



**Factors Associated with Increased Symptoms of Depression among South Africans Living
with Chronic Illness**

By

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Signed by candidate

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19/1/23

Acknowledgments

I would like to dedicate this work to my family without whom none of this would be possible.

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Abstract

Background

Depression is one of the leading causes of disability in developing countries. People living with chronic illnesses are more vulnerable to developing depression. Although this connection is well established, the factors associated with severe depressive symptoms in people living with a chronic illness are poorly understood. South Africa has a high prevalence of depression and chronic illness, particularly HIV and Diabetes, yet the literature is sparse regarding depressive symptoms, particularly severe depression symptoms, in this group. To address this gap, this study aims to investigate the risk factors associated with severe depression symptoms among South Africans living with a chronic illness.

Methods

Secondary data analysis was done using a quantitative cross-sectional design. De-identified data was obtained from the parent study (Project Mind), utilising the baseline data from this cluster randomised controlled trial of a brief intervention for depression and risky alcohol use in primary care amongst patients living with HIV or diabetes mellitus. Cases included in this study were those who were at risk for depression at the baseline interview. Depression was measured using the 20-item Centre for Epidemiological Studies Depression Scale (CES-D) tool and those scoring 16 or above were identified as being at risk for depression. Factors associated with severe symptoms of depression were explored separately in diabetes and HIV groups using unadjusted and adjusted logistic regression models. The dependent variable was severe depression symptoms (a binary categorical variable), indicated by a CES-D score of 29 or more. Independent variables included sociodemographic, chronic illness diagnosis, biological markers of chronic illness control, alcohol and drug use, adherence and numbers of different types of traumatic experiences.

Results

The study sample comprised mainly female participants and ages ranged from 19 to 88 years. The majority were unemployed (57%), did not complete high school (67%), and reported earning less than R2000 per month (76%). Over 70% of the 1 117 participants scored above the threshold for severe depression symptoms in this study and of the 525 participants who reported using alcohol, 27% were using alcohol at high risk levels. In the adjusted model for the HIV group, female participants (OR 1.871, CI 1.179 - 2.969), those using alcohol at high risk levels (OR 1.627, 1.038 - 2.551) and participants reporting ten or more trauma types (OR 2.191, 1.218 - 3.942) were significantly more likely to report increased symptoms of depression compared to other participants. In the diabetes group, only those who had experienced 7-9 (OR 2.500; CI 1.423 - 4.392) and 10 or more trauma types (OR 3.275; CI 1.598 - 6.710) were significantly associated with severe depression symptoms.

Conclusion

Findings from this study have provided insight into the characteristics of patients living with a chronic illness who may be at risk for severe depression. Income support, risky alcohol use, or traumatic experiences should be explored as targets for intervention in this vulnerable group.

Introduction

Mental disorders are highly prevalent and significantly contribute to the global burden of disease. Globally, mental disorders are among the leading causes of disability-adjusted life years (DALYs) and years of life lived with disability (YLDs) (1). For example, depressive disorders account for roughly 1.84% of DALYs and 5.45% of YLDs, (IHME, 2019) (2). Further, systematic reviews and meta-analyses indicate that approximately 17.6% (one in five) of the global population have met the criteria for a CMD within the previous 12 months and 29.2% have experienced a CMD at some time in their lives (3). Available data indicate that the burden of mental disorders is particularly significant in low and middle income countries (LMICs) (4). In LMICs, it has been predicted that by the year 2030, depression will be the leading cause of disability among developing countries (5).

Similar to other LMICs, the prevalence of depression in South Africa is particularly high. Data from a South African nationally representative sample reported that the lifetime prevalence of developing a mental illness is 30%, with depression accounting for 9.7%, with a prevalence rate of 4.9% in the last 12 months (6). In certain high risk groups such as pregnant women (7), people living in conflict and war-torn environments (8), and people living with a chronic disease (9) the prevalence of depression is estimated to be even higher.

Several studies suggest a high prevalence of depression among people living with chronic illnesses. A recent meta-analysis published in 2019 explored the prevalence of mental illness among people living with a chronic disease in developing countries. It demonstrated that prevalence trends were similar in both developed and developing countries. The study found an increased risk of mental illness among those with chronic illness, with a prevalence of mental illness of 36.6% in this population (10). For example, research suggests that people living with diabetes have two times the risk of developing depression compared to those without diabetes (11). People living with HIV are also up to 4 times more likely to be depressed than those without HIV (12).

A few studies in South Africa have explored the relationship between chronic illnesses and depression. A study by Jansen van Vuuren et al 2019, examining patients with pre-existing diabetes, found a 46.6% prevalence of depression among this population group (6). However, this study involved a small cohort of 176 patients from a diabetic clinic in rural KwaZulu Natal. A meta-analysis found that depression is also noted to be twice as likely to occur in people living with HIV (PLWHIV) compared to those who were HIV negative (13). Within South Africa, a study by Freeman et al 2014, which examined 900 people spanning 5 provinces, showed that among PLWHIV, the prevalence of depression was as high as 41% (14). Locally research on the association between depression and chronic diseases remains limited in comparison to international studies. Furthermore, South Africa has an incredibly high burden of chronic illnesses including HIV (13.1%) (15) and diabetes (13%) (15), necessitating further investigation.

Although depression is highly prevalent in patients with comorbid chronic diseases, the majority of depression diagnoses remain undetected (15). It is estimated that 30% of South Africans have a mental illness in their lifetime as classified by the DSM IV, however, most of these go untreated. There are multiple barriers to receiving mental health care treatment in

LMIC settings. The most prominent reasons, as described in the South African context, are 1) Attitudinal barriers such as a low perceived need for treatment and stigma; and 2) multiple structural barriers (16). Structural barriers include the availability of health services (or lack thereof) and the financial costs associated with accessing them (17).

If left untreated, symptoms of depression in people with chronic illnesses may lead to numerous negative implications (18). For example, PLWHIV and depression show decreased levels of social and occupational functioning and subjective quality of life (18)(14)(13). A meta-analysis of treatment adherence in PLWHIV showed that those with depression have a significantly lower adherence to ARVs (42% lower) than those without depression(4) (19). This in turn can lead to treatment failure and continued spread of disease. In people living with diabetes, depression has been associated with an increased risk for symptom severity, including micro- and macro-vascular complications, and increased work disability (20). This leads to higher use of medical services and ultimately, increased health care costs for these patients (20). This is hypothesized to be linked to chronic stress causing activation of the HPA axis leading to chronic inflammation. Furthermore, depression in diabetic patients has been linked to negative self-care behaviors, for example, poor diet, lack of exercise and poor medication adherence (20) all of which, contribute to poor health outcomes.

Factors associated with depression in the general population

Since there are limited studies investigating factors of depression in those with chronic illness, this section will explore factors associated with depression in the general population and when there is available data on the chronic disease - this will be highlighted. Thereafter, factors associated with increased severity of depressive symptoms in patients living with a chronic illness will be highlighted

Many factors may predispose people with chronic illnesses to develop depression. These include a host of multilevel interactive influences. These can be contextualized within population based research by investigating individual factors embedded within a larger social system (21). These systems do not act in isolation, but are interactive and reinforcing, therefore influencing the individuals’ health behavior(22). Relevant factors that contribute to increasing rates of depression in people living with chronic illness may also be categorized as socio-demographic, disease-related (biological), and psycho-social factors. These categories are identified and discussed below (Table 1).

<i>Sociodemographic</i>	<i>Psychosocial Factors</i>	<i>Disease Related Factors</i>
<i>Age</i>	<i>Illicit drug use</i>	HIV status
<i>Sex</i>	<i>Alcohol use</i>	Diabetes status

<i>Marital status</i>	<i>Tobacco use</i>	<i>HBA1c/VL</i>
<i>Level of education</i>	<i>Trauma History</i>	<i>Treatment adherence</i>
<i>Employment</i>		
<i>Income</i>		

Table 1: Risk Factors for Depression

Sociodemographic factors

Sociodemographic factors such as age, gender, marital status, level of education and income have been identified as important in explaining the variability in the prevalence of depression (23)(24).

Gender

Research has shown that the prevalence of depression differs significantly based on gender. Depression is shown to be twice as prevalent in females compared to males (23)(25). However, there are similar trends in both genders, for example, both males and females showed an initial increase in depression rates followed by a decrease over a lifespan(26). In a Canadian National Population Health Survey rates of depression for females were higher (9.6%) in the 12 to 24 age group and lower (3.1%) in those ages 65 and above (23)(27). For males, the prevalence of 12-month depression was 5.3% in the 12-24 age group and decreased to “too low to report” in the over 65 age group (25)(23). For both genders, index depression that occurs later in life is usually associated with other comorbidities(28).

Marital Status

There is evidence that marital status may influence depression prevalence (29). However, this is often closely linked to, and thus cofounded by, other factors such as gender and age. In unmarried men (single, widowed or divorced) the risk of developing depression is higher compared to that of unmarried women (30). Higher rates of depression correlated to increasing age in both single people and those in common law relationships (unmarried in a relationship). In the elderly population, unmarried people (widowed, divorced, never married) are at higher risk for depression than elderly married people. However, more specifically, among the elderly unmarried population, those who were widowed were more likely to develop depression compared to those who were never married (30).

Level of Education

The relationship between the level of education and depression is unclear with contradictory evidence (31). Lower rates of depression have been observed in individuals who do not complete high school compared to those who study further (23). However, education level has also been seen to be protective from depression over the course of a life span (31)

Socioeconomic status

The prevalence of depression has been found to vary based on socioeconomic status (SES). Those in the lowest SES group are two times more likely to develop depression compared to

those in the highest SES (23)(32). Furthermore, children of families with a low SES were observed to higher risk of experiencing symptoms of depression in adulthood (33).

Unemployment

It is widely accepted that unemployment is associated with impaired mental health (34). Unemployment is also associated with poorer psychosocial outcomes and wellbeing (35). Being unemployed increases the risk of developing symptoms of depression, with men and women being equally affected (36).

Psychosocial Factors

Alcohol Use

Depression is one of the most common mental illnesses that co-occur with alcohol use (37). The existence of either an AUD or a depressive disorder doubles the risk for the development of the second. Patients that have AUD as a comorbidity of their depression, often have a more complicated presentation with a poorer prognosis compared to patients without AUD (38). The South African Stress and Household Survey found that people with hazardous alcohol use had an 11.8% lifetime prevalence, and a 6.1% 1 year prevalence, for developing a major depressive disorder (37).

Tobacco Use

There is a high occurrence of tobacco use in people with mental illness (39). Research suggests a direct correlation between cigarette use and the development of depression (40). Increased quantities of tobacco have been linked to worsening the severity of the illness (41) and a decrease in life expectancy (39). It is postulated that this high co-occurrence of tobacco use and depression is due to the 'self-medication' use of cigarettes to treat depressive symptoms (42). Furthermore, cigarette use leads to an increase in medical comorbidities, which subsequently increases depression (39).

Illicit Substance Use

There is a strong association between hazardous substance use and increased rates of depression (43). This comorbidity results in an increase in the severity of the symptoms and a poorer prognosis (44). According to the SASH study, substance users in South Africa are more likely to be male, white and employed. This study found that substance users, irrespective of the kind of substance used, are more likely to be depressed. The odds ratio for the development of major depression in substance users over a lifetime is 8.6, and 4.3 for 12-month. Cannabis was highlighted to significantly increase the risk of developing symptoms of depression compared to other substances (37).

Trauma

Traumatic experiences, especially childhood trauma, have been associated with increased rates of depression in adulthood (45). The term 'Trauma' encompasses traumatic experiences

such as abuse that is physical, emotional, sexual and also includes neglect (46). Research suggests that childhood trauma may negatively impact the development of children and adolescents and lead to an earlier onset of depression (47). In a South African study - children aged 10 to 17 – demonstrated a prevalence of physical abuse to be 56.3%, emotional abuse at 35.5%, and sexual abuse at 9% (48). Traumatic experiences are also linked to current HIV risky behaviors. This is demonstrated regardless of gender, the type, or the severity of the trauma experienced (49) .

Biological Risk Factors

HIV

Depression is a common complication of HIV. The relationship between depression and HIV is complex. Depression may be the result of HIV, however, depression itself increases the vulnerability of acquiring HIV (50). Depression is associated with adverse clinical outcomes in PLHIV (12). This population is likely to experience stigma, increased physical illnesses and periods of chronic stress which catalysis the development of depression (51). Untreated depression in PLHIV has many negative implications such as poorer quality of life, poorer response to treatment and increased mortality (12).

