Mesh]) OR ("Drug Administration Schedule"[Mesh])) OR ("Time Factors"[Mesh])) OR (early OR immediate OR delayed OR timing OR time to treatment)) OR (care cascade)) AND (((("Antiretroviral Therapy, Highly Active"[Mesh]) OR ("Anti-Retroviral Agents"[Mesh])) OR (Antiretroviral OR anti-retroviral OR antiviral OR anti-HIV agents OR Antiretroviral therapy OR ART OR highly active antiretroviral therapy OR HAART OR ARV))) AND ((HIV OR human immune deficiency syndrome OR acquired immune deficiency syndrome OR immunodeficiency syndrome OR AIDS virus) OR ("HIV"[Mesh] OR "HIV Infections"[Mesh]))))) AND (Southern Africa[Text Word] OR South Africa[Text Word] OR Botswana[Text Word] OR Namibia[Text Word] OR Zimbabwe[Text Word] OR Mozambique[Text Word] OR Angola[Text Word] OR Eswatini[Text Word] OR Lesotho[Text Word] OR Malawi[Text Word] OR Zambia[Text Word])) AND (((((("Stress Disorders, Post-Traumatic"[Mesh]) OR ("Intimate Partner Violence"[Mesh])) OR ("Sexual Trauma"[Mesh])) OR ("Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh])) OR ("Suicide"[Mesh])) OR**

		("Suicide, Attempted"[Mesh])) OR (Sexual trauma OR Sexual Abuse Trauma OR Intimate partner violence OR IPV OR Intimate Partner Abuse OR spousal abuse OR Post traumatic stress disorder OR Post-Traumatic Stress Disorder OR PTSD OR suicide OR attempted suicide OR Suicidality OR Depression OR Depressive Symptoms OR Unipolar Depression OR Major Depressive Disorder)) Sort by: **Most Recent**

Universal Test and Treat (UTT)/Same Day Initiation (SDI)

Updated Research Search

Database		
PubMed	MESH	Keywords
		Universal Test and Treat OR UTT OR Same Day Initiation OR SDI
		Anti-Retroviral Therapy OR ART
		HIV
Search: **(("Universal Test and Treat" OR UTT OR "Same Day Initiation" OR SDI) AND (HIV)) AND (Anti-Retroviral Therapy OR ART)** Sort by: **Most Recent**		
https://www.ncbi.nlm.nih.gov/sites/myncbi/1LwlVrv_cv_5m/collections/61561734/public/		
Filter TW		Southern Africa OR South Africa OR Botswana OR Namibia OR Zimbabwe OR Mozambique OR Angola OR Eswatini OR Lesotho OR Malawi OR Zambia

APPENDIX 5: Consent Forms (Parent Study)

UNIVERSITY OF CAPE TOWN

PART A: ORAL CONSENT SCRIPT

Study Title: A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa

Principal Investigators: Drs. John A. Joska and Kathleen Sikkema

PURPOSE

Thank you for showing interest in our research study. The goal of our research is to evaluate support programs for women with HIV in this clinic. At this point, we would like to ask you some questions about your life experiences and your feelings. It is possible that you will be eligible to take part in the larger study. If you are eligible, we will tell you more about that study and give you the choice to participate or not.

PROCEDURES

It will take about 15-20 minutes of your time to answer these questions today. I will ask you some questions about your wellbeing and life experiences you have had, including any experiences with sexual abuse and partner violence. Based on your responses, I may refer you to places where you can get help. You are free not to answer any questions that make you uncomfortable. You can also ask me any questions as we go along or stop participating at any time. We will not record any information that can identify you at this point, although if you are eligible and want to participate, we will need to ask your name. I will go over this in detail if you are eligible. We will only keep this information as part of your study record if you are eligible and decide to take part in the larger study.

RISKS/DISCOMFORTS

The questions I will ask you may make you feel uncomfortable or upset. You may also feel embarrassed, shy, angry or sad.

BENEFITS

You will not benefit directly from completing this survey today, and you will not receive any additional services at the clinic. However, you may receive referrals for additional services within the clinic or in the community, if necessary. By participating, you will help us learn information that will help us to evaluate programs for women at this clinic.

