

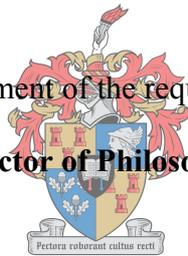
**The development and validation of the Visual Screening Tool for  
Anxiety Disorders and Depression in people living with  
hypertension and/or diabetes**

By

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Thesis submitted in fulfilment of the requirements for the degree of

**Doctor of Philosophy**



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## **DECLARATION**

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## SUMMARY

People living with hypertension and/or diabetes have an increased prevalence of depression and anxiety disorders. This contributes to functional limitations, poor quality of life, increased financial burden and increased suffering. The identification of these mental disorders can contribute to addressing the burden imposed by them. However, there are barriers to the identification of these disorders, particularly in the South African context. These include a lack of tools that can be applied to the diverse South African cultural and language groups and people with different levels of education; as well as that a number of screening tools fail to meet acceptability for sensitivity in the South African population.

Attempts to improve availability of screening tools for use at primary health care have included the translation of screening tools previously developed in high-income countries. However, translated screening tools are often plagued with methodological flaws. In order to address some of these limitations, visual screening tools for depression have been developed. These tools do not require a patient to be able to read and write, and have been found to be appropriate for use in people with low levels of education. They have been shown to be effective in the identification of depression in low-income countries.

In this study, I aimed to develop and validate a visual screening tool for both depression and anxiety disorders in people living with hypertension and/or diabetes for use at primary health care level. The items for the visual screening tool were based on the Hospital Anxiety and Depression Scale (HADS). Compared to similar screening tools, the HADS has been found to be an appropriate screening tool for anxiety disorders and depression in people with diabetes, and those with low levels of education. However, the HADS is only appropriate for people who are able to read and write.

My study was divided into two phases with each informing the final conclusion.

In phase one (reported as one publication), I developed the visual screening tool items by asking an artist, Ms Jane Metelo-Liquito, to draw pictures depicting symptoms of depression and anxiety disorders. The drawings were based on the HADS. These were shown to a group of participants recruited from the general population, primary health care centres and a maternal mental health clinic. This was to ascertain the applicability of the drawings across cultures, languages and varying levels of education. The findings from phase one of the study indicated which drawings were applicable and appropriate for inclusion in the visual screening tool named the Visual Screening Tool for Anxiety Disorders and Depression (VISTAD).

In phase two of the study, I validated the VISTAD. Participants diagnosed with hypertension and/or diabetes were recruited from five primary health care centres in the Eastern Cape. This province has been identified to have a high prevalence of hypertension and diabetes.

Using the Mini Neuropsychiatric Interview (M.I.N.I) we demonstrated that 40% of our sample had panic disorder, followed by depression (32%), post-traumatic stress disorder (33%), generalised anxiety disorder (17%), and then social phobia and agoraphobia (10% for both). Current available prevalence rates of depression and anxiety disorders in the hypertension and/or diabetes populations are mostly based on research conducted in high-income countries and as such my results are a valuable addition for researchers and clinicians.

Using the WHO quality of life assessment instrument (WHOQOL-BREF) as research tool, I found that our participants reported poor quality of life across the domains of physical health, psychological health and environment, but not for the social relationships domain. There were statistically significant differences in the physical and environment domain of people living with hypertension and/or diabetes comorbid with other medical conditions compared to participants without other medical conditions. The majority of participants in my study had lower levels of education, were unemployed and financial dependent on support from others

and our results were largely in keeping with available literature in similar groups. The positive association with the social relationships domain could possibly be explained by the fact that most participants were reliant on interdependent social structures.

Only 15% of my sample reported hazardous and harmful alcohol use whilst 17% reported any other drug related problems. These are relatively low levels within the South African context but are likely explained by the fact that the majority of my participants were female and that the sample's average age was 49.

The overarching goal of phase two was the validation of the VISTAD (chapter 4) which was developed in phase one. Validation was done against the M.I.N.I and my findings showed that the VISTAD has high accuracy in detecting depression and moderate accuracy in detecting anxiety disorders in adults with a diagnosis of hypertension and/or diabetes attending primary health care centers. The VISTAD is self-administered and any primary health care worker can easily be trained to score it. I demonstrated that it can be administered to patients independent of level of education, language and cultural background.