Viral Load

Depression is associated with increased Viral (VL) levels in PLHIV (52) and may occur in all stages of HIV (12). PLHIV with symptomatic HIV has higher rates of depression compared to asymptomatic people (13). HIV causes neurobiological changes that predispose to depression. HIV results in chronic cytokine activation causing neurotoxicity, including neurotoxicity of dopamine neurons. This also results in a decrease Brain Derived Neurotropic factor (BDNF) (53). Depression causes an impaired immune response in PLHIV – with a decrease the activity of natural killer cells that may lead to an increase in Viral load (52).

Treatment Adherence - ART

There is a strong and consistent relationship between depression and ART nonadherence. This relationship is bidirectional. Poor treatment adherence is linked to increasing treatment failure, high viral loads and worsen complications of HIV (54). Depression itself is also a factor in poor adherence to ART (55).

Diabetes

Diabetes is significantly linked to increased depression prevalence as compared to the general population (56). This may be due to the activation of pro-inflammatory pathways as was as lifestyle factors (including diet and exercise) that predispose to depression (57). This comorbidity results in increased diabetic complications and poorer treatment outcomes(58)

HBA1C

Research surrounding the association between HbA1C and the severity of depression remains unclear (59). While poor glycemic control is more prevalent in diabetic distress, it is not necessarily associated with changes in depressive symptoms (60). Diabetic distress

encompasses the subjective experience of anxiety, guilt and denial due to diabetes and the implications thereof. Diabetic Distress is also linked to adverse health outcomes (61)

Treatment Adherence (Diabetes)

Research has demonstrated a significant association between depression and poor adherence to treatment (62). This relationship is often bidirectional and may lead to worse clinical outcomes (63).

Factors associated with increased severity of depressive symptoms

Literature is sparse regarding factors associated with severe depressive symptoms in those living with a chronic illness. Data is available from studies conducted in patients with diseases such as chronic kidney disease (64), spondyloarthritis (65) and other rare chronic diseases such as neurofibromatosis (66). In these studies lack of exercise, low levels of education, and poor general health were related to increased severity of depressive symptoms (65). The symptom severity of chronic illness, the perception of the severity of such symptoms, feeling less in charge of one's illness and lack of concern were also linked to increased severity of depression (66). Social Support was seen as an important protective of depression in a few studies (64)(67)(66) with increased depressive symptoms observed in those living alone (64). Certain factors such as having good coping mechanisms including a constructive attitude and actively engaging in life were protective in that they were associated with decreased severity of symptoms (66).

Depression in populations with chronic illnesses has been well researched in developed countries; however, data from South African settings remains scarce. This poses a problem when wanting to implement meaningful health promotion and prevention locally. In the South African population, with a high frequency chronic illness, along with the proven co-occurrence of depression and the known negative implications, further research is required to understand the contributing factors to depression. This may help mitigate the progress of these illnesses and improve the health outcomes of these populations. Currently, there is a dearth of information regarding factors associated with depression symptoms in those living with chronic illnesses, especially in a South African Context. Studies focusing specifically on factors associated with the severity of depression in this population are also limited. This study aims to address this disparity.

Aim

This research aims to investigate the risk factors associated with the increased severity of depression among South Africans living with a chronic illness.

Methods

Study design

This research is a secondary data analysis using a quantitative cross-sectional design.

Project MIND

The baseline data is taken from patients receiving treatment for HIV or diabetes who participated in Project MIND. Project MIND is a Cluster Randomized Control Trial that endeavored to test approaches to better incorporate mental health counseling into chronic disease care at a PHC level. This was done by comparing two different approaches in delivering mental health care. The “dedicated” approach where facility based counsellors (FBC) in the PHC had the sole responsibility of providing mental health care. On the other hand, the “designated” approach – trained HIV counselors already providing a service at the PHC to deliver – were tasked with delivering 3 sessions of a blended motivational interviewing and problem solving therapy intervention in addition to their usual duties(68)(69).

Setting

This study was conducted at 24 Primary Health Care clinics throughout the Western Cape – in both urban (15 clinics) and rural (9 clinics) settings that offered separate HIV and Diabetic Clinics within the same PHC. These selected clinics varied in terms of size and available resources to better reflect the array of PHCs in the province.

Study participants and procedures for Project MIND[KS1]

From May 2018 to March 2019, 1200 participants were recruited from the 24 primary care clinics. All patients presenting for routine HIV and Diabetes treatment at these primary care clinics were approached and asked by their healthcare provider about recent alcohol use and low mood before being referred to a study assessor for study eligibility screening. The study was then explained to these patients, and verbal consent was taken. Patients that were willing to be included in the study, and who were deemed to be eligible were given an appointment for an enrolment visit.

For Project MIND, people were enrolled if they were interested in study participation. They were eligible for the study if they were above the age of 18, and were already diagnosed and receiving treatment at the PHC for either HIV or Diabetes. Those with suspected alcohol use were screened and those with an AUDIT (Alcohol use disorder identification test) score between 8 and 22 were included. If depressed, they were eligible for the study if they scored 16 or above on the CES-D (Centre for Epidemiological Studies and Depression scale). Those who were not agreeable and those who were already diagnosed with a mental health condition were excluded from this study.

At the enrolment visit, which was performed in the PHC – patients were re-screened and informed consent for trial participation was obtained (Appendix 1 and 2). [KS2]The Assessors performed these interviews at baseline in isiXhosa, Afrikaans and English. Then computer-

assisted personal interviews lasting for 60 minutes were performed. Information that was obtained in these interviews included socio-demographic, psychosocial and biological data. A blood sample was then taken from patients – to determine their initial Viral Load and/or their HbA1C. Participants received a grocery voucher for completing the baseline survey.

Participants for this secondary analysis

Data for this specific study has been extracted from the database for participants who scored 16 or above in the CES D. Those who scored above 29 were assessed to have severe depression.

Measures

Data for this study was collected using the following measures (Appendix 3):^[KS3]

Socio-demographic questionnaire

Information was collected from participants' age, sex, marital status, level of education, employment status, and level of income.

Alcohol Use Disorder Identification Test (AUDIT)

This is a screening tool to measure harmful alcohol use (70). The AUDIT consists of 10 questions and measures alcohol consumption, dependence and related problems (71). It includes questions such as 'How often do you have a drink containing alcohol?' and 'Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?' Hazardous alcohol use is considered when there is a score of 8 or more. The AUDIT is reliable and has been validated for use in the South African population (16).

Center for Epidemiologic Studies Depression Scale (CES-D)

The CES-D is a 20 item scale that measures feelings and behaviors linked to depression occurring in the past week(29). It is scored between 0 and 60 with a score of 16 or more suggesting depression. A score of over 29 is indicative of severe depression. The scale measures the frequency of symptoms consistent with DSM V criteria for depression. This includes questions on dysphoria, anhedonia, appetite, sleep disturbance, cognitive impairment, guilt, feelings of helplessness, fatigue, psychomotor agitation, and suicidality (72).

Biomarkers

HbA1c for participants with Diabetes and Viral Load for those with HIV indicate the severity of the respective conditions as well as treatment failure. Biomarkers were examined as continuous variables. Results were further dichotomized as normal (if HBA1C of < 7% and a viral load < 1000 copies/ul) or abnormal.

Adherence

Three scales were used to measure adherence. The AIDS Clinical Trial Group (ACTG) is a questionnaire for participants on Antiretroviral Treatment (ART) which examines current

medication used and doses missed in the preceding 4 days (73). The CASE Adherence Index consists of 3 questions to assess adherence of ART (74). The Visual Analog Scale (VAS) was used in participants with Diabetes and assesses adherence over 1 month. Results for the ACTG and VAS were recorded as continuous variables and further dichotomized using a predetermined cut off score (90%).

Drug Use Disorder Identification Test (DUDIT)

This self-reported screening questionnaire consists of 11 items that measure patterns of illicit substance use (75). The DUDIT has been validated for use in South Africa (76) It evaluates the amount of substance use and assesses the criteria of substance dependence in accordance with DSM IV and ICD 10 (75)

Trauma History Questionnaire (THQ)

The THQ is a 24 item self-reported instrument used to examine the experiences of traumatic events. This includes physical, sexual, general trauma and other crimes(77). Examples of questions relating to sexual abuse include “Has anyone ever made you have intercourse, oral or anal sex against your will? If yes, please indicate the nature of the relationship with person” and crime – “Has anyone ever tried to take something from you by using force or the threat of force, such as a stick-up or mugging”. The THQ indicates the extent and timing and frequency of the exposure (78).

Ethical Considerations

All data for this study was obtained from “Project Mind” (Pan African Clinical Trial registry – trial registration number – ACT201610001825403). This study was submitted to the Human Research Ethics Committee at the Faculty of Health Sciences, University of Cape Town, South Africa. HREC Ref: 774/2021. Ethics approval was granted on 3 December 2021. Non-essential identifying information was used in the data collection and storage. Secondary data will be stored on a locked and secure computer. No further recruitment was performed.

Statistical Analysis[KS4][KS5]

Data was analysed using SPSS. Descriptive statistics were conducted and presented as frequencies for categorical variables and continuous variables means, standard deviations, medians and ranges were reported as appropriate. Both the unadjusted and adjusted factors associated with severe depression symptoms were explored using logistic regression. The dependent variable was a binary variable indicating the presence or absence of severe depression symptoms. Independent variables included sociodemographics, chronic illness diagnosis, biological markers of chronic illness control, alcohol and drug use, adherence, and traumatic experiences. Results of the regression models were reported as odds ratios accompanied by 95% confidence intervals. Statistically significant association will be considered where the p-value is less than 0.05.

Results

Table 1 details the sociodemographic and health characteristics of participants. A total of 1 117 participants were recruited into this study, of which the majority were female (n=900, 86%) and most of the sample were between the ages of 19 and 88 years old. Of the total sample, just over half of the participants were not in a relationship (n=673, 60.3%) and about two thirds of all participants did not complete high school (n=746, 66.8%). Further, the majority were unemployed (n=631, 56.5%) and most participants reported having an income that was lower than R2000 a month (n=852, 76.3%).

Of the total sample of participants only 73 (6.5%) had both HIV and DM, while 567 (50.8%) had HIV only and 477 (42.7%) had DM only. Notably, the majority of respondents were at risk for severe depression (n=820, 73.4%) with scores of 24 or above on the CESD-20. In this study sample, 53% of participants did not consume alcohol (n=592); however, of the participants who did consume alcohol, – most (n=299, 26.8%) screened positively for hazardous alcohol use. Participants who currently smoked compromised 30.4% (n=340) of the study sample. Of those having experienced different types of trauma, the minority of respondents reported experiencing fewer than 3 different types of trauma (n=263, 23.5%).

Table 1. Sociodemographic and health characteristics of the sample (N=1117)

Variable	N (%)
Gender	
Male	217 (19.4)
Female	900 (80.6)
Age (med, range)	46, 19-88
Relationship status	
In a relationship	438 (39.4)
Not in a relationship	673 (60.6)
Education	
Didn't complete high school	746 (66.8)
Completed high school	371 (33.2)
Employment Status	
Unemployed	631 (56.5)
Employed	330 (29.5)
Pensioners	156 (14.0)
Average monthly income	
< R2000	852 (76.3)
R2000 to R4000	206 (18.4)
> R4000	59 (5.3)
Condition	
HIV only	567 (50.8)
DM only	477 (42.7)
HIV and DM	73 (6.5)
Depression (CES-D)	
No	297 (26.6)
Yes	820 (73.4)
Alcohol risk (AUDIT)	
No drinking	592 (53.0)
Low	95 (8.5)
Moderate	131 (11.7)
Severe	299 (26.8)
Current smoking	
Non-smoker	777 (69.6)
Smoker	340 (30.4)
Trauma History Questionnaire	
0-3 trauma types	263 (23.5)
4-6 trauma types	348 (31.2)
7-9 trauma types	297 (26.6)
10 or more trauma types	209 (18.7)

The adjusted and unadjusted associations between sociodemographic and health related variables and severe depression in people living with HIV and Diabetes are reported in Tables 2 and 3, respectively.