VOLUNTARY PARTICIPATION

Now that I have given you more information about the study, I want to remind you that you do not have to agree to be in this study, and you may change your mind at any time. If you say no, it will not affect the care you receive from this clinic. I'm going to give you a card with numbers you can call if you have questions or concerns about this study at any point.

PERMISSION TO PROCEED

Do you have any questions about anything I just told you? Is it okay for me to proceed with asking you questions about yourself? Remember you can say no at this time or at any point of me asking.

☐ Yes ☐ No

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IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

UNIVERSITY OF CAPE TOWN

PART B: ELIGIBILITY CONFIRMATION SCRIPT

Thank you for answering our questions about your life experiences and your feelings. As noted, you are eligible, and we are pleased you are interested to participate in our study. Before we finalise your appointment to learn about study details and decide if you want to participate the study, we need to confirm some medical details about you. For this, we would like to ask your permission to access your medical records at the clinic.

WHAT INFORMATION WILL WE ACCESS?
We need to access your medical records to confirm three things: your exact age, the date you were diagnosed with HIV, and the date you first started or intend to start with antiretroviral therapy (ART). We will not look at any other information or record any of the information in your medical records during this stage of the study. This information will be treated with strict confidentiality. Your response to our screening today will not be included in your medical record or shared with staff at the clinic. To access your medical records, we will need your name and surname, clinic folder number, and contact information. Your name and medical file number will not be connected to the answers you have given me today, although there will be a locked file where your study ID number will be linked to your name.

WHO WILL ACCESS YOUR MEDICAL RECORDS AND WHEN WILL THIS HAPPEN?
A member of our study team will access your medical records. Our team is extensively trained and supervised by the project director based at the University of Cape Town. We will ensure that all of your information remains strictly confidential. We will access your medical records before you come in for your first assessment. You will receive the date and time for your first assessment today. Once we have confirmed that you are eligible to participate, the research team will contact you and re-confirm the appointment for your first visit.

PERMISSION TO ACCESS YOUR MEDICAL RECORDS
Do you have any questions about anything I just told you? Do you remember what we are checking in your medical records? Remember you can say no at this time.

By signing below, I (initial only) …… provide permission for access to my medical records as part of the research study entitled: **"A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa"**

Signed at (*place*) ……..…… on (*date*) ……..…… 20 __.

……
Signature of participant

FOR RESEARCH ASSISTANT:

Research Assistant name: ……..

Participant Screener ID: ……..

Date: ……..

Signature: ……..

UNIVERSITY OF
CAPE TOWN

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of the Research Project: A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa

PRINCIPAL INVESTIGATORS: Drs. John A. Joska and Kathleen Sikkema

ADDRESS: Department of Psychiatry and Mental Health, J-block, Groote Schuur Hospital, Anzio Road, Observatory, 7925
Tel: 021-404 2164/021-4042154

KEY INFORMATION:

You are being invited to take part in a research project. I will read through this form with you, which describes the details of the study. Please ask if you need an explanation of words or information that you do not understand. If you agree to participate, you will sign this form. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.
This study has been approved by the **Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town.** The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- This study is taking place at local clinics in the Cape Town Metropolitan area where people go to receive HIV care.
- The purpose of the research is to evaluate a counselling treatment program for women who have experienced sexual trauma. Sexual trauma is any unwanted or threatening sexual experience, and it can cause stress and affect starting and staying on HIV treatment. HIV treatment is also known as antiretroviral medication, or "ARVs". We will assess whether a counselling program we have developed can help women improve their stress related to trauma and ARVs.
- Approximately 350 people will participate in this part of the study. All participants will be over the age of 18 and will be female patients at the clinic who have experienced sexual trauma, feel stress, and recently started taking ARVs.

What will happen in this research study?

- If you agree to participate and sign the form, you will be asked to attend four research visits and a counselling program over twelve months. Each research visit will take approximately 60-90 minutes, where you will answer questions about yourself, mental health, coping strategies, sexual behavior, and HIV treatment and care. Research visit 1 will take place within the next few days, visit 2 will take place in 4 months, visit 3 will take place in 8 months, and visit 4 will take place in 12 months.
- After completing visit 1, you will receive one of two counselling services: (1) ImpACT+: six individual counselling sessions (60 minutes each) and six follow-up check-ins (30 minutes each); or (2) Problem Solving (PST): three individual counselling sessions (60

minutes each). We will decide this randomly, like when you toss a coin. You cannot choose which part of the study you will be put into.