I believe that the VISTAD represents an important contribution towards furthering the integration of the management of mental health conditions into the primary health care system. Firstly, it addresses the challenges posed by cultural, language, educational and time factors when attempting to screen for common mental disorders. Secondly, the VISTAD includes symptoms of depression and anxiety disorders in one screening tool. Literature recommends that the assessment of depressive disorders should include anxiety disorders since these disorders often co-exist in chronic physical conditions.

It is well known and widely reported in the literature that primary health care access to mental health specialists is severely limited. Thus, the true integration of mental health care into primary health will improve the early identification and management of depression and anxiety

disorders in people living with chronic illnesses. The availability of simple to use and culturally appropriate tools such as the VISTAD brings this goal much closer to becoming a reality.

## OPSOMMING

Mense wat saamleef met hipertensie en/of diabetes het 'n hoër prevalensie van depressie en angssteurings. Dit dra by tot funksionele inkortings, swak lewenskwaliteit, hoër finansiële las en lyding. Identifisering van hierdie psigiatriese siektes kan bydra daartoe om die las wat deur hulle veroorsaak word aan te spreek. Daar bestaan egter struikelblokke wat identifisering bemoeilik, veral in die Suid Afrikaanse konteks. Dit sluit die gebrek van instrumente wat gebruik kan word in die diverse Suid Afrikaanse kulturele- en taalgroepe asook mense met verskillende vlakke van opleiding in, sowel as die feit dat baie siftingsinstrumente nie aanvaarbare sensitiwiteit toon in die Suid Afrikaanse populasie nie.

Pogings om die beskikbaarheid van siftingsinstrumente vir gebruik in primêre gesondheidsorg te verbeter het ook die vertaling van siftingsinstrumente wat in hoë inkomste lande ontwikkel is ingesluit. Vertaalde instrumente toon egter dikwels metodologiese foute. Visuele siftingsinstrumente vir depressie is ontwikkel om sommige van hierdie tekortkominge aan te spreek. Sulke instrumente benodig nie dat 'n pasiënt kan lees of skryf nie en is al gewys om toepaslik te wees vir gebruik in mense met lae vlakke van opleiding. Hulle is bewys om effektief te wees met die identifisering van depressie in lae inkomste lande.

My doel met hierdie studie was om 'n visuele siftingsinstrument vir beide depressie en angssteurings te ontwikkel en geldig te bewys in mense met hipertensie en/of diabetes vir gebruik op primêre gesondheidsorgvlak. Die items vir die visuele siftingsinstrument was gebaseer op die "Hospital Anxiety and Depression Scale (HADS)". Die HADS is bewys om, in vergelyking met soortgelyke instrumente, 'n toepaslike siftingsinstrument vir angssteurings en depressie te wees in mense met diabetes sowel as diegene met 'n lae vlak van opleiding. Die HADS is egter net toepaslik vir pasiënte wat kan lees en skryf.

My studie was verdeel in twee fases en elk het die finale gevolgtrekking toegelig.

Tydens fase een (gerapporteer as een publikasie) het ek die visuele siftingsinstrument items ontwikkel deur 'n kunstenaar, Me Jane Metelo-Liquito, te vra om sketse te teken wat simptome van depressie en angssteurings voorstel. Die sketse was gebaseer op die HADS. Hierdie is vertoon aan 'n groep deelnemers wat gewerf is vanuit die algemene populasie, primêre gesondheidsorgsentrums en 'n moederlike geestesgesondheidskliniek. Dit was om die toepaslikheid te bepaal van die sketse regoor die kulturele, taal en opvoedingsvlak spektrum. Die bevindinge van fase een van my studie het aangedui watter sketse toepaslik en aanvaarbaar was vir insluiting in die visuele siftingsinstrument genoem die “Visual Screening Tool for Anxiety Disorders and Depression (VISTAD)”.

Tydens fase twee van die studie is die geldigheid van die VISTAD bewys. Deelnemers, gediagnoseer met hipertensie en/of diabetes, is gewerf vanuit vyf primêre gesondheidsorgklinieke in die Oos Kaap. Die provinsie is geïdentifiseer om 'n hoë prevalensie van hipertensie en diabetes te hê.