In the sample of people living with HIV, the results showing an association between severe depressive symptoms and sociodemographic- and health-related variables were similar in the adjusted and unadjusted models. After adjusting for the effects of other variables, women living with HIV were more likely to experience severe symptoms of depression compared to men (OR 1.871, CI 1.179 - 2.969). Additionally, participants who had completed high school (OR 0.554, 0.378 - 0.814) were less likely to have severe depression symptoms. Similarly, participants who had an income of between R2000 and R4000 a month were less likely to have severe depressive symptoms (OR 0.628, CI 0.399 - 0.987) compared to participants who earned less than R2000 a month. After adjusting for the effects of other variables, respondents who were at high risk for an alcohol use disorder (OR 1.627, 1.038 - 2.551) or who had experienced 10 or more different types of trauma (OR 2.191, 1.218 - 3.942) were significantly more likely to report increased symptoms of depression compared to other participants.

Investigations into the unadjusted associations between severe depressive symptoms and people living with diabetes revealed that participants who were currently smoking cigarettes were more likely to have severe depression (OR 1.657, CI 1.003 - 2.737), while those participants who were more adherent to diabetic medication were less likely to have severe symptoms of depression (OR 0.648, CI 0.424 - 0.992) compared to those who were poorly adherent. After adjusting for the effects of other variables, only statistically significant associations between severe depressive symptoms and trauma were noted. Respondents that had experienced 7 to 9 different types of trauma (OR 2.500; CI 1.423 - 4.392), or 10 or more trauma types (OR 3.275; CI 1.598 - 6.710) were more likely to have severe depressive symptoms compared to those who had experienced fewer types of trauma.

Table 2. Unadjusted and adjusted associations between socio-demographic and health related variables and severe depression among PLWHAs

Variable	Yes (%), n=479	No (%), n=161	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Gender				
Male	83 (17.3)	40 (24.8)	1.00	1.00
Female	396 (82.7)	121 (75.2)	1.577 (1.027 - 2.421)	1.871 (1.179 - 2.969)*
Age (med, range)	39, 19-71	41, 19-62	0.987 (0.970 - 1.005)	0.989 (0.970 - 1.007)
Relationship status				
In a relationship	141 (29.6)	59 (36.9)	1.00	1.00
Not in a relationship	336 (70.4)	101 (63.1)	1.392 (0.955-2.029)	
Education				
Didn't complete high school	301 (62.8)	83 (51.6)	1.00	1.00
Completed high school	178 (37.2)	78 (48.4)	0.629 (0.439 - 0.902)	0.554 (0.378 - 0.814)*
Employment				
Unemployed	326 (68.1)	100 (62.1)	1.00	
Employed	139 (29.0)	57 (35.4)	0.748 (0.511 - 1.095)	
Pensioners	14 (2.9)	4 (2.5)	1.074 (0.346 - 3.335)	
Average monthly income				
< R2000	384 (80.2)	116 (72.0)	1.00	1.00
R2000 to R4000	77 (16.1)	38 (23.6)	0.612 (0.394 - 0.951)	0.628 (0.399 - 0.987)*
> R4000	18 (3.8)	7 (4.3)	0.777 (0.317 - 1.906)	0.959 (0.377 - 2.441)
HIV and DM				
No	423 (88.3)	144 (89.4)	1.00	
Yes	56 (11.7)	17 (10.6)	1.121 (0.631 - 1.992)	

Alcohol risk (AUDIT)				
No drinking	168 (35.1)	65 (40.4)	1.00	1.00
Low	43 (9.0)	16 (9.9)	1.040 (0.548 - 1.975)	1.132 (0.585 - 2.191)
Moderate	65 (13.6)	31 (19.3)	0.811 (0.485 - 1.357)	0.915 (0.534 - 1.569)
Severe	203 (42.4)	49 (30.4)	1.603 (1.050 - 2.448)	1.627 (1.038 - 2.551)*
Current smoking				
Non smoker	298 (62.2)	101 (62.7)	1.00	
Smoker	181 (37.8)	60 (37.3)	1.022 (0.707 - 1.479)	
Adherence to ARVs				
VAS - Adherence < 90%	145 (30.3)	47 (29.2)	1.00	
VAS - Adherence 90-100%	334 (69.7)	114 (70.8)	0.950 (0.642 - 1.405)	
Trauma History Questionnaire				
0-3 trauma types	78 (16.3)	40 (24.8)	1.00	1.00
4-6 trauma types	136 (28.4)	51 (31.7)	1.368 (0.830 - 2.252)	1.317 (0.789 - 2.197)
7-9 trauma types	146 (30.5)	43 (26.7)	1.741 (1.045 - 2.902)	1.697 (0.994 - 2.896)
10 or more trauma types	119 (24.8)	27 (16.8)	2.260 (1.284 - 3.979)	2.191 (1.218 - 3.942)*
Viral Load				
<40	305 (63.7)	107 (66.5)	1.00	
40-999	84 (17.5)	19 (11.8)	1.551 (0.900 - 2.673)	
>999	90 (18.8)	35 (21.7)	0.902 (0.576 - 1.412)	

Table 3. Unadjusted and adjusted associations between socio-demographic and health related variables and severe depression among PLWD

Variable	Yes (%)	No (%)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Gender				
Male	70 (17.6)	32 (20.9)	1.00	1.00
Female	27 (82.4)	121 (79.1)	1.235 (0.774 - 1.971)	1.397 (0.850 - 2.295)
Age (med, range)	54, 19-85	56, 21-88	0.989 (0.971 - 1.006)	0.992 (0.974 - 1.011)
Relationship status (missing, n=3)				
Married	164 (41.4)	73 (48.3)	1.00	
Living with partner	19 (4.8)	5 (3.3)	1.691 (0.608 - 4.705)	
Widow/widower	74 (18.7)	23 (15.2)	1.432 (0.832 - 2.465)	
Divorced/separated	59 (14.9)	19 (12.6)	1.382 (0.769 - 2.483)	
Never married/single	80 (20.2)	31 (20.5)	1.149 (0.698 - 1.890)	
Education				
Didn't complete high school	292 (73.6)	115 (75.2)	1.00	
Completed high school	195 (26.4)	38 (24.8)	1.088 (0.708 - 1.672)	
Employment				
Unemployed	83 (46.1)	67 (43.8)	1.00	
Employed	118 (29.7)	41 (26.8)	1.054 (0.670 - 1.656)	
Pensioners	96 (24.2)	45 (29.4)	0.781 (0.497 - 1.227)	
Average monthly income				
< R2000	291 (73.3)	116 (75.8)	1.00	
R2000 to R4000	81 (20.4)	27 (17.6)	1.196 (0.736 - 1.944)	
> R4000	25 (6.3)	10 (6.5)	0.997 (0.464 - 2.140)	
HIV and DM				
No	341 (85.9)	136 (88.9)	1.00	

Yes	56 (14.1)	17 (11.1)	1.314 (0.737 - 2.342)	
Alcohol risk (AUDIT)				
No drinking	294 (74.1)	115 (75.2)	1.00	
Low	31 (7.8)	12 (7.8)	1.010 (0.502 - 2.036)	
moderate	26 (6.5)	14 (9.2)	0.726 (0.366 - 1.440)	
Severe	46 (11.6)	12 (7.8)	1.499 (0.767 - 2.933)	
Current smoking				
Non smoker	307 (77.3)	130 (85)	1.00	1.00
Smoker	90 (22.7)	23 (15)	1.657 (1.003 - 2.737)*	1.592 (0.951 - 2.665)
Adherence				
DM				
VAS - Adherence < 90%	131 (33)	37 (24.2)	1.00	1.00
VAS - Adherence 90-100%	264 (66.5)	115 (75.2)	0.648 (0.424 - 0.992)*	0.758 (0.487 - 1.179)
Trauma History Questionnaire				
0-3 trauma types	99 (24.9)	61 (39.9)	1.00	1.00
4-6 trauma types	135 (34)	57 (37.3)	1.459 (0.936 - 2.276)	1.432 (0.904 - 2.268)
7-9 trauma types	99 (24.9)	23 (15)	2.652 (1.523 - 4.618)*	2.500 (1.423 - 4.392)*
10 or more trauma types	64 (16.1)	12 (7.8)	3.286 (1.641 - 6.579)*	3.275 (1.598 - 6.710)*
HBA1C				
Good control (HBA1C <7)	77 (19.4)	29 (19)	1.00	
Poor control (HBA1C >7)	320 (80.6)	124 (81)	0.972 (0.605 - 1.562)	

Discussion

Several important findings emerged from this study. First, a high proportion of participants in the MIND trial screened at risk for severe depression. This was similar in the HIV and diabetes cohorts. Second, several factors were associated with the risk for high levels of depressive symptoms among the HIV cohort in the adjusted model, including gender, education, income, high risk for alcohol use disorder and experiencing multiple types of trauma. Third, in the diabetes cohort, only experiencing multiple types of trauma was significantly associated with severe depressive symptoms in the adjusted models.

In both the HIV and diabetes samples, the majority of participants (73.4%) screened at risk for severe depression. While most of the available studies recruiting patients with these chronic conditions investigate the prevalence of depression in people living with diabetes (79) or in those living with HIV (80),^[CVDW6] their aim is not to explore levels of depression severity. In this study, participants received an evidence-based psychological treatment shown to be effective in reducing depression as part of an intervention trial (81). However, evidence-based treatments for depression include the use of both psychotropic medication and psychological interventions, with severe depression requiring more specialised psychiatric care^{[KS7][DH8]} compared to mild or moderate depression (82).^[KS9] This study expands on the available literature and exposes the vulnerability and unmet needs of this population, given that mental health services are not currently integrated into general healthcare services at the primary care level^[KS10] (83).

In participants with HIV, several factors were associated with increased symptoms of depression. In line with existing literature on risk factors for depression generally (23,25,31,84), being female, having a lower level of education and a lower income were associated with increased severity of depression in this cohort. While a lower income was associated with higher odds of experiencing severe depressive symptoms, an income exceeding a threshold of R4000 a month showed no significant association with depressive severity. Similarly, recent data from a systemic review (85)^{[CVDW11][CVDW12]} showed that an increase in income was associated with an improvement in wellbeing and mental health, with the largest effect being for changes in income that moved study participants out of poverty. Although R4000 per month does not represent a so-called 'living wage' in^[CVDW13] South Africa at the time of the study, this amount may have been enough to protect individuals from housing and food insecurity (86). Further, a global survey found that an increase in income was associated with an increase in emotional wellbeing till a threshold of a specific annual income (\$60 000 to \$75 000 a year), following which no further increase in wellbeing was noted (87)^{[CVDW14][DH15][CVDW16]}.

In this study, hazardous alcohol use was significantly associated with increased odds of severe depressive symptoms in participants living with HIV. There is overwhelming existing literature that establishes the bidirectional relationship between alcohol and depression with the existence of one doubling the risk of developing the other (37,38). Some studies from LMICs support the association between alcohol use and the risk of developing symptoms of depression, in people living with HIV (88,89), although the findings in the literature generally regarding substance use and depression are variable^[CVDW17] (90).^[CVDW18] Given the known impact of alcohol use and depression on antiretroviral adherence^[CVDW19] (91,92), it seems important to intervene regarding alcohol and depression symptoms in this population.

In this study in both HIV and Diabetes cohorts, experiencing multiple different types of trauma was associated with an increase in severe depressive symptoms. In South Africa the prevalence of trauma is exceptionally high. South Africa has one of the highest rates of motor vehicle accidents globally (93) and the mortality rate related to interpersonal violence is almost seven times higher than the average global rate (94). Further, multiple South African studies reveal high rates of direct and indirect trauma exposure (95,96) including physical and sexual assault. The association between trauma, especially childhood trauma, and depression has been demonstrated in populations around the world, including [CVDW20]South Africa (95,97,98). Additionally, although there are a few studies that explore the association between trauma and Diabetes (26,27,28) and between trauma and HIV (29,30,31), no studies have explored the association [CVDW21]between depression severity and traumatic experiences in chronic disease populations.

This study highlights the need for integrating screening and interventions for mental health in chronic disease at every level of healthcare. Although there is a move towards task sharing mental healthcare services to general healthcare providers, nurses and counsellors in South Africa (104), integration of services remains limited (68,105). The recommended programmes differ in management with a focus on psychological management for mild depression and a combination of psychotropic and psychotherapy for moderate and severe depression (105). However screening distinguishing between mild, moderate and severe depression has not been recommended in national guidelines, thereby increasing the likelihood of undetected severe depression (106). To address this gap, a focus on establishing guidelines for screening for severe depression especially in those with chronic illness is recommended. This would guide psychotropic treatment, thereby improving not only the depressive symptoms of participants but also their chronic illnesses and ultimately improving their quality of life. Further, given that trauma was significantly associated with risk for severe depression among both HIV and diabetes cohorts, the findings from this study suggest that patients would benefit from psychological interventions with a trauma focussed approach.