- If you are assigned to ImpACT+, you will attend individual counselling sessions to help you cope with sexual trauma, stress and HIV. The first six sessions will occur weekly and last 60 minutes. During the sessions we will discuss coping with sexual trauma, stress and ARVs, improving health behaviors, and getting social support. The last six sessions will be brief check-in sessions at the clinic, occur monthly, and last 30 minutes.
- If you are assigned to PST, you will attend three individual counselling sessions to discuss stressors in your life and problem solve around how to manage stress. The sessions will occur weekly and last 60 minutes.
- Regardless of which group you are in, intervention sessions may be audio recorded to make sure all parts of the treatment are included in each session. You do not have to consent to audio recording to take part in the study, and may change you mind at any time. *Please make a "X" on the last page if you DON'T want sessions to be recorded.*
- Regardless of which group you are in, we will review your medical record at the HIV clinic to confirm information about your health and HIV care, such as viral load, CD4 count, HIV care visits, and ARV visits. This information will be collected for the 12-month period after visit 1. If the staff cannot get information from the medical record, they will find information from the National Health Laboratory Service (NHLS) database. *Please make a "X" on the last page if you DON'T want us to look at your medical records.*
- Regardless of which group you are in, we plan to measure how much HIV and ARVs are in your blood. At visit 2, 3 and 4 a trained staff person will take a small sample of your blood. After visit 4, we will tell you if your blood test results show that you are not virally suppressed. If you would like us to, we can send your test results (not your blood) to the HIV clinic so your provider can help with your care. *Please make a "X" on the last page if you DON'T want us to take any blood samples from you.*
- A small number of women who are in ImpACT+ will be randomly selected at the end of the study for an in-depth interview to understand their experiences in the counselling program. These interviews will be audio recorded and held in a private space.

Why have you been invited to participate?

- We would like to invite you to participate because your HIV care provider at this clinic has referred you. We are inviting female patients at this clinic to participate who have reported an experience of sexual abuse or assault in the questionnaire you did with our research staff. Also, you recently started ARVs, which is a focus of the counselling programs we are evaluating.

What will your responsibilities be?

- You will attend all study visits on time and participate as fully as possible in the counselling sessions and the 4 research visits. This means that you will answer questions as fully and honestly as possible. If there are questions you do not want to or cannot answer, you should say so. You do not have to participate in any discussions or activities that you do not want to.
- We will ask for your contact details so that we can keep in touch with you and make sure you come back for the study visits. We will also ask you for a second telephone number from a family member or friend, in case we cannot reach you. It is your choice whether or not you wish to give us a second telephone number.
- During visits 2, 3, and 4 (at 4 months, 8 months, and 12 months), you will be asked to provide a small sample of blood (about 6 ml). The procedure will take about 10 minutes. Your name will not be attached to any documents and the blood sample collected. The sample will only be identified with a study identification number.

- At the end of the study, we may also invite you to participate in an optional, in-depth individual interview, where you can share your experiences in the counselling program so that we may learn how to best design treatment programs for women. If you choose not to participate in an in-depth interview, you can still complete this portion of the study.

Will you benefit from taking part in this research?

- You may get some benefit from the study by receiving either one of the two counselling programs. The counselling sessions may help you cope more effectively with stress, reduce emotional distress, engage in HIV care, or improve overall well-being.. You will also help us learn information that will help us evaluate and improve programs for women living with HIV who have experienced sexual trauma.

Are there risks involved in your taking part in this research?