Deur die “Mini Neuropsychiatric Interview (M.I.N.I)” te gebruik het ons gedemonstreer dat 40% van ons groep aan panieksteuring ly, gevolg deur post traumatiese stressteuring (33%), depressie (32%), algemene angssteuring (17%) en dan sosiale fobie en agorafobie (beide 10%). Huidig beskikbare prevalensiekoerse vir depressie en angssteurings in hipertensie en diabetes populasies is hoofsaaklik gebaseer op navorsing uitgevoer in hoë inkomste lande en derhalwe is my resultate 'n waardevolle toevoeging vir navorsers en kliniese personeel.

Deur die WGO se lewenskwaliteit assesseringsinstrument “(WHOQOL-BREF)” te gebruik het ek bevind dat ons deelnemers swak lewenskwaliteit rapporteer oor die domeine van fisiese gesondheid, psigiese gesondheid en omgewing, maar nie vir die sosiale verhoudings domein nie. Daar was statisties beduidende verskille tussen die fisiese en omgewings domeine van

mense met hipertensie en/of diabetes te same met ander mediese toestande in vergelyking met die sonder ander mediese toestande.

Die meerderheid van die deelnemers in ons studie het laer vlakke van opleiding gehad, was werkloos en finansiël afhanklik van ander en my resultate is dus meereendeels in lyn met beskikbare resultate in soortgelyke groepe. Die positiewe assosiasie met die sosiale verhoudinge domein kan moontlik verduidelik word deur die feit dat die meeste deelnemers deel van was interafhanklike sosiale strukture.

Slegs 15% van studiegroep het gevaarlike en skadelike alkoholgebruik gerapporteer, terwyl 17% enige ander dwelm-verwante probleme gerapporteer het. Binne die Suid Afrikaanse konteks is hierdie relatiewe lae vlakke wat waarskynlik verklaar kan word deur die feit dat die meerderheid van ons deelnemers vroulik was en die gemiddelde ouderdom van die groep 49.

Die oorkoepelende doel van fase twee was om die VISTAD (hoofstuk vier), wat in fase een ontwikkel is, geldig te bewys. Dit is gedoen teen die M.I.N.I. en my bevindinge het gewys dat die VISTAD hoë akkuraatheid het om depressie te bespeur en gemiddelde akkuraatheid om angssteurings te bespeur in volwassenes met hipertensie en/of diabetes wat primêre gesondheidsorgsentra bywoon. Die VISTAD word self beantwoord en enige primêre gesondheidsorgwerker kan maklik opgelei word om die totaal te bereken. Ek het demonstreeer dat die instrument onafhanklik van opleidingsvlak, taal en kulturele agtergrond gebruik kan word.

Ek glo die VISTAD verteenwoordig 'n belangrike bydrae tot die verbeterde integrasie van die hantering van psigiatriese toestande binne die primêre gesondheidsorgsisteem. Eerstens spreek dit die uitdagings aan wat kultuur, taal, opleidingsvlak en tydsfaktore bring wanneer ons probeer sif vir algemene psigiatriese siektes. Tweedens sluit die VISTAD simptome van beide depressie en angssteurings in een visuele siftingsinstrument in. Literatuur beveel aan dat die

assessering van depressiewe steurings ook angssteurings moet insluit aangesien hierdie steurings dikwels saam voorkom in kroniese fisiese siektes.

Dit is ook welbekend en word wyd in die literatuur gerapporteer dat die primêre gesondheidsorgvlak se toegang tot psigiatriese spesialiskennis ernstig beperk is. Die ware integrasie van psigiatriese sorg binne primêre gesondheidsorg sal die vroeë identifikasie en hantering van depressie en angssteurings in mense met kroniese siektes verbeter. Die beskikbaarheid van kultureel toepaslike instrumente soos die VISTAD wat eenvoudig is om te gebruik bring hierdie doelwit veel nader aan 'n realiteit.