Limitations

The findings of this study need to be considered in light of several limitations. First, this study used baseline data from a randomized control trial and was limited to patients willing to participate in an intervention study who completed this assessment. Second, the assessment of depression severity was conducted using a screening tool, rather than a diagnostic tool which may have led to an over-estimation of the number of severe depression cases. Third, given this study recruited participants living with HIV or Diabetes attending primary healthcare facilities in the Western Cape, we cannot generalize these findings to other chronic conditions in other settings.

Despite these limitations, this study is one of very few studies exploring the prevalence and associations of possible severe depression among people living with HIV or Diabetes. Further research needs to further explore the prevalence, associations, and implications of severe depression among South Africans living with a chronic disease and qualitatively explore the needs of this vulnerable population.

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**APPENDIX 1: PARTICIPANT INFORMATION SHEET AND GENERAL INFORMED CONSENT FOR TRIAL
PARTICIPANTS (Active arms)**

Project MIND

Introduction: Hello. My name is _____. I am from the South African Medical Research Council (SAMRC). We are asking you to take part in a research study. You qualify for this study because you are at least 18 years of age, you are receiving care for HIV and diabetes and because you report risky alcohol use or depression. Before you agree to take part you should understand what it involves. This pamphlet is to help you decide if you would like to take part in this study. If you have any questions, which are not fully explained in this pamphlet, please ask the project team. You should not agree to take part unless you are happy about all that is involved.

Why are we doing this?

The purpose of this study is to improve the availability of mental health services for chronic disease patients. We are testing two ways of delivering mental health services to people living with HIV and/or diabetes. If you decide to participate you will be one of 1200 patients receiving health services that will participate in the study. Your participation will us identify the best way of providing mental health services to patients like yourself.

What We're Asking of You.

Today- We will ask you to answer a set of questions about yourself, your health, adherence to your treatments, alcohol and drug use and your mental well-being. We will also ask you for contact information so that we can stay in touch with you during the study. To help us keep in contact with you, we would like to take a photograph of you so that we know who we are looking for the right person. At the end of the study, this photograph will be given to you to keep. We are also asking your permission to access some information about your chronic disease from your health records. Next you will receive your first intervention session. In total we will take about an hour and a half of your time.

During the next few weeks- We will ask you to attend 3 more counselling sessions (once a week for 3 weeks). These sessions will take place at the clinic during standard clinic operating hours. The first session is next week. These sessions will help you improve your problem solving and coping skills. You will need to come to the clinic for 1 hour for the first session, and then 45 minutes for each of the remaining two sessions. We would like to audio-record these counselling sessions so we can check that you are receiving a good quality service. These recordings will be stored on a password protected computer for one year, after which they will be destroyed.

In six months' time- We will ask you to return to the clinic for a follow-up interview about your health, adherence to treatment, alcohol use and mental well-being. This will last about 45 minutes. We will also ask to take a blood sample from you to test for the amount of HIV in your blood (viral load) if you are HIV

positive, or your HbA1C level if you are diabetic. The total amount of blood to be drawn will be less than 25 millilitres (ml), which is less than two tablespoons.

You may also be asked to take part in a more in-depth interview after the main study. This interview will ask you for feedback on the counselling sessions. These interviews will be audio-recorded. The recordings will be destroyed within a year after the results have been published. If you are chosen and agree to take part in one of these activities, we will ask you to sign another consent forms.

In one year's time. We will ask you to return for the last time and answer the same questions about yourself, your chronic disease, and your mental well-being as well as questions about your use of other health and social welfare services. We will also ask to take a blood sample from you to test for the amount of HIV in your blood (viral load) if you are HIV positive, or your HbA1C level if you are diabetic. The total amount of blood to be drawn will be less than 25 millilitres (ml), which is less than two tablespoons. After the testing, any remaining blood will be disposed of by the laboratory in line with all relevant safety policies and guidelines. The appointment will last about an hour.

Potential Risks or Discomforts - There are some risks to taking part in this study. Answering some of our questions may make you uncomfortable. It is ok if you do not want to talk about certain topics. You can also take a break at any time. You may also feel uncomfortable or nervous when blood is taken from you. Blood will be drawn by your usual nurse/ care provider to minimise discomfort. If you are distressed by any topic or test results, we will ensure that you access services to help you cope with these experiences..

Potential Benefits of Taking Part in The Study: If you take part in this study you may improve your well-being, reduce your alcohol use, and improve your quality of life. You will also help us understand the best way to help patients with a mental illness who receive treatment for a chronic disease.

Confidentiality and Privacy.

Any information obtained during the consent processes and this study will remain confidential. It will be disclosed only as required by law as noted in the following two exceptions: 1) If you tell us that you are about to hurt yourself or someone else. 2) Or if you are involved in the neglect and/or abuse of a child. In either case, we will report that information to the appropriate authorities. In addition, the MRC ethics committee will have access to your information. Anyone who is working with any of the information you give us has to sign an agreement not to share what you tell us. The only confidential data are information from the consent and locator forms, which will be stored in double-locked file cabinets. The consent forms will be destroyed after one year of completion of these activities.

Participation and Withdrawal.

During the 12-month period of this study, your treatment at this clinic will continue as usual. This study will not change the medications you receive. Participation is voluntary. You can choose not to participate in the intervention. If you decide to participate, you may choose to stop your participation at any time. You may refuse to answer questions you do not want to answer. Your decision to take part or not take part in this study or to leave the study will not affect your current or future treatment at this clinic.

Who is funding the study?

The study is being conducted by the South African Medical Research Council, University of Cape Town and Oxford University in collaboration with the Western Cape Department of Health. It is funded by the Medical Research Council in the U.K.

Reimbursement

Today- For your time today will give you a voucher of R75, refreshments, and R50 for transport.

Over the next few weeks- We will give you refreshments and R50 for transport to attend each intervention session. We will give you a voucher of R100 for completing all three counselling sessions.

In six months' time- We will give you refreshments, a gift voucher of R120 for completing a follow up assessment and for completing biological testing. You will also receive R50 for transport.

In one year's time- We will give you refreshments, a voucher of R150 for completing this follow-up assessment and for completion of follow-up biological testing. You will also receive R50 for transport.

Future Contact.

In the future, we may contact you to ask if you want to participate in additional study activities. You will complete a separate consent form if you agree to participate.

I consent to be contacted about future study activities (Please check the appropriate box).

Yes No

Who to Contact with Questions.

This study has been approved by the South African MRC Ethics Committee, The University of Cape Town's Ethics committee, and Oxford University's Ethics Committee. The study will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, and the South African Guidelines for Good Clinical Practice.

If you have any questions or concerns about the research, please contact Dr. Bronwyn Myers (Principal Investigator) at +021 938 0993 or write to bmyers@mrc.ac.za, or Medical Research Council (MRC) P.O. Box 19070, Tygerberg 7505, South Africa.

Rights of Research Participants.

You can decide you do not want to participate at any time. If you have any questions about your rights as a participant, you can contact the chairperson of the MRC ethics committee, Prof Danie du Toit at 021 938 0687 or email: adri.labuscagne@mrc.ac.za.

Indicating Consent.

Please let us know if you have any questions before signing this consent form. Please initial next to each item to show that you agree/disagree to what is required:

	Agree	Disagree	What We're Asking of You
1			I agree to continue in the study, which has been fully described to me. This means that I agree to answer questions today.
2			I agree to provide contact information
			I agree for study staff to contact friends and relatives if I cannot be reached by telephone
3			I agree to have my photograph taken as part of the contact information (Not mandatory)
4			I agree to allow information about my HIV or diabetes care to be extracted from my health records
5			I understand that one week from now and again a week later and again a week later I will be asked to return to participate in an intervention.
6			I understand that in about 6 months from now I will be asked to return to continue for a follow up interview
7			I agree to give a blood sample in 6 months time for testing of viral load and HbA1C.
8			I understand that in about 12 months from now I will be asked to return for a follow up interview

9			I agree to give a blood sample in 12 months time for testing of viral load and HbA1C.
10			I understand that my participation in this study is completely voluntary, and there will be no penalty if I choose not to participate.

Please also provide a full signature to show whether you agree to some intervention sessions being audio-taped to check for staff quality. (This is not a study requirement).

Agree	Disagree	
		I agree to some intervention sessions being audio-taped for quality control purposes.

DECLARATION BY PARTICIPANT

By signing below, I, _____ (**Participant's Full Name**) agree to take part in the **Project MIND study**.

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 pressured to take part. I also understand that I do not give up any rights by signing below.
- 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 researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.
- I have received a card with information about rights of research subjects and who to contact with questions.

Participant's Signature

Date
(DD/MM/YYYY)

Signed at (Place)

Witness (If participant is illiterate)

Date
(DD/MM/YYYY)

DECLARATION BY PROJECT STAFF

I, _____ (**Project Staff's Full Name**) declare that:

- I explained the information in this document to _____ (**Participant's Full Name**)
- 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

- I gave her a card with information about rights of research subjects and who to contact with questions.

Project Staff's Signature

Date
(DD/MM/YYYY)

Signed at (Place)

Witness (If participant is illiterate)

Date

APPENDIX 2: PARTICIPANT INFORMATION SHEET AND GENERAL INFORMED CONSENT FOR TRIAL PARTICIPANTS (Control arms)

Project MIND

Introduction: Hello. My name is _____. I am from the South African Medical Research Council (SAMRC). We are asking you to take part in a research study. You qualify for this study because you are receiving care for HIV and diabetes and because you report risky alcohol use or depression. Before you agree to take part you should understand what it involves. This pamphlet is to help you decide if you would like to take part in this study. If you have any questions, which are not fully explained in this pamphlet, please ask the project team. You should not agree to take part unless you are happy about all that is involved.

Why are we doing this?

The purpose of this study is to improve the availability of mental health services for chronic disease patients. We are testing two ways of delivering mental health services to people living with HIV and/or diabetes. If you decide to participate you will be one of 1200 patients receiving health services that will participate in the study. Your participation will us identify the best way of providing mental health services to patients like yourself.

What We're Asking of You.

Today- We will ask you to answer a set of questions about yourself, your health, adherence to your treatments, alcohol and drug use and your mental well-being. We will also ask you for contact information so that we can stay in touch with you during the study. To help us keep in contact with you, we would like to take a photograph of you so that we know who we are looking for the right person. At the end of the study, this photograph will be given to you to keep. We are also asking your permission to access some information about your chronic disease from your health records. Next you will receive some mental health information and referral to mental health services. In total we will take about an hour of your time.

In six months' time- We will ask you to return to the clinic for a follow-up interview about your health, adherence to treatment, alcohol use and mental well-being. This will last about 45 minutes. We will also ask to take a blood sample from you to test for the amount of HIV in your blood (viral load) if you are HIV positive, or your HbA1C level if you are diabetic. The total amount of blood to be drawn will be less than 25 millilitres (ml), which is less than two tablespoons

In one year's time. We will ask you to return for the last time and answer the same questions about yourself, your chronic disease, and your mental well-being as well as questions about your use of other health and social welfare services.. We will also ask to take a blood sample from you to test for the amount of HIV in your blood (viral load) if you are HIV positive, or your HbA1C level if you are diabetic. The total amount of blood to be drawn will be less than 25 millilitres (ml), which is less than two tablespoons. After the testing, any remaining blood will be disposed of by the laboratory in line with all relevant safety policies and guidelines. The appointment will last about an hour.

Potential Risks or Discomforts - There are some minor risks to taking part in this study. Answering some of our questions may make you uncomfortable. It is ok if you do not want to talk about certain topics. You can also take a break at any time. You may also feel uncomfortable or nervous when blood is taken from you. Blood will be drawn by your usual care provider to minimise risk and discomfort. If you are distressed by any topic or test results, we will ensure that you access services to help you cope with these experiences.

Potential Benefits of Taking Part in The Study: If you take part in this study you will be referred to mental health services which could improve your quality of life. You will also help us understand the best way to help patients with a mental illness who receive treatment for a chronic disease.

Confidentiality and Privacy.