- This study may make you feel uncomfortable as you talk about sexual trauma, mental health, HIV, and taking ARVs. You may feel embarrassed or shy. Sometimes painful and emotional information about sexual trauma is shared. You should feel free to mention your feelings or concerns to any member of the study team. If you do have a problem, you can ask us to speak to your clinic doctor or nurse to see if they can help you. If they cannot or you need more help, we will arrange to refer you to a mental health clinic near to you for treatment.
- Every effort will be made to keep your information confidential and protected. No information will be shared with anyone outside of the study team, including your health care providers or your employers. We will not record your name during any activities, so no one will know what you said during the discussions. All documents will be stored in a locked filing cabinet or on a password protected computer, which only study staff can access. Institutional personnel may access it as part of routine audits. Your study information will be identified only by a unique study number, not your name, to protect your privacy. This study number will be used for any laboratory blood results or information about you. Data identified only by this study code ID, not your name (de-identified), will be sent to our study team at Columbia University. Any documents containing your name and personal information will be kept separate from other study records, and will be stored in a secure way. A list matching participant names with study ID numbers will also be securely stored, and available only to study staff at the University of Cape Town. If we write about this study, your identity will remain anonymous.
- Taking blood has some minor risks:
  - You may experience some pain when blood is taken;
  - Other than this short pain, the discomfort should be minimal;
  - In less than 10% of cases, a small amount of bleeding under the skin will produce a bruise;
  - The prick may be visible and sore to the touch for a short period of time after the collection, with possible redness or swelling in the area;
  - You may feel dizzy or light-headed (syncope) for a short period of time;
- These are the main risks. You should feel free to mention your feelings or concerns to any member of the study team.

If you do not agree to take part, what alternatives do you have?

- You are free not to participate or to withdraw at any time during the study. Your HIV care at the clinic will not be affected in any way. You may continue to attend your clinic. It would be helpful for the study team to let us know why you have decided not to take part, but you are free to not give a reason.

Who will have access to your medical records?

- The information collected about you will be treated as confidential and protected. If we write about this work, your identity will remain anonymous. Only the study team will have full access to the information.

What will happen to the blood we take from you?

- The blood samples used to measure the ARV levels in your blood will be stored in a locked freezer at the University of Cape Town. We will use information from the samples, and from what you tell us, to describe ARV adherence and viral level of HIV. We will report this information in journals and at meetings. The names of people in the study are always confidential, and the blood samples will be de-identified and not available to researchers outside of the study team for additional testing.
- Five years after completion of the study, the biospecimens will be permanently de-identified and destroyed. The samples will not be used for any purposes outside of this study.

What is a Certificate of Confidentiality?

- To help us protect your privacy, and because our study team includes members from the United States, we received a Certificate of Confidentiality from the National Institutes of Health (NIH). This is a U.S. policy that protects the confidentiality of your study participation. The Certificate of Confidentiality does not stop you or a member of your family from telling others about yourself or your involvement in this research.

Will you be paid to take part in this study and are there any costs involved?

- No, you will not be paid to take part in the study but your time and transport costs will be covered for your study visits. The study staff will give you ZAR50 for each study treatment visit for transport reimbursement. We will also give you ZAR150 for each ASSESSMENT visit, which will take about 1 ½ hours, using a cashless payment system to your cell phone. There are four of these assessment visits.

- The study team will not be providing your ARV medication, you will receive them as part of your HIV treatment at the local clinic. Your decision to participate in this study will not affect your current or future health care at the clinic.

May you choose to not participate or to withdraw from this study?

- You may choose not to be in the study. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, we will not ask for any more information from you. All data that have already been collected for the study will be kept. If you withdraw, we ask that you contact Dr. John Joska at UCT. You can call him on his phone at 021-4042164 or 021-4042154. You can also write to him at Department of Psychiatry and Mental Health, J-block, Groote Schuur Hospital, Anzio Road, Observatory, 7925.

In case of an emergency or if you feel you need to contact one of the study staff about questions or problems, you can do so by phoning:
Dr. John Joska at tel no 021-4042164

- You can also contact the Human Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town 021-4066338 if you have any concerns or complaints that have not been adequately addressed by the research staff.

A description of this study will be posted on ClinicalTrials.gov, an online record of research studies by the United States National Library of Medicine at the National Institutes of Health. Your information will not be included in the online study description.