## **ABBREVIATIONS**

AIDS: Acquired Immune Deficiency Syndrome

APA: American Psychiatric Association

AUC: Area Under Curve

AUDIT: Alcohol Use Disorders Identification Test

AVIDI: Akena's Visual Depression Inventory

CES-D: Center for Epidemiologic Studies Depression Scale

Coef: Coefficient Correlation

DSM: Diagnostic and Statistical Manual of Mental Disorders

DUDIT: Drug Use Disorders Identification Test

GAD: Generalised Anxiety Disorder

GAD-7: Generalised Anxiety Disorder 7

GA-VAS: General Anxiety - Visual Analogue Scale

GHQ-12: General Health Questionnaire 12

HADS: Hospital Anxiety and Depression Scale

HIV: Human Immunodeficiency Virus

IDF: International Diabetes Federation

K6: Kessler Psychological Distress Scale 6

K10: Kessler Psychological Distress Scale 10

LR: Likelihood Ratios

M.I.N.I: Mini International Neuropsychiatric Interview

PHQ: Patient Health Questionnaire

PHQ-9: Patient Health Questionnaire

PTSD: Post-Traumatic Stress Disorder

QOL: Quality of Life

ROC: Receiver operating characteristics

SD: Standard Deviation

Std Err: Standard Error

TAT: Thematic Apperception Test

US: United States

VAMS: Visual Analogue Mood Scale

VISTAD: Visual Screening Tool for Anxiety Disorders and Depression

WHO: World Health Organization

WHO-5: World Health Organization Wellbeing Index

WHOQOL-BREF: WHO quality of life assessment instrument

## CHAPTER ONE

### Introduction and Literature Review

#### 1.1 Introduction

The global community, including low- and middle-income countries, is faced with an increasing prevalence of non-communicable diseases (Allen 2017; Islam et al., 2014; Mayosi et al., 2009; World Health Organization WHO), 2010). These diseases such as diabetes and hypertension have been on the rise, with more than one billion individuals suffering worldwide, according to Khan (2011). They are also highly prevalent in South Africa, with 2.3 million people living with diabetes (International Diabetes Federation (IDF), 2015), and 30% of the South African adult population living with hypertension (Kandala, Tigbe, Manda & Stranges, 2013). Both these non-communicable diseases account for 17 million visits annually to primary health care (Department of Health, 2013). Singularly, diabetes reduces life expectancy by five to ten years (Kumar & Clark, 2017). Hypertension, according to Seedat (2015), also reduces life expectancy in men and women, and it is the sixth leading risk factor for a life of disability, contributing more than eleven million disability-adjusted life years. In South Africa, hypertension is estimated to have caused 46 888 deaths and 390 860 disability-adjusted lives in the year 2000 (Peltzer & Phaswana-Mafuya, 2013). When co-morbid, hypertension and diabetes further reduce life expectancy and increase mortality risk (Safar, Gnakaméné, Bahous, Yannoutsos & Thomas, 2017).

In recent years, researchers have observed co-morbidity between diabetes and hypertension, and depression and/or anxiety disorders (Atlantis, Vogelzangs, Cashman & Penninx, 2012; Anderson, Freedland, Clouse, & Lustman, 2001; Calvin, Gaviria, & Rios, 2015; Egede et al., 2016; Lin & Von Korff, 2008; Mendenhall, Norris, Shidhaye & Prabhakaran 2014; Roy & Llyod, 2012; Rustad, Musselman & Nemeroff, 2011; Stein et al., 2014; Thomas, Jones, Scarinci & Brantley, 2003). One of the early studies was conducted by Rabkin, Charles and Kass (1983)

and reported a three-fold higher frequency of major depression in patients treated for hypertension. The first report on the relationship between hypertension and emotional stress was made by Moschcowitz in 1919. Consistent with early research, current research has shown that individuals diagnosed with hypertension have increased prevalence of anxiety disorders (Greene, Neria & Gross, 2016). Recent research by Schutte et al. (2015) and Stein et al. (2014) has supported Moschcowitz' association of emotional stress and hypertension by showing that anxiety disorders and depression are significantly associated with the subsequent diagnosis of hypertension in a South African population.

Also, the symptoms of depression in people with diabetes are more likely to be severe compared to those without diabetes (Hermanns et al., 2013). The association between diabetes and depression was first mentioned in 1684 the English physician, Thomas Willis who identified emotional factors such as grief and sadness as the cause of diabetes (Geringer, 1990). People with diabetes are nearly twice as likely to have depression compared to those without diabetes (Roy & Lloyd, 2012). Depression, according to Roy and Lloyd (2012) maybe a consequence of diabetes. Roy and Lloyd (2012) base this on biochemical and physiological changes associated with diabetes, and also the psychosocial burden imposed by a chronic condition. The association between diabetes and depression remains poorly understood (Snoek, Bremmer & Hermanns, 2015), with no agreement on the causality and direction of this association. What is known from research and clinical practice is that people with diabetes are more likely to have depression compared to those without diabetes.