Any information obtained during the consent processes and this study will remain confidential. It will be disclosed only as required by law as noted in the following two exceptions: 1) If you tell us that you are about to hurt yourself or someone else. 2) Or if you are involved in the neglect and/or abuse of a child. In either case, we will report that information to the appropriate authorities. In addition, the MRC ethics committee will have access to your information. Anyone who is working with any of the information you give us has to sign an agreement not to share what you tell us. The only confidential data are information from the consent and locator forms, which will be stored in double-locked file cabinets. The consent forms will be destroyed after one year of completion of these activities.

Participation and Withdrawal.

During the 12-month period of this study, your treatment at this clinic will continue as usual. This study will not change the medications you receive. Participation is voluntary. You can choose not to participate in the study. If you decide to participate, you may choose to stop your participation at any time. You may refuse to answer questions you do not want to answer. Your decision to take part or not take part in this study or to leave the study will not affect your current or future treatment at this clinic.

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Today- For your time today will give you a voucher of R75, refreshments, and R50 for transport.

In six months' time- We will give you refreshments, a gift voucher of R120 for completing a follow up assessment and for completing biological testing. You will also receive R50 for transport.

In one year's time- We will give you refreshments, a voucher of R150 for completing this follow-up assessment and for completion of follow-up biological testing. You will also receive R50 for transport.

Future Contact.

In the future, we may contact you to ask if you want to participate in additional study activities. You will complete a separate consent form if you agree to participate.

I consent to be contacted about future study activities (Please check the appropriate box).

Yes No

Who to Contact with Questions.

This study has been approved by the South African MRC Ethics Committee, The University of Cape Town's Ethics committee, and Oxford University's Ethics Committee. The study will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, and the South African Guidelines for Good Clinical Practice.

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Indicating Consent.

Please let us know if you have any questions before signing this consent form. Please initial next to each item to show that you agree/disagree to what is required:

	Agree	Disagree	What We're Asking of You
1			I agree to continue in the study, which has been fully described to me. This means that I agree to answer questions today.
2			I agree to provide contact information
3			I agree for study staff to contact friends and relatives if I cannot be reached by telephone
4			I agree to have my photograph taken as part of the contact information (Not mandatory)
5			I agree to allow information about my HIV or diabetes care to be extracted from my health records
6			I understand that in about 6 months from now I will be asked to return to continue for a follow up interview
7			I agree to give a blood sample in 6 months' time for testing of viral load and HbA1C.
8			I understand that in about 12 months from now I will be asked to return for a follow up interview
9			I agree to give a blood sample in 12 months' time for testing of viral load and HbA1C.
10			I understand that my participation in this study is completely voluntary, and there will be no penalty if I choose not to participate.

DECLARATION BY PARTICIPANT

By signing below, I, _____ (*Participant's Full Name*) agree to take part in the **Project MIND study**.

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 pressured to take part. I also understand that I do not give up any rights by signing below.
- 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 researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.
- I have received a card with information about rights of research subjects and who to contact with questions.

Participant's Signature

Date
(DD/MM/YYYY)

Signed at (Place)

**Witness(If participant is
illiterate)**

**Date
(DD/MM/YYYY)**

DECLARATION BY PROJECT STAFF

I, _____ (***Project Staff's Full Name***) declare that:

- I explained the information in this document to _____
(Participant's Full Name)
- 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
- I gave her a card with information about rights of research subjects and who to contact with questions.

Project Staff's I Signature

**Date
(DD/MM/YYYY)**

Signed at (Place)

**Witness (If participant is
illiterate)**

Date

APPENDIX 3: BASELINE ASSESSMENT INTERVIEW SCHEDULE

Strengthening South Africa's health system through integrating treatment for mental illness into chronic disease care (Project MIND).

Interview Schedule: Baseline Assessment

Participant Number

Interviewer Number

Site

Date

(format DD/MM/YYYY)

Start Time

GENERAL INSTRUCTIONS

Assessor to read: We will work through the questionnaire as follows: I will ask the questions and give you the answer choices. You will be asked to pick the answer that is the closest to how you feel. I will enter your answer into the tablet. The interview will take about 45 minutes to complete. There are no right or wrong answers. Please answer just what you think.

PLEASE REMEMBER THAT YOUR NAME WILL NOT BE ENTERED INTO THE TABLET. No one at the clinic will see your answers, and the information that you provide will only be used to report numbers of people who have been asked these questions, and numbers of people who answered yes to certain questions.

Section 2: Demographic Characteristics

2.1. First we would like to *measure your height and weight, and then* ask you a few questions about yourself.

2.2. Weight: _____ (kg) (USE SCALE)

2.3. Height: _____ (cm) (USE MEASURING TAPE OR WALL 'RULER')

Throughout the questionnaire, please indicate the correct response.

2.4. Note gender of patient, if not sure, ask

How would you describe yourself?

Male	1
Female	2

2.5. What was your age at your last birthday _____ years

2.6. Note race of patient if not sure, ask

How would you describe yourself?

African	1
Coloured	2
Asian/Indian	3
White	4
Other	97
If other, specify	

2.7. What is your current marital status? (indicate one only)

Married	1
Living with partner	2
Widow/widower	3
Divorced or separated	4
Never married (single)	5
Other	97
If other, specify	

2.8. What is the highest level of education you have passed?

Less than one year completed	1
Sub A/Class 1/Grade 1	2
Sub B/Class 2/Grade 2	3
Standard 1/Grade 3	4
Standard 2/Grade 4	5
Standard 3/Grade 5	6
Standard 4/Grade 6	7
Standard 5/Grade 7	8
Standard 6/Grade 8	9
Standard 7/Grade 9	10

Standard 8/Grade 10	11
Standard 9/Grade 11	12
Standard 10/Grade 12	13
Further studies – incomplete	14
Diploma/other post school studies – complete	15
Degree	16

Section 3: Economic Factors

3.1. Now we would like to ask a few questions about where you live and your work.

3.2. How would you describe your current living situation?

I have a place to live where I can stay as long as I want	1
I am living in a place, but may not be able to stay there in the future	2
I do not have any regular place where I can live	3
Other	4

3.3. If responded “other” in 3.2., please specify : _____

3.4. Which of the following describes your current employment status?

Unemployed and looking for work	1
Unemployed and not looking for work	2
Employed part-time	3
Employed full-time	4
Self-employed	5

3.5. What is your main source of income?

Formal employment	-
Self-employment	-
Odd jobs	-
Government grant (childhood/disability)	-
Income from investments	-
Maintenance	-
Student/Scholar/learner	-
Pensioner	-
No income	-
Other	-
If other specify:	

3.6. On average, what is your monthly income?

<u>Less than R600</u>	-
<u>R600-1000</u>	-
<u>R1001-2000</u>	-
<u>R2001-4000</u>	-
<u>More than R4000</u>	-
<u>Don't know</u>	-

Section 4: Household & Structural Factors

4.1. Let us speak about your household and what it can afford.

4.2. How often do the people in the household go hungry or have no food to eat?

Never	1
Seldom	2
Sometimes	3
Often	4

4.3. Which best describes the type of house in which you live? Please choose one answer only:

House or brick structure on a separate stand or yard or on farm	1
Traditional dwelling/hut/structure made of traditional materials	2
Flat	3
Town/cluster/semi-detached house (simplex, duplex or triplex)	4
Unit in retirement village	5
Dwelling/house/flat/room in backyard	6
Informal dwelling/shack IN the backyard of a formal house	7
Informal dwelling/shack NOT in backyard e.g. in an informal/squatter settlement or on farm	8
Room/flatlet not in backyard but on a shared property e.g granny flat	9
Caravan/tent	10
Worker's hostel	11
Other	97
4.4. If other, specify	

4.5. What is the main material of your house walls? Please choose one answer only:

Bricks & plaster/finished	1
Bare brick/cement block	2
Corrugated iron/zinc	3
Wood	4
Plastic	5
Cardboard	6
Mixture of mud and cement	7
Wattle and daub	8
Mud	9
Other	97
4.6. If other, specify	

4.7. What is the main material of your house's roof? Please choose one answer only:

Tiles	1
Corrugated iron/zinc	2
Thatching	3
Asbestos	4
Plastic	5
Cardboard	6
Other	97
4.8. If other, specify	

4.9. What is the main source of drinking water for your household? Please choose one answer only:

Piped (tap) water in dwelling	1
Piped (tap) water on site or in yard	2
Borehole on site	3
Rain water tank on site	4
Neighbour's tap	5
Public or communal tap (either free or paid)	6
Water carrier/tanker	7
Borehole off site/communal	8
Flowing water/stream/river	9
Stagnant water/dam/pool	10
Well	11
Spring	12
Other	97
4.10. If other, specify	

4.11 What type of toilet does your household use? Please choose one answer only:

Flush toilet (connected to sewage)	1
Flush toilet (with septic tank)	2
Chemical toilet	3
Pit latrine with ventilation pipe	4
Pit latrine without ventilation pipe	5
Bucket toilet	6
No facility/bush/field	7
Other	97
4.12. If other, specify	

4.13. What is the main source of energy for cooking in your household? Please choose one answer only:

Electricity from mains	1
Electricity from generator	2

Gas	3
Paraffin	4
Wood	5
Coal	6
Animal dung	7
Solar energy	8
Other	97
4.14. If other, specify	

4.15. Does your household have any of the following items in good working order? Read each item and indicate the presence of each

	Yes	No
Television	1	0
Video recorder/DVD player	1	0
Radio	1	0
Gas or Electric stove	1	0
Fridge/freezer	1	0
Private motor vehicle in running condition	1	0
Bicycle	1	0
Bed	1	0
Sofa or sofa set	1	0
Kitchen sink	1	0

4.16. do you know how much money your household spends in a month?

Yes.....1

No.....99 **(If no skip to 4.18)**

4.17. How much does your household usually spend in a month?

R _____

4.18. In which of the following ranges, would you say your household EXPENDITURE generally falls?	R0	1
	R1 – R199	2
	R200 – R399	3
	R400 – R799	4
	R800 - R1 199	5
	R1 200 – R1 799	6
	R1 800 - R2 499	7
	R2500 - R4 999	8
	R5 000 – R9 999	9
	R10 000 or more	10
	Do not know	99

	Refuse	97
--	--------	----

Section 5: This Health Care Facility

5.1. How long did it take you to get here? (Estimate time taken from leaving home to arriving at facility- one way only).

_____Hours _____minutes

5.2. How much time did you spend at the clinic the last time you came to collect your ARV or diabetes medication

_____hrs _____minutes

5.3. How much time did you spend at the clinic the last time you came to see the health care provider for your HIV or diabetes care?

_____hrs _____minutes

5.4. What would you have been doing if you weren't at the clinic today?

Circle "Yes" or "No" on every row.	Activity	Yes	No
	Working for pay	1	0
	Doing unpaid community work or volunteer work	1	0
	Doing household chores such as cleaning, cooking, shopping for food, maintenance and repairs, working in the garden, gathering wood, gathering water, housework etc.	1	0
	Taking care of children	1	0
	Leisure activities (sport, watching TV, listening to music, reading, visiting friends and family, going to movies etc)	1	0
	Attending school or other educational institution	1	0
	Nothing	1	0
	I don't know	99	
	Other	97	
	5.5. If other, specify		

5.6. In coming to the clinic today, how much did you pay for:

Read out each item. If no money spent, code as "0" for each item	Category	Tick if cost incurred	Cost in Rands (format RR, CC)
	Transport yourself (one way)		5.8
	Transport carer/supporter (one way)		5.9
	Clinic/hospital fees		5.10
	Medicines		5.11
	Food during visit for yourself		5.12
	Food during visit for your carer/supporter		5.13
	Accommodation, for yourself if you need to stay the night nearby		5.14
	Accommodation, for your carer/supporter if you need to stay the night nearby		5.15
	Someone to take over your tasks while you are here (including childcare)		5.16
	Phoning or sms'ing		5.17
	Other (see 5.7),		5.18
	5.7. If other costs incurred, please specify:		

5.19. Did you lose income from the time you took from your job to come here today?

Yes	1
No	0
Not working/applicable	99

5.20. If YES to 5.19., How much money did you lose? _____(Rand) (e.g. 324.89)

5.21. Who helps you with taking your treatment and bringing you to the clinic?

Circle "Yes" or "No" on every row.	Person	Yes	No
	Husband/wife	1	0
	Father/mother	1	0
	Son/daughter	1	0
	Boyfriend/girlfriend	1	0
	Other relatives	1	0
	Friends	1	0
	Nobody	1	0
	Don't know	99	
	Other	97	
	5.22. If other, specify _____		

If no to all, skip to section 6.