Information and Consent Summary

Ensure that each participant clearly understands each of the following points:

- **You are being asked to participate in this research study for female patients who have experienced sexual trauma, feel stress, and recently started taking ARVs.**

- **As a participant in the study you will:**
  - **Be randomly selected to participate in either three counselling sessions OR six counselling sessions plus six maintenance check-ins.**
  - **Attend 4 study visits where you will do assessments and answer questions about yourself, mental health, coping strategies, sexual behavior, and HIV treatment and care.**
    - **At visits 2, 3 and 4, you will also provide a blood sample.**
    - **Information from your medical record will be collected for twelve months after visit 1.**

- **Everything you share during the visit is confidential. Only study staff involved in this study will see your answers to those questions. The clinic staff will not have access to your answers from the assessments.**

- **Your participation in this study is completely voluntary.**

- **Your participation or decision not to participate in the study WILL NOT affect your care at this clinic.**

- **You can withdraw from the study at any time without repercussion and continue receiving care at this clinic.**

Declaration by participant

By signing below, I ……..…….. agree to take part in a research study entitled: **"A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa"**

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurized to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Any procedure the participant has not permitted is initialed here:

- _____ Blood sample
- _____ Medical record review
- _____ Audio recording of intervention sessions

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of participant

Declaration by treatment partner/associate/ relative of participant (IF UNABLE TO READ OR WRITE)

By signing below, I ……..…… have read and understood this consent form about the research study entitled: **"A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa",** on behalf of

……..(name of participant), and state that she understands the study

…….(relationship to participant)

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of treatment partner/associate/relative of participant

---

Declaration by investigator/study coordinator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged her to ask questions and took adequate time to answer them.
- I am satisfied that she adequately understands all aspects of the research, as discussed above
- I will maintain confidentiality at all times.

Signed at (*place*) ..... on (*date*) ……..…….. 20__.

.....
Signature of investigator

APPENDIX 6: Human Research Ethics Committee (HREC) Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

15 October 2021

HREC REF: 658/2021

Prof J Joska
Division of Neuropsychiatry
Neurosciences Building-GSH
Email: john.joska@uct.ac.za
Student: crookes.charles@gmail.com

Dear Prof Joska

PROJECT TITLE: PREDICTORS OF EARLY VERSUS LATE ANTIRETROVIRAL THERAPY (ART) INITIATION IN A SAMPLE OF WOMEN IN KHAYELITSHA, CAPE TOWN. EXPLORING THE EFFECTS OF SOCIO-DEMOGRAPHICS, SEXUAL TRAUMA, INTIMATE PARTNER VIOLENCE (IPV) AND MENTAL HEALTH SYMPTOMS ON INITIATION TIMES TO TREATMENT-MMED CANDIDATE-DR CHARLES G CROOKES-SUB-STUDY LINKED TO HREC/REF 137/2019

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020; 06 July 2020 & 01 July 2021.

Approval is granted for one year until the 30 October 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Charles Crookes will also be involved in this study.

Please quote the HREC REF 658/2021 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/REF 658/2021sa

APPENDIX 7: Institutional and National Approval

Private Bag X828, PRETORIA, 0001 Civitas Building, c/o Struben and Thabo Sehume Streets
Tel (012) 395 8000, Fax (012) 395 8918

13 July 2020

To Whom It May Concern:

RE: A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes
among HIV-infected women with sexual trauma in South Africa

Dear Stephan Rabie

This letter serves as a confirmation that your trial has been approved on the South African National Clinical Trial Registry. Your unique identification number for the registry is **DOH-27-072020-6207**

Please be advised that you are responsible for updating your trial record information on SANCTR, or for informing us of changes to your trial.

Please note that it is now a WHO requirement to include, at a minimum, summary results or a link to summary results within the trial registration record. This should be done within 12 months of the study completion date.

Please do not hesitate to contact us at +27 21 938 0222 or email sanctradmin@mrc.ac.za should you have any questions.

Yours faithfully,

SANCTR Administration Team

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

CITY HEALTH

Dr Natacha Berkowitz
Epidemiologist: City Health

T: 021 400 6864 **F**: 021 421 4894
E: Natacha.Berkowitz@capetown.gov.za

Ref: 24822 2020-03-10

RE: A randomized trial of ImpACT+, a coping intervention to improve clinical and mental health outcomes among HIV-infected women with sexual trauma in South Africa

Dear John Joska

Your research request has been approved as per your protocol. Please refer to the subsequent pages for the approval of any facilities or focus areas requested. Approval comments on any proposed impact on City Health resources are also provided.