The co-morbidity with depression and anxiety disorders complicates the burden caused by diabetes and hypertension. Moreover, depression and anxiety disorders also contribute to global disability (WHO, 2017). Depression and anxiety disorders remain largely undetected and untreated at primary health care level. They are often treated at tertiary level institutions as opposed to primary health care settings, with Mash (2006) arguing that general practitioners

often feel unprepared to deal with common mental disorders. As a result, they may avoid dealing with these and feel irritated by patients who present and/or bring up symptoms associated with common mental disorders, or refer these patients to a specialist level when they could have been managed at a primary health care level (Mash, 2006).

Because of its accessibility, availability, and continuity of care for the majority of the general population in many countries, primary health care is an ideal setting for instituting measures that prevent the onset of non-communicable diseases and well as delivering effective management where these chronic conditions have been diagnosed (García-Campayo et al., 2015; Gillam, 2008). Health systems that are oriented towards primary health care are more likely to deliver better health outcomes and greater public satisfaction at lower costs, suggests Macinko, Starfield, and Shi (2003). However, a major challenge, according to Gillam (2008), is the establishment of effective interventions targeting multiple conditions and risk factors affecting key groups. These interventions must be appropriately adapted to local epidemiological, economic, and sociocultural contexts, adds Gillam (2008). With the increasing burden of diabetes, hypertension, depression and anxiety disorders, and the associated co-morbidity, the integration of mental health services into primary care is recommended.

## **1.2 Primary health care**

Ustun and von Korff (1995) define primary health care as the first point of contact where help is sought from the medical system and it thus provides continuity of care for common disorders and coordination of the delivery of care for different types of health and social services. From this description it is clear that primary health care settings are critical for people living with chronic illnesses such as hypertension and/or diabetes and thus co-morbid illnesses such as depression and/or anxiety disorders should also be managed here. However, these disorders remain largely unrecognised and untreated.

Researchers have consistently highlighted the shortage of mental health services in the South African public health system (Andersen, Kagee, O’Cleirigh, Safren & Joska, 2015). This, despite the overwhelming evidence on the burden of these conditions and their cost to society when they coexist (Dismuke & Egede, 2011; Egede et al., 2016; Sumlin et al., 2014), as well as the Alma Ata Declaration which reaffirmed that health is a state of complete physical, mental and social wellbeing, and not merely the absence of disease. While South Africa has adopted the underpinning principles of primary health as envisaged in the Alma-Ata declaration, the implementation has been mostly of a biomedical orientation. This does not recognise that mental disorders which present at primary care owe their origin to a complex array of genetic, biological, psychological and social factors (Patel et al., 2016).

There is increasing evidence suggesting that many clinical problems observed at primary health care level are related to mental disorders. Local and international research has demonstrated that an increasing number of visits to primary health care are due to mental disorders (Trump & Hugo, 2006). Approximately 25–33% of primary health care patients in Ireland present with mental health problems (Hughes, Bryne & Synnott, 2010) and more than half (58%) of visits to general practitioners in South Africa are due to conditions caused or exacerbated by mental disorders (Trump & Hugo, 2006). Although as many as one in four people attending primary care providers may be suffering from a mental disorder, less than half are recognised and treatment is often inadequate (Mash, 2006).

### **1.3 The impact of the co-morbidity between diabetes, hypertension and depression and anxiety disorders**

The coexistence of hypertension and/or diabetes with depression and anxiety disorders has been shown to have a significant burden including human, social and economic costs. It has a

devastating impact on self-care (Sumlin et al., 2014), decreases adherence to treatment regimens, decreases quality of life (Goldney, Phillips, Fisher & Wilson, 2004), increases mortality risk (Egede & Ellis, 2010) and inflates financial burden associated with health care (Dismuke & Egede, 2011; Hutter et al., 2010). The economic impact of common mental disorders has been well documented, and the economic costs of depression have been staggering world-wide (Rizvi et al., 2015).

Doherty and Gaughran (2014) report that this co-morbidity often results in complicated treatments and poorer outcomes than having either problem alone. That is, either one of the physical diseases, or one or both of them, with one, or both, of the mentioned common mental disorders. In addition to the negative impact of these conditions, mental disorders in patients with chronic physical diseases remain largely undetected and untreated at primary care level (Chou, Huang, Goldstein & Grant, 2013; Lotfi, Flyckt, Krakau, Mårtensson & Nilsson, 2010; Petersen & Lund, 2011). This leads to prolonged patient suffering and increased risk of greater disability (Chou et al., 2013).