Section 6: HIV

6.1. Have you ever been told that you have HIV?

Yes	1
No	0*

*If yes, continue. If no, skip to Section 7.

In what month and year were you diagnosed with HIV?

6.2.	Month
6.3.	Year

6.4 Are you taking antiretroviral medication (ARVs) for HIV?

Yes	No
1	0

If no, skip to Section 7: Diabetes.

In what month and year were you started on ARVs?

6.5.	Month
6.6.	Year

6.7 In the past 3 months have you attended any HIV-clinic appointments?

Yes	No
1	0

If yes, to 6.7, continue to 6.8. If no, skip to 6.11.

6.8. How many HIV clinic appointments did you attend in the past three months? _____

6.9. How many HIV clinic appointments did you miss in the past three months ? _____

6.10. Of the clinic appointments you missed in the past 3 months, how many did you reschedule and complete?
 _____ (answer must be less than or equal to # given in 6.8)

Show patient a calendar of the last month. Apart from visits to this clinic for your ARVs/usual HIV care, have you used this clinic or any other health service in the last **month (4 weeks)**?

Health service	Yes	No	Number of visits or days	Amount spent at these visits (e.g.359.00)	
6.11 This clinic not for ARVS			6.12.	6.13	
6.14 A different public health clinic			6.15	6.16.	
6.17 A public emergency/outpatient department			6.18.	6.19	
6.20 Inpatient stay in a public hospital (past 6 months)			6.21	6.22.	6.23 Hospital name:
6.24 A private hospital emergency/outpatient department			6.25.	6.26	

6.27 Inpatient stay in a private hospital (past 6 months)			6.28	6.29.	6.30 Hospital <u>name</u>
6.31 Private doctor visit			6.32.	6.33	
6.34 Traditional healer visit			6.35	6.36.	
6.37 Faith-based healer (e.g. church)			6.38.	6.39	
6.40 NGO/support group			6.41	6.42	

6.43 *Show patient a calendar of the last month.* Apart from visits to this clinic for your ARVs/usual HIV care, have you used any of the following services in the **last 4 weeks (month)**?

Specify in relation to the calendar date	Type of service	Yes	No	If yes amount spent
Read out each option one at a time. IF YES Then ask: How much did you have to pay the provider for each?	Traditional medicines	1	0	6.44
	Private Chemist/Pharmacy medicines or vitamins	1	0	6.45
	Special faith-based medicines/treatments	1	0	6.46
	Special foods for recommended diet (over and above normal food spending)	1	0	6.47

6.48 Did you lose income or take time off work because you were sick in the last month (4 weeks)

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

6.49. If YES to 6.48, How much money did you lose? _____ (Rand) (e.g. 324.89)

6.50. If YES to 6.48, How much days off work did you take? _____

6.51. Did you lose your job or stop working because of your sickness in the past 6 months?

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

If No or not applicable, then skip to 6.42.

6.52. How long were you away from work because of your illness in the past 6 months?

6.53 Days 6.54 Weeks 6.55 Months

6.56. Did you return to work after losing your job or stopping working when you felt better?

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

6.57. **Read aloud:** The next few questions are about the ARVs that you take. We need to understand how people with HIV are really doing with their pills. Many people do not take all their pills. Don't worry about telling us that you don't take all your pills. We want to understand what is **really** happening, not what you think we "want to hear."

6.58. Do you take a one –a-day pill or a number of different pills? (circle correct response)

- a. One a day
- b. Number of different pills

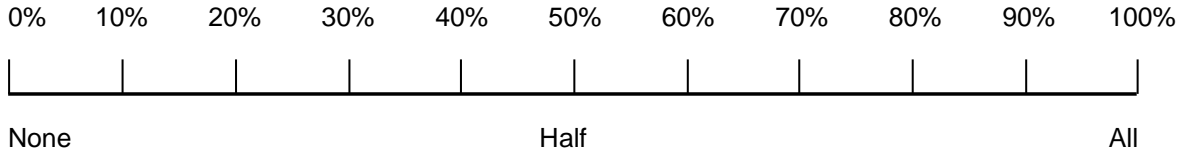
How sure are you that:

	Not at all sure	Somewhat sure	Very sure	Extremely sure
6.59 You will be able to take all or most of your HIV medication as directed	0	1	2	3
6.60 Your HIV medication has a positive effect on your health	0	1	2	3
6.61 Your body will not be able to fight HIV if you do not take your medicine	0	1	2	3

6.62. Please give us your best guess as to how much of your HIV medicines (ARVs) you have taken in the **last month**.

Interviewer: Show participant the scale (**see showcards**)

Examples: **0%** means you have **taken no doses**
50% means you have **taken half** your doses
100% means you have **taken every single dose**



CASE Adherence Index questionnaire

6.63. How often do you feel that you have difficulty taking your HIV medications on time? By 'on time' we mean no more than two hours before or two hours after the time your doctor told you to take it. (*circle correct response*)

- 4 Never
- 3 Rarely
- 2 Most of the time
- 1. All of the time

6.64. On average, how many days per week would you say that you missed at least one dose of your HIV medications?

- 1 Every day
- 2 4-6 days/week
- 3 2-3 days/week
- 4 Once a week
- 5 Less than once a week
- 6 Never

6.65. When was the last time you missed at least one dose of your HIV medications?

Within the past week	1
1-2 weeks ago	2
3-4 weeks ago	3
Between 1 and 3 months ago	4
More than 3 months ago	5

Never	6
-------	---

6.66 Thinking about the last 4 days, on how many days did you miss taking all your doses of ARVs?

- None
- One day
- Two days
- Three days
- Four days

6.67. How many times in the last month have you missed a pill? _____

6.68. How many times in the last three months have you missed a pill? _____

6.69. If you missed a pill, what was the main reason? _____

6.70. **Read:** Here is a list of possible reasons why some people miss taking their ARVs. How often have you missed taking your medications because you: **(Circle one response for each question.)**

		Never	Rarely	Sometimes	Often
6.71	Forgot to take them	0	1	2	3
6.72	Could not get to the doctor's office to pick up my ARVs	0	1	2	3
6.73	Were afraid someone would see me take them	0	1	2	3
6.74	Ran out of them early because I gave them to someone who needed them too	0	1	2	3
6.75	The pharmacy or your doctor did not have the medications when I came to pick them up	0	1	2	3
6.76	Wanted to avoid having side effects	0	1	2	3
6.77	Were too tired or fell asleep	0	1	2	3
6.78	Felt too sick	0	1	2	3
6.79	Didn't have food to take with the pills	0	1	2	3

6.80	Someone other than my doctor/health care provider told me to stop	0	1	2	3
6.81	Felt depressed or too stressed	0	1	2	3
6.82	Felt good or healthy	0	1	2	3
6.83	Decided to only take traditional medicines/herbs	0	1	2	3
6.84	Had a change in daily routine	0	1	2	3
6.85	I was drinking alcohol	0	1	2	3
6.86	I was using drugs	0	1	2	3
6.87	I was afraid to become too healthy again and lose my government disability grant	0	1	2	3
6.88	I was told by my traditional healer to stop taking them	0	1	2	3
6.89	I was told by my religious leader to stop taking them	0	1	2	3
6.90	Felt that the ARVs were toxic (poisonous)	0	1	2	3
6.91	Other (yes/no) 6.93 How often do these reasons apply to you?	0	1	2	3
6.92	If other please specify _____				

Section 7: Diabetes

7.1. Have you ever been told that you have diabetes (sugar)?

Yes	1
No	0*

If yes, continue. If no, skip to Section 8.

In what month and year were you diagnosed with diabetes?

7.2.	Month
7.3.	Year

7.4. Are you taking medication for diabetes? (Diabetes medication can be pills or injections.)

Yes	1
No	0*

If no, skip to Section 8: Lifestyle.

7.5 Do you know your last blood sugar level reading taken at the clinic?

	Yes (go to 7.6)
	No (skip to 7.7)

	Don't know/ forgot (skip to 7.7)
--	---

7.6. What was your last blood sugar level at the clinic?

	Reading
--	---------

7.7. Have you ever had any diabetes related complications (loss of eye sight, amputation):

Yes	No
1	0

The next few questions ask about your appointments at the clinic.

7.8 In the past 3 months have you attended any diabetes clinic appointments?

Yes	No
1	0

If yes, to 7.8., continue to 7.9. If no, skip to 7.10.

7.9. How many diabetes clinic appointments did you attend in the past three months? _____

7.10. How many diabetes clinic appointments did you miss in the past three months ? _____

7.11. Of the diabetes clinic appointments you missed in the past 3 months, how many did you reschedule and complete ? _____

*Show patient a calendar of the last month. Apart from visits to this clinic for your usual diabetes care, have you used this clinic or any other health service in the last **month (4 weeks)**?*

Health service	Yes	No	Number of visits or days	Amount spent at these visits (e.g.359.00)	
7.12 This clinic not for diabetes care			7.13	7.14	
7.15 A different public health clinic			7.16.	7.17.	
7.18 A public emergency/outpatient department			7.19	7.20	
7.21 Inpatient stay in a public hospital (past 6 months)			7.22.	7.23.	<u>7.24 Hospital name</u>

7.25 A private hospital emergency/outpatient department			7.26	7.27	
7.28 Inpatient stay in a private hospital (past 6 months)			7.29.	7.30.	<u>7.31 Hospital name</u>
7.32 Private doctor visit			7.33	7.34	
7.35 Traditional healer visit			7.36.	7.37.	
7.38 Faith-based healer (e.g. church)			7.39	7.40	
7.41 NGO/support group			7.42	7.43	

7.44 Show patient a calendar of the last month. Apart from visits to this clinic for your usual diabetes care, have you used any of the following services in the **last month (4 weeks)**?

Specify in relation to the calendar date	Type of service	Yes	No	If yes amount spent
Read out each option one at a time. IF YES ask: How much did you have to pay the provider for each?	Traditional medicines	1	0	7.45
	Private Chemist/Pharmacy medicines or vitamins	1	0	7.46
	Special faith-based medicines/treatments	1	0	7.47
	Special foods for recommended diet (over and above normal food spending)	1	0	7.48

7.49 Did you lose income or take time off work because you were sick in the last month (4 weeks)

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

7.50. If YES to 7.49, How much money did you lose? _____ (Rand) (e.g. 324.89)

7.51. If YES to 7.49, How much days off work did you take? _____

7.52. Did you lose your job or stop working because of your sickness in the past 6 months?

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

If No or not applicable, then skip to 7.58.

7.53. How long were you away from work because of your illness in the past 6 months?

7.54 Days _____ 7.55 Weeks _____ 7.56 Months _____

7.57. Did you return to work after losing your job or stopping working when you felt better?

<u>Yes</u>	<u>1</u>
<u>No</u>	<u>0</u>
<u>Not working/applicable</u>	<u>99</u>

7.58 Read aloud: The next few questions are about your diabetes management plan. Many people struggle to take their medication as they are supposed to. Don't worry about telling us that you don't take all your medication. We want to understand what is **really** happening, not what you think we "want to hear."

How sure are you that:

	Not at all sure	Somewhat sure	Very sure	Extremely sure
7.59 You will be able to take all or most of your diabetes medication as directed	0	1	2	3

7.71. Thinking about the last 4 days, on how many days did you miss taking any of your diabetes medicine?

- None
- One day
- Two days
- Three days
- Four days

7.72. How many times in the last month have you missed taking any of your diabetes medicine?

7.73. How many times in the last three months have you missed taking any of your diabetes medicine?

7.74. If you missed taking some of your medicine, what was the main reason? _____

7.75. **Read:** Here is a list of possible reasons why some people miss taking their diabetes medication. How often do these reasons apply to you? **(Circle one response for each question.)**

		Never	Rarely	Sometimes	Often
7.76	I forgot	0	1	2	3
7.77	Could not get to the clinic to pick up medicines	0	1	2	3
7.78	I was afraid someone would see me take them	0	1	2	3
7.79	I ran out of the medicine early because I gave it to someone who needed them too	0	1	2	3
7.80	The pharmacy or doctor did not have the medications when I came to pick them up	0	1	2	3
7.81	I wanted to avoid having side effects	0	1	2	3
7.82	I was too tired or fell asleep	0	1	2	3
7.83	I felt too sick	0	1	2	3
7.84	I didn't have food to take with the medicine	0	1	2	3
7.85	Someone other than my doctor/health care provider told me to stop	0	1	2	3

7.86	I felt depressed or too stressed	0	1	2	3
7.87	I felt good or healthy	0	1	2	3
7.88	I decided to only take traditional medicines/herbs	0	1	2	3
7.89	I had a change in daily routine	0	1	2	3
7.90	I was drinking alcohol	0	1	2	3
7.91	I was taking drugs	0	1	2	3
7.92	I was afraid to become too healthy again and lose my government disability grant	0	1	2	3
7.93	I was told by my traditional healer to stop taking them	0	1	2	3
7.94	I was told by my religious leader to stop taking them	0	1	2	3
7.95	I had no money for the special foods for my diet	0	1	2	3
7.96	Other 7.98 How often do these reasons apply to you?	0	1	2	3
7.97	If other please specify _____				

Section 8: Your lifestyle

8.1. Read: The next questions are about your use of alcohol in the last 12 months. We know that many people who have HIV or diabetes drink alcohol. Don't worry about telling us that you drink alcohol. We want to understand what is really happening, not what you think we "want to hear."