Eastern & Khayelitsha:

Contact Person: Dr Virginia De Azevedo (Area East Manager)

Tel/Cell: 021 360 1258/083 629 3344

Email: Virginia.DeAzevedo@capetown.gov.za

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinic and its patients must be arranged with the relevant Manager such that normal activities are not disrupted.
3. A copy of the final report must be uploaded to http://web1.capetown.gov.za/web1/mars/ProjectClosure/UploadReport/0/8274, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (8274). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises
6. If this research gives rise to a publication , please submit a draft before publication for City Health comment and include a disclaimer in the publication that "the research findings and recommendations do not represent an official view of the City of Cape Town "

Thank you for your co-operation and please contact me if you require any further information or assistance.

Kind Regards
Dr Natacha Berkowitz Epidemiologist: City Health

Facilities

Area	Subdistrict	Facilities		
Area East	Khayelitsha	**Facility name**	**Interaction start date**	**Interaction end date**
		Matthew Goniwe CDC	2020-05-01	2025-05-01
		Town Two CDC	2020-05-01	2025-05-01

Please note

- If a requested facility does not appear in the list above, its interation request has been rejected and the reason for the rejection can be viewed in the link below
- Approval comments for facilities may exist. These comments can be viewed in the link below.

http://web1.capetown.gov.za/web1/mars/ProjectFacility/Read/0/8274

Impacted resources

Impacted resource	Decision	Comment
Admission of patients	Approved	approved

APPENDIX 8: AIDS and Behavior (Journal) - Instruction to Authors

Manuscript Preparation

- Type double-spaced on one side of 8 ½ × 11-inch white paper using generous margins on all sides, (including copies of all illustrations and tables).

- A title page is to be provided and should include the title of the article, authors name (no degrees), authors affiliation, and suggested running head, and Declarations. The affiliation should

  comprise the department, institution (usually university or company), city, and state (or nation) and should be typed as a footnote to the authors name. The suggested running

  head should be less than 80 characters (including spaces) and should comprise the article title or an abbreviated version thereof. For office purposes, the title page should include the complete mailing address, telephone number, fax number, and email address of the one author designated to review proofs.

- Declarations

  All manuscripts must contain the following sections on the Title Page under the heading 'Declarations'.

  If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

  • Funding (information that explains whether and by whom the research was supported)

  • Conflicts of interest/Competing interests (include appropriate disclosures)

  • Ethics approval (include appropriate approvals or waivers)

  • Consent to participate (include appropriate consent statements)

• Consent for publication (consent statement regarding publishing an individual's data or image)

• Availability of data and material (data transparency)

• Code availability (software application or custom code)

• Authors' contributions

Please see the relevant sections in the submission guidelines for further information.

- With the exception of Brief Reports and Behavioral Surveillance Reports, initial submissions to AIDS and Behavior do not have word or page limits. Briefer and more succinct papers tend to review better and papers may be reduced in length as part of the review process. However, the length of the original submission is left to author discretion.

- An abstract is to be provided, preferably no longer than 150 words.

- A list of 4-5 key words is to be provided directly below the abstract. Key words should express the precise content of the manuscript, as they are used for indexing purposes.

- All sections should carry headings (such as INTRODUCTION, METHODS, RESULTS, DISCUSSION, CONCLUSIONS, etc.), typed flush left. All acknowledgments (including those for grant and financial support) should be typed in one paragraph (so−headed) on a separate page, that directly precedes the References section.

- Illustrations (photographs, drawings, diagrams, and charts) are to be numbered in one consecutive series of Arabic numerals. The captions for illustrations should be typed on a separate sheet of paper. All illustrations must be complete and final, i.e., camera-ready. Photographs should be large, glossy prints, showing high contrast. Drawings should be high quality laser prints or should be prepared with india ink. Either the original drawings or good−quality

photographic prints are acceptable. Artwork for each figure should be provided on a separate sheet of paper. Identify figures on the back with authors name and number of the illustration. Electronic artwork submitted on disk should be in the TIFF or EPS format (1200 dpi for line and 300 dpi for halftones and grayscale art). Color art should be in the CYMK color space. Artwork should be on a separate disk from the text, and hard copy must accompany the disk.