The detection and treatment of depression and anxiety disorders can help address the burden imposed by these disorders (Lecrubier, 2001). Jenkins et al. (2013) and Van Oers and Schlebusch (2013) identified the lack of appropriate screening tools as one of the barriers in detecting mental health problems. Especially multicultural societies such as South Africa with its 11 official languages lack screening tools that can be applied to a diverse range of cultural and language groups. Language may preclude the marginalised and previously disadvantaged groups, and those who do not speak the language of primary health care professionals, from receiving the best available care.

#### **1.4 Screening and detection of depression and anxiety disorders**

The poor detection of mental disorders in people living with diabetes has been identified as one of the biggest challenges in treatment and management (Balhara, 2011). The Behavioural Risk Factor Surveillance System conducted in the United States found that up to 45% of the cases of mental disorders and severe psychological distress go undetected among patients who receive treatment for diabetes (Li et al., 2010). Consequently, the IDF (2015) has recommended screening for depression and anxiety disorders in order to improve detection rates and provide appropriate care. Patients living with diabetes, according to Li et al. (2010), should be regularly screened for common psychiatric disorders. Fisher et al. (2008) suggested screening for distress, anxiety and affective disorders several times per year, perhaps at each clinical contact, particularly in younger adults and those with complications/co-morbidities. Detection of mental disorders is likely to lead to a correct diagnosis where appropriate, and presents the opportunity of facilitating appropriate referrals to health professionals (Hermanns et al., 2013).

Screening has important implications for an individual's health (Akena, Joska, Obuku & Stein, 2012), day-to-day clinical practice and public health policy (Hermanns et al., 2013). In 2010, the United States identified the need to increase the detection of depression and anxiety disorders during routine care at primary health care level. Thus, the importance of enhancing the ability of lay workers to provide expert-supervised community based treatment was identified. This aimed at addressing the heavy reliance on mental health professionals to assist with screening. Gilbody, House, and Sheldon (2005) note the substantial potential for screening tools to improve the ability of non-specialists to recognise and manage depression. The importance of identifying and managing mental disorders in those with physical health problems is well established in literature (McHugh, Brennan, Galligan, McGonagle & Bryne, 2013). Globally, there has been an increased focus on the integration of mental health into

primary health care led by the World Health Organization; and the South African National Department of Health has expressed commitment to the integration of mental health into primary care. In order for this to be successful, resources are required, including tools that would enable non specialists and lay health care workers working at primary health care to identify people living with common mental disorders which are often seen at primary health care.

A number of screening tools have been developed and recommended for use in people with diabetes. However, these tools require administration by mental health care specialists, are not applicable across cultures, and are not appropriate for people with low levels of education. Screening tools such as the Kessler scales have failed to meet acceptability for sensitivity and positive predictive value in the South African population (Andersen et al., 2011).

The accuracy of non-traditional screening tools is likely to address the heavy reliance on mental health specialists who are not available and accessible to all mental health care patients. Furthermore, these tools can address the language barriers associated with traditional screening tools. Alexander, Arnkoff, Kaburu and Glass (2013) previously identified language in screening as a contributing factor to the non-detection of mental health problems. Screening tools are often translated into other languages for use by other cultural groups. In making screening tools available for use across different languages, research evidence has shown that the meaning of key concepts are often lost in translation (Kerr & Kerr, 2001). Steele and Edwards (2007) have shown that the translation process is often plagued by practical and methodological difficulties that threaten the validity of cross-cultural research projects. The translation of concepts across cultures is crucial in order to develop culturally appropriate measurement tools, diagnosis, and services for people with depression and anxiety disorders (Hermanns et al., 2013).

Educational status, according to Foxcroft (2004), is also an important factor to be considered when developing a screening tool. Screening tools for depression and anxiety perform poorly and are less accurate when screening in people with lower levels of education (Hanlon, Luitel, Kathree et al., 2014; Hermanns et al., 2013; Reddy, Philpot, Ford & Dunbar 2010). The consideration for level of education is an important factor particularly in the South African context. South Africa has been widely reported as country with poor quality of education (Branson and Leibbrandt, 2013; Organisation for Economic Co-operation and Development' South Africa's Policy Brief, 2015). Furthermore, globally, the World Economic Forum ranked South Africa's quality of education amongst the poorest at 137 out of 139 countries (Baller, Dutta & Lanvin, 2016).