8.2.. How often do you have a drink containing alcohol? (If never skip to Section 7)

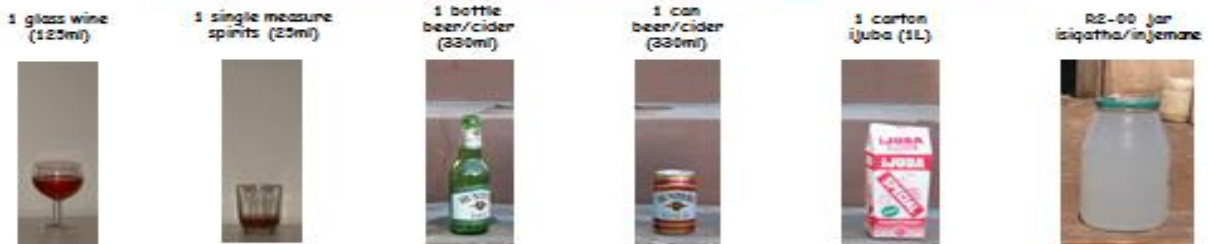
4 or more times a week	4
2-3 times per week	3
2 to 4 times a month	2
Monthly or less	1
Never	0

8.3. On how many days did you drink alcohol in the past month?

	Days
--	------

8.4. Show participant the picture of the standard drinks. Explain: Different alcohol containers have different amounts of alcohol. E.g a small can of beer is 1 standard drink but a quart has 2 standard drinks. The next few questions ask about the number of standard drinks you usually drink.

Quantities of different drinks that are the same as ONE standard drink



The number of standard drinks in commonly purchased quantities of alcohol



8.5.. How many standard drinks containing alcohol do you have on a typical day when you are drinking?

Please note that one drink is equivalent to one 340 ml can or bottle of beer, cider or cooler, one 120ml glass of wine, or one 25ml tot of spirits. One quart of beer is the same as 2 drinks).

10 or more	4
7 or 9	3
5 or 6	2
3 or 4	1
1 or 2	0

8.6.. Thinking about all the types of alcohol available. During the last 12 months, what is the largest number of standard drinks you had on any single day? Was it:

24 or more	8
12 to 23	7
At least 8, but less than 11	6
5 to 7	5
4	4
3	3
2	2
1	1

8.7. Below is a list of questions about your drinking behaviour. Please choose the option that best reflects your behaviour.

		Daily or almost daily	Weekly	Monthly	Less than monthly	Never
8.8	How often do you have six or more drinks on one occasion?	4	3	2	1	0
8.9	How often do you have nine or more drinks on one occasion?	4	3	2	1	0
8.10	How often during the last year have you found that you were not able to stop drinking once you have started?	4	3	2	1	0
8.11	How often during the last year have you failed to do what was normally expected from you because of drinking?	4	3	2	1	0
8.12	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	4	3	2	1	0
8.13	How often during the last year have you had a feeling of guilt or remorse <u>after</u> drinking?	4	3	2	1	0
8.14	How often during the last year have you been unable to remember what happened the night before because you had been drinking?	4	3	2	1	0

		Yes during the last year	Yes, but not in the last year	No
8.15	Have you or someone else been injured as a result of your drinking?	4	2	0
8.16	Has a relative, friend, or a doctor or another health worker been concerned about your drinking or suggested you cut down?	4	2	0

8.17 Have you received treatment or counselling for alcohol-related problems? Yes No

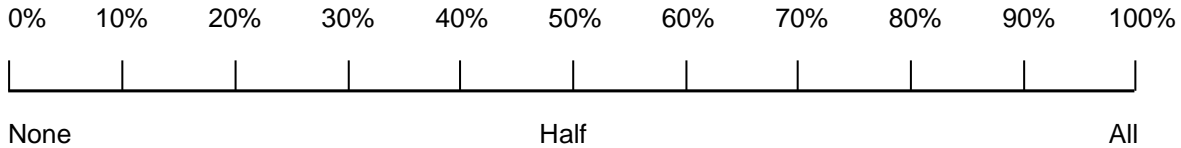
8.18. Read: The next few questions ask about how ready you are to make changes to your use of alcohol. Remember there are no right or wrong answers. Please let me know where you fall on the readiness to change ruler:

Interviewer: Show participant the scale

Examples: **0%** means you are not ready to change at all

50% means you are considering changing but are still unsure

100% means you have decided to change and are already taking action or steps to change.



_____ % ready to make a change

8.19. Read: The next few questions are about your use of tobacco. We know that many people who have HIV or diabetes smoke. Don't worry about telling us that you smoke. We want to understand what is really happening, not what you think we "want to hear."

8.20. Do you smoke cigarettes, pipes or chew tobacco? NO YES

If NO: Did you smoke in the past and quit? NO YES (if no skip to 8.24)

At what age did you quit? Years

If YES: At what age did you start smoking? Years

8.21. Are you a daily smoker? NO YES (if no skip to 8.24)

8.22. If yes, How many per day?

8.24. Read: The next few questions ask about your use of drugs other than alcohol and tobacco in the last 12 months. We know that many people use drugs like dagga. Don't worry about telling us that you use drugs. We want to understand what is really happening, not what you think we "want to hear." Here are a few questions about your use of drugs during the past 12 months.

- 8.25. How often do you use drugs other than alcohol and cigarettes? Drugs include substances like dagga (ganja or weed), methamphetamine or tik, ecstasy, mandrax, cocaine, heroin, unga. **If never skip to Section 8)**

4 or more times a week	4
2-3 times per week	3
2 to 4 times a month	2
Monthly or less	1
Never	0

- 8.26. Do you use more than one type of drug on the same occasion?

4 or more times a week	4
2-3 times per week	3
2 to 4 times a month	2
Monthly or less	1
Never	0

- 8.27. How many times do you take drugs on a typical day when you use drugs?

7 or more	4
5 to 6	3
3 to 4	2
1-2	1
0	0

- 8.28. Here are some more questions about your drug use behaviour. Please choose the option that best reflects your behaviour.

	In the past 12 months....	Daily or almost every day	Every week	Every month	Less than once a month	Never
8.29	How often are you influenced heavily by drugs?	4	3	2	1	0
8.30	Have you felt that your longing for drugs was so strong that you could not resist it?	4	3	2	1	0
8.32	How often have you not been able to stop taking drugs once you started?	4	3	2	1	0
8.32	How often have you taken drugs and then neglected to do something you should have done?	4	3	2	1	0
8.33	How often have you needed to take a drug the morning after heavy drug use the day before?	4	3	2	1	0
8.34	How often have you had guilt feelings or a bad conscience because you used drugs?	4	3	2	1	0

		Yes over the past year	Yes, but not over the past year	No
8.35	Have you or anyone else <u>ever</u> been hurt (emotionally or physically) because you used drugs?	4	2	0
8.36	Has a relative or a friend, a doctor or a nurse, or anyone else, been worried about your drug use or said to you that you should stop using drugs?	4	2	0

Section 9: Your feelings

9.1. Below is a list of ways you may have felt or behaved. Please indicate how often you have felt this way during the past month by choosing the appropriate response.

CES-D		Rarely or none of the time	Some or a little of the time	Occasionally or a moderate amount of the time	Most or all of the time
9.2.	I was bothered by things that usually don't bother me.	0	1	2	3
9.3	I did not feel like eating; my appetite was poor.	0	1	2	3
9.4	I felt that I could not shake off the blues, even with the help from family or friends.	0	1	2	3
9.5	I felt that I was just as good as other people.	3	2	1	0
9.6	I had trouble keeping my mind on what I was doing.	0	1	2	3
9.7	I felt depressed.	0	1	2	3

9.8	I felt that everything I did was an effort.	0	1	2	3
9.9	I felt hopeful about the future.	3	2	1	0
9.10	I thought my life had been a failure.	0	1	2	3
9.11	I felt fearful.	0	1	2	3
9.12	My sleep was restless.	0	1	2	3
9.13	I was happy.	3	2	1	0
9.14	I talked less than usual.	0	1	2	3
9.15	I felt lonely.	0	1	2	3
9.16	People were unfriendly.	0	1	2	3
9.17	I enjoyed life.	3	2	1	0
9.18	I had crying spells.	0	1	2	3
9.19	I felt sad.	0	1	2	3
9.20.	I felt that people dislike me.	0	1	2	3
9.22	I could not get "going".	0	1	2	3

9.22. **Read:** Here is a list of ways you may have felt or behaved. During the last 30 days, how often did you:

K-10		None of the time	A little of the time	Some of the time	Most of the time	All of the time
9.23.	feel tired out for no good reason?	1	2	3	4	5
9.24.	feel nervous?	1	2	3	4	5
9.25.	feel so nervous that nothing could calm you down?	1	2	3	4	5
9.26.	feel hopeless?	1	2	3	4	5
9.27.	feel restless or fidgety?	1	2	3	4	5
9.28.	feel so restless you could not sit still?	1	2	3	4	5
9.29.	feel depressed?	1	2	3	4	5

9.30	feel that everything was an effort?	1	2	3	4	5
9.31.	feel so sad that nothing could cheer you up?	1	2	3	4	5
9.32.	feel worthless?	1	2	3	4	5

Section 10. Coping and stress

10.1. Read: People sometimes look to others for companionship, assistance, or other types of support to help them cope. How often is each of the following kinds of support available to you if you need it?

Social support		None of the time	A little of the time	Some of the time	Most of the time	All of the time
10.2	Someone you can count on to listen to you when you need to talk	1	2	3	4	5
10.3	Someone to give you information to help you understand a situation	1	2	3	4	5
10.4	Someone to give you good advice about a crisis	1	2	3	4	5
10.5	Someone to confide in or talk to about yourself or your problems	1	2	3	4	5
10.6	Someone whose advice you really want	1	2	3	4	5
10.7	Someone to share your most private worries and fears with	1	2	3	4	5
10.8	Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5
10.9	Someone who understands your problems	1	2	3	4	5
10.10	Someone to help you if you were confined to bed	1	2	3	4	5
10.11	Someone to take you to the doctor if you needed it	1	2	3	4	5
10.12	Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5
10.13	Someone to help you with daily chores if you were sick	1	2	3	4	5
10.14	Someone who shows you love and affection	1	2	3	4	5
10.15	Someone to love and make you feel wanted	1	2	3	4	5
10.16	Someone who hugs you	1	2	3	4	5
10.17	Someone to have a good time with	1	2	3	4	5
10.18	Someone to get together with for relaxation	1	2	3	4	5
10.19	Someone to do something enjoyable with	1	2	3	4	5
10.20	Someone to do things with to help you get your mind off things	1	2	3	4	5

10.21. **Read:** I am going to describe ways you might think, feel and act when faced with a problem in everyday living. A problem is something important in your life that bothers you a lot, but you don't know right away how to make it better or stop it from bothering you so much. Please tell me how true each of these statements is for you.