- Tables should be numbered (with Roman numerals) and referred to by number in the text. Each table should be typed on a separate sheet of paper. Center the title above the table, and type explanatory footnotes (indicated by superscript lowercase letters) below the table.

- AIDS and Behavior does not have a limit on number of authors. However, if deemed to be excessive the editor may request author justifications and reductions.

AIDS and Behavior uses Vancouver style as outlined in the American Medical Association Manual of style: A Guide for Authors and Editors, 10th Edition.

A reference number is allocated to a source in the order in which it is cited in the text. In text, identify references as Arabic numerals in brackets (1). If the source is referred to again, the same number is used. References are listed in numerical order in the Reference List at the end of the paper. Do not alphabetize. Use abbreviated names of journals according to the journal list in PubMed. List all authors and/or editors up to 6; if more than 6, list the first 3 followed by “et al.” The following are examples.

1) McKirnan DJ, Vanable PA, Ostrow DG, Hope B. Expectancies of sexual "escape" and sexual risk among drug and alcohol-involved gay and bisexual men. J Subst Abuse. 2001;13(1-2):137-54.

2) van der Straten A, Cheng H, Moore, J et al. The use of the diaphragm instead of condoms in a phase III diaphragm trial. AIDS Behav. 2009; 13(3):564-72.

3) Eaton LA, Kalichman SC. Changes in transmission risk behaviors across stages of HIV disease among people living with HIV. J Assoc Nurses AIDS Care. 2009 Jan-Feb;20(1):39-49.

4) Bangsberg D, Hecht F, Charlebois E, Chesney M, Moss A. Comparing objectives measures of adherence to HIV antiretroviral therapy: electronic medication monitors and unannounced pill counts. AIDS Behav 2001, 5:275–281.

5) Richman D, Bozzette S, Morton S, et al. The prevalence of antiretroviral drug resistance in the US. Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, 2001 [abstract LB-17].

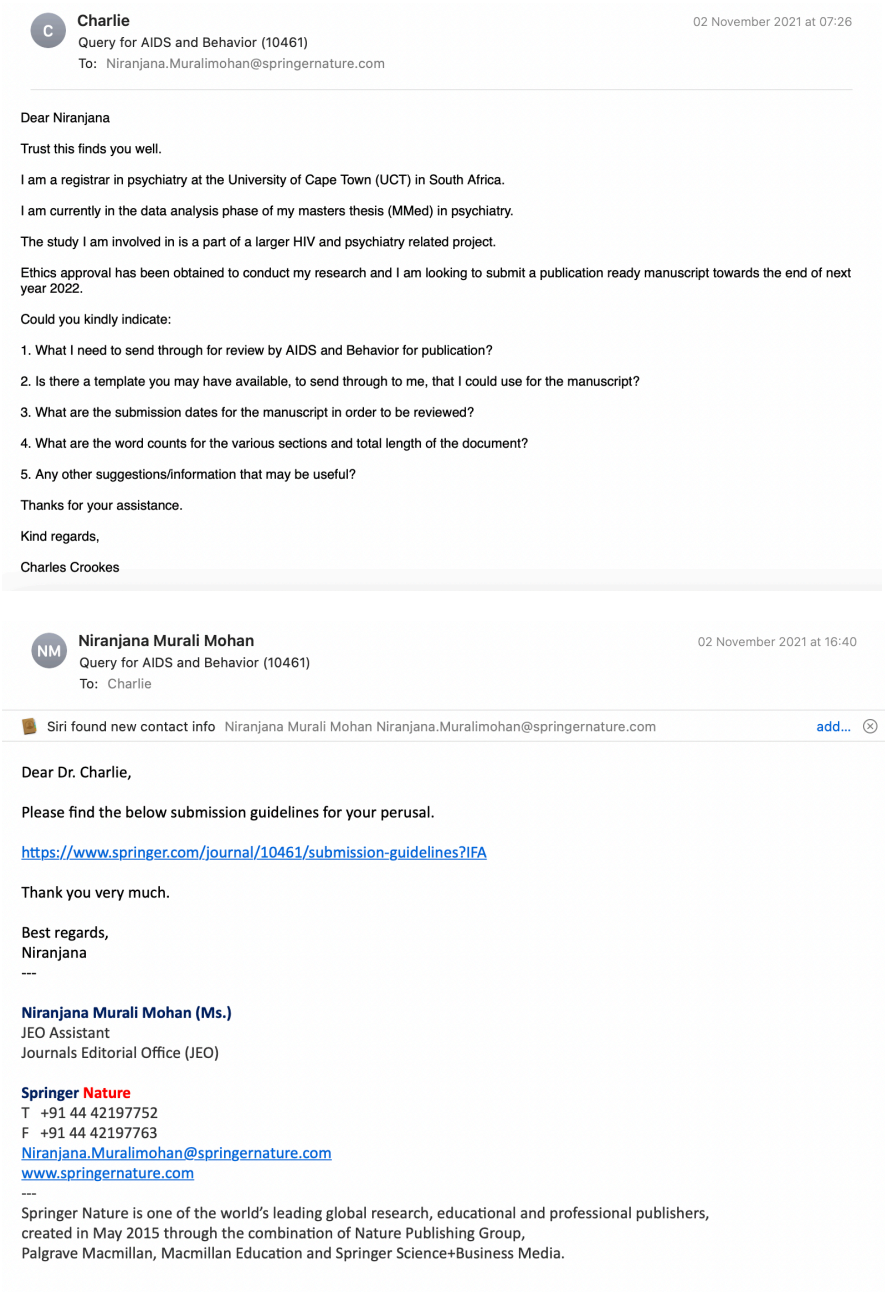
6) Hirsch MS, D'Aquila RT, Kaplan JC. Antiretroviral therapy. In: DeVita VT, Hellman S, Rosenberg SA, eds. AIDS: Biology, Diagnosis, Treatment and Prevention. 4th ed. Philadelphia, PA: Lippincott-Raven; 1997.