Social problem-solving		Not at all true of me	Slightly true of me	Moderately true of me	Very true of me	Extremely true of me
10.22	I feel afraid when I have an important problem to solve	0	1	2	3	4
10.23	When making decisions, I do not think carefully about my many options	0	1	2	3	4
10.24	I get nervous and unsure of myself when I have to make an important decision	0	1	2	3	4
10.25	When my first efforts to solve a problem fail, if I keep going and try again, I know I will find a way to solve the problem.	0	1	2	3	4
10.26	Sometimes even difficult problems can have a way of moving my life forward in positive ways	0	1	2	3	4
10.27	If I avoid problems, they will generally go away on their own	0	1	2	3	4
10.28	When I can't solve a problem, I get very frustrated	0	1	2	3	4
10.29	If I am faced with a difficult problem, I probably will not be able to solve it on my own no matter how hard I try	0	1	2	3	4
10.30	Whenever I have a problem, I believe that it can be solved	0	1	2	3	4
10.31	I try to do anything I can in order to avoid problems in my life	0	1	2	3	4
10.32	Difficult problems make me very upset	0	1	2	3	4
10.33	When I have a decision to make, I take time to think about the positive and negative things that can happen from each possible option before I act	0	1	2	3	4
10.34	When problems happen in my life, I like to deal with them as soon as possible	0	1	2	3	4
10.35	When I am trying to solve a problem I go with the first good idea that comes to mind	0	1	2	3	4
10.36	When I am faced with a difficult problem, I believe that I will be able to solve it on my own if I try hard enough	0	1	2	3	4
10.37	When I have a problem to solve, one of the first things I do is get as many facts about the problem as possible	0	1	2	3	4
10.38	When a problem happens in my life, I put off trying to solve it for as long as possible	0	1	2	3	4
10.39	I spend more time avoiding my problems than solving them	0	1	2	3	4

10.40	Before I try to solve a problem, I set a specific goal so that I know exactly what I want to accomplish	0	1	2	3	4
10.41	When I have a decision to make, I do not take the time to consider the pros and cons of each option	0	1	2	3	4
10.42	After I have tried to solve a problem, I think carefully about how much my life has changed for the better	0	1	2	3	4
10.43	I put off solving problems until it is too late to do anything about them	0	1	2	3	4
10.44	When I am trying to solve a problem, I think of as many options as possible until I cannot come up with any more ideas	0	1	2	3	4
10.45	When making decisions, I go with my "gut feeling" without thinking too much about what can happen	0	1	2	3	4
10.46	I am too impulsive when it comes to making decisions	0	1	2	3	4

10.47 The next few questions are about how you may feel about your ability to deal with your problems. Please tell me how true each of these statements are for you:

Generalised self efficacy scale	Not at all true	Hardly true	Moderately true	Exactly true
10.48. I can always manage to solve difficult problems if I try hard enough	1	2	3	4
10.49. If someone disagrees with me, I can find the means and ways to get what I want.	1	2	3	4
10.50. It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
10.51. I am confident that I could deal well with unexpected events.	1	2	3	4
10.52. Thanks to my resourcefulness, I know how to handle unexpected situations.	1	2	3	4
10.53. I can solve most problems if I make the necessary effort.	1	2	3	4
10.54. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
10.55. When I am faced with a problem, I can usually find several solutions.	1	2	3	4
10.56. If I am in trouble, I can usually think of a solution.	1	2	3	4
10.57. I can usually handle whatever comes my way.	1	2	3	4

11.1. Read: Many people experience a lot of stress in their lives. I would like to ask you about whether you have ever experienced any serious or stressful life events. For each type of event, please tell me whether it happened, and if it did, the number of times and your age when it happened (give your best guess). Also let me know the nature of your relationship to the person involved, and the specific nature of the event, if appropriate.

TRAUMA HISTORY QUESTIONNAIRE					
Crime-related events	No	Yes	If yes		
			# of times (R if repeated)	Age when this first happened = <i>more than 16 years or 16 years and younger</i>	Relationship
11.2. Has anyone ever tried to take something directly from you by using force (e.g. mugging)?			11.3.	11.4. older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.5. Has anyone ever attempted to rob you or actually robbed you?			11.6.	11.7. older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.8. Has anyone ever attempted to or succeeded in breaking into your home when you weren't there?			11.9.	11.10 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.11. Has anyone ever tried to or succeed in breaking into your home while you were there?			11.12	11.13. older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
General Disaster and Trauma					
11.14. Have you ever had a serious accident at work, in a car or somewhere else?			11.15	11.16 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
1.1. Have you ever experienced a natural disaster such as			11.18	11.19	n/a

tornado, hurricane, flood where you felt you or your loved ones were in danger of death or injury?				older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	
11.20. Have you ever experienced a man-made disaster such as a train crash, building collapse, bank robbery, fire etc where you felt you or your loved ones were in danger of death or injury?			11.21.	11.22 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.23. Have you ever been exposed to dangerous chemicals or radioactivity that might threaten your health?			11.24.	11.25 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.26. Have you ever been in any other situation in which you were seriously injured?			11.27.	11.28 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.29. Have you ever been in any other situation in which you feared you might be killed or seriously injured?			11.30	11.31 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
11.32. Have you ever seen someone seriously injured or killed?			11.33.	11.34 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	11.35. Friend, family partner or stranger
12.1. Have you ever seen dead bodies (other than at a funeral) or had to handle dead bodies for any other reason?			12.2	12.3 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	12.4 Friend, family partner or stranger
12.5 Have you ever had a close friend or family member murdered, or killed by a drunk driver?			12.6.	12.7 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	

12.8. Have you ever had a spouse, romantic partner or child die?			12.9	12.10 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	
12.11. Have you ever had a serious or life-threatening illness?			12.12	12.13 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
12.14. Have you ever received news of a serious or life-threatening illness or death of someone close to you?			12.15	12.16 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	12.17. Friend, family partner or stranger
12.18. Have you ever had to engage in combat while in military service in an official or unofficial war zone?			12.19	12.20 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>	n/a
			If yes...		
Physical and sexual experiences	No	Yes	Repeated?	How often	Age first happened
12.21. Has anyone ever made you have intercourse, oral or anal sex against your will? _____			12.22	12.23	12.24 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
12.25. Has anyone ever touched private parts of your body or made you touch theirs, under force or threat?			12.26	12.27	12.28 <u>older than 16 years</u> <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
12.29. Have there been any other situations in which another person tried to force you to have unwanted sexual contact?			12.30	12.31	12.32 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
12.33. Has anyone, including family members or friends, ever			12.34	12.35	12.36

attacked you with a gun, knife or some other weapon?					older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
12.37. Has anyone, including family members or friends, ever attacked you without a weapon and seriously injured you?			12.38	12.39	12.40 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
12.41 Has anyone in your family ever beaten, 'spanked' or pushed you hard enough to cause injury?			12.42	12.43	12.44 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>
Other events	No	Yes	If yes, What was it?	How often	Age first happened
12.45 Have you experienced any other extraordinarily stressful situation or event that has not been covered?			12.46	12.47	12.48 older than 16 years <input type="checkbox"/> 16 years and younger <input type="checkbox"/>

Section 13. Your general health and daily life

13.1. READ: Now I am going to ask you some questions about other health conditions you might have.

Under each heading, please tick the ONE box that best describes your health TODAY.

13.2. MOBILITY

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

13.3. SELF-CARE

- I have no problems washing or dressing myself
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

13.4. USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have some problems doing my usual activities
- I am unable to do my usual activities

13.5. PAIN / DISCOMFORT

- I have no pain or discomfort
- I have some pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

13.6. ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

The best health you can imagine 100

95

90

85

80

75

70

65

60

55

50

45

40

35

30

25

20

15

10

5

0

The worst health you can imagine

YOUR HEALTH TODAY =

13.7. We would like to know how good or bad your health is TODAY.

13.8. This scale is numbered from 0 to 100.

13.9. 100 means the best health you can imagine.
0 means the worst health you can imagine.

13.10. Mark an X on the scale to indicate how your health is TODAY.

13.11. Now, please write the number you marked on the scale in the box below.

Record end time: __ (H) (Mins)

WE HAVE NOW REACHED THE END OF OUR INTERVIEW

THANK YOU VERY MUCH

APPENDIX 4 – ETHICAL APPROVAL



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



E-52 Room 45- Old Main Building
Groota Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

03 December 2021

HREC REF: 774/2021

Dr C van der Westhuizen

Alan J Flisher Centre for Public Mental Health
Psychiatry & Mental Health-GSH
Email: Clare.vanderwesthuizen@uct.ac.za
Student: hdipka@gmail.com

Dear Dr van der Westhuizen

PROJECT TITLE: FACTORS ASSOCIATED WITH INCREASED SYMPTOMS OF DEPRESSION AMONG SOUTH AFRICANS LIVING WITH CHRONIC ILLNESS-MASTERS CANDIDATE-DR DIPIKA HARIPERSAD-SUB-STUDY TO LINKED 089/2015

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 December 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 Dipika Haripersad will also be involved in this study

Please quote the HREC REF 774/2021 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.



FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30/11/2023
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee		Date Signed	14/11/2022

Note: Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za.

Please clarify your plan for research-related activities during COVID-19 lockdown.

Please use the latest form found on our website:

<http://www.health.uct.ac.za/fhs/research/humanethics/forms>

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	10/11/2022		
HREC REF Number	774/2021	Current Ethics Approval was granted until	31/12/22
Protocol title	Factors associated with increased symptoms of depression among South Africans living with chronic illness		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes, could you please provide the HREC Reference number for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	089/2015 (main study)		
Principal Investigator	Dr Claire van der Westhuizen		





Department / Office Internal Mail Address	Alan J Flisher Centre for Public Mental Health
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1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval? Note: Any annual approvals for Full Committee review MUST be submitted on the monthly HREC submission dates. (Please send electronic copy for full committee review to hrec-submission@uct.ac.za)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please (tick ✓) appropriate box for billing purposes:

<u>Submission Type</u>	<u>Description</u>	<u>New fee (Vat Incl.)</u>	<u>tick ✓</u>
<i>Research funded solely from UCT departmental/divisional/group budget</i>	Annual evaluation of research progress report for re-certification	R0,00	<input type="checkbox"/>
<i>Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges</i>	Annual evaluation of research progress report for re-certification	R0,00	<input checked="" type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R7000,00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	R3 710.00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R6000.00	<input type="checkbox"/>
<i>Annual re-certification / Progress report (FHS016 Form)</i>	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	R1 500,00	<input type="checkbox"/>

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	Not Applicable
Billing Address of Sponsor:	
Vat Number:	



Contact person	
Telephone number	
Email Address	
2. Internal Journal Billing:	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation for approval

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3. Protocol status (tick ✓)

<input type="checkbox"/>	Open Enrolment
<input checked="" type="checkbox"/>	Closed to enrolment (tick ✓)
<input type="checkbox"/>	Research-related activities are ongoing
<input type="checkbox"/>	Research-related activities are complete, long-term follow-up only
<input checked="" type="checkbox"/>	Research-related activities are complete, data analysis only
<input type="checkbox"/>	Main study is complete but sub-study research-related activities are ongoing
<input type="checkbox"/>	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	1200
Number of participants enrolled, since last HREC Progress report (continuing review)	0
Additional number of participants still required	0

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	N/A
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6. Cumulative summary of participants

Total number of participants who provided consent	N/A
Number of participants determined to be ineligible (i.e. after screening)	
Number of participants currently active on the study	
Number of participants completed study (without events leading to withdrawal)	
Number of participants withdrawn at participants' request (i.e. changed their mind)	
Number of participants withdrawn by PI due to toxicity or adverse events	
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
Secondary data received and currently working with Project MIND team members to analyse the data.

8. Protocol violations and exceptions (tick ✓ all that apply)

<input checked="" type="checkbox"/>	No prior violations or exceptions have occurred since the original approval
<input type="checkbox"/>	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
<input type="checkbox"/>	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

<input checked="" type="checkbox"/>	No Prior amendments have been made since the original approval
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<input type="checkbox"/>	Prior amendments have been reported since the last review and have already been approved
<input type="checkbox"/>	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).

Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.
Not Applicable

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable
If yes, please describe:		

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.					
Agency Name		Report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
		DSMB report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If yes, please explain:	



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12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:	
<input type="checkbox"/>	Increased
<input type="checkbox"/>	Decreased
<input checked="" type="checkbox"/>	Shown no change
If there has been a change, please explain:	

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

13. Insurance


Please confirm that valid no fault insurance is still in place? (tick ✓)		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not Applicable – N/A
If yes, please complete the following:		
Insurer's name:		
Policy no.		*Coverage Period:
<p>For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.</p>		

14. Statement of conflict of interest

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	



15. Signature

My signature certifies that the above is complete and correct.			
Signature of PI		Date	10/11/2022