7) Ray SC. Simplot for Windows, version 2.5. Available at: http.//www.med.jhu.edu/deptmed/sray/download/. Accessed November 7, 2001.

Verify that every instance of a number in text corresponds to the numbered reference.

Footnotes should be avoided. When their use is absolutely necessary, footnotes should be numbered consecutively using Arabic numerals and should be typed at the bottom of the page to which they refer. Place a line above the footnote, so that it is set off from the text. Use the appropriate superscript numeral for citation in the text.

Correspondence with AIDS and Behavior:



Charlie 02 November 2021 at 07:26
Query for AIDS and Behavior (10461)
To: Niranjana.Muralimohan@springernature.com

Dear Niranjana

Trust this finds you well.

I am a registrar in psychiatry at the University of Cape Town (UCT) in South Africa.

I am currently in the data analysis phase of my masters thesis (MMed) in psychiatry.

The study I am involved in is a part of a larger HIV and psychiatry related project.

Ethics approval has been obtained to conduct my research and I am looking to submit a publication ready manuscript towards the end of next year 2022.

Could you kindly indicate:

1. What I need to send through for review by AIDS and Behavior for publication?

2. Is there a template you may have available, to send through to me, that I could use for the manuscript?

3. What are the submission dates for the manuscript in order to be reviewed?

4. What are the word counts for the various sections and total length of the document?

5. Any other suggestions/information that may be useful?

Thanks for your assistance.

Kind regards,

Charles Crookes

Niranjana Murali Mohan 02 November 2021 at 16:40
Query for AIDS and Behavior (10461)
To: Charlie

Siri found new contact info Niranjana Murali Mohan Niranjana.Muralimohan@springernature.com add...

Dear Dr. Charlie,

Please find the below submission guidelines for your perusal.

https://www.springer.com/journal/10461/submission-guidelines?IFA

Thank you very much.

Best regards,
Niranjana

Niranjana Murali Mohan (Ms.)
JEO Assistant
Journals Editorial Office (JEO)

Springer Nature
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www.springernature.com

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created in May 2015 through the combination of Nature Publishing Group,
Palgrave Macmillan, Macmillan Education and Springer Science+Business Media.

APPENDIX 9: Plagiarism Declaration - Turnitin

Plagiarism Declaration

"This thesis/dissertation has been submitted to the Turnitin module (or equivalent similarity and originality checking software) and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor."

Name: Charles Gerald Crookes

Student number: CRKCHA001

Signature:

Date:
30/01/2023

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