In keeping with the focus of primary health care, there is a need to address how mental health care services are integrated into primary health care. The integration is not about the insertion of a team to manage severe mental disorders on outreach visits by specialists, but rather ensuring that primary health care workers are equipped to provide physical and mental care simultaneously in one visit. This would also ensure focus on prevention and health promotion.

### **1.5 Visual screening tools and analogue scales for depression and anxiety disorders**

Non traditional screening tools for depression and anxiety disorders include visual analogue scales which typically use 100mm horizontal line with written descriptors at either side of the line, to express the extremes in feeling (Klimek et al., 2017). A visual analogue scale, according to Scott and Huskisson (1975) is a straight line with ends showing extreme limits of sensation or response to be measured, or the mood in question. Visual analogue scales are available in different forms, and these include scales with a middle point, graduations or numbers, meter-shaped scales analogue scales, box-scales, scales consisting of circles equidistant from each other and scales with descriptive terms at intervals along a line (Scott & Huskisson, 1975).

These scales were first developed in 1921, and Aitken (1969) was among the first to report on their administration assessing depressed mood in participants. These scales would measure people's feelings, where words fail to fully capture a person's subjective experience. Aitken (1969) argued that people might have an appreciation of how they feel, however, words might fail to fully full capture their subjective experience. Since Aitken (1969), a number of visual analogue scales have been developed and validated in high income countries (Di Benedetto, Kent & Lindner, 2008; Williams, Morlock & Feltner, 2010). Furthermore, visual analogue scales are generally used in the assessment of pain (Tamiya et al., 2002; Haefeli & Elfering, 2006; Hawker, Mian, Kendzerska & French, 2011) and depression in people with stroke (Brumfitt & Sheeran, 1999) or acquired brain injury with severe complex disabilities following acquired brain injury (Turner-Stokes, Kalmus, Hirani & Clegg, 2005), and assess the severity of illness (Ahearn, 1997).

Amongst the validated analogue scales is the Visual Analogue Mood Scale (VAMS) developed by Stern, Arruda, Hooper, Wolfner and Morey (1997). The VAMS has simple cartoon faces which depict a range of "moods". Each face is placed at the end of a 100 cm line with a neutral face placed at the opposite end. Participants are required to indicate where they see themselves by placing a mark on the area in question, for example 'tired' versus 'neutral'). The VAMS, according to Stern et al. (1997) is a reliable measure of internal mood states and can be used with people who have impaired language comprehension. The VAMS was specifically created for use with post-stroke and other neurologically impaired patients with aphasia and other communication disorders using the 100m line with two cartoon faces connecting the line (Stern et al., 1997).

The General Anxiety - Visual Analogue Scale (GA-VAS) is a 100 mm line shown administered as a daily diary format to assess average anxiety over the past 24 hours (Williams et al., 2010). The distance from the left edge of the line to the mark placed by the patient is measured to the nearest millimeter and used in analyses as the patient GA- VAS score.

Puertas, Patel and Marshall (2004) developed a visual analogue scale, the FACES test, which is a visual representation of mood, consisting of seven graded faces, 1 being happiest mood and 7 being saddest mood. Puertas et al. (2004) hypothesized that a visual analogue scale could be useful in an environment where literacy was not universal like Western societies. The FACES test performed poorly and people with low levels of literacy had difficulties with completing it. As a result, this visual analogue scale was not recommended because of its low accuracy.

Another visual analogue scale is the Distress Thermometer which was developed National Comprehensive Cancer Network for measuring distress, even distress unrelated to cancer (Holland, 2013). It has a single question which asks patients to place circle a number from 0 to 10 which best describes how much distress they have been experiencing in the past week including today. Patients are further asked to indicate problem areas from a list of 39 items where a patient is required to read.

Some of these visual analogue scales can prove to be problematic. For example, stroke patients may have difficulty in perceiving the spatial relations of the scale and may not be able to accurately complete it. Some degree of hemispatial neglect has been proposed in patients living with depression and patients experiencing manic symptoms (Ahearn, 1997). Also, the self rating screening instruments that the visual analogue scales are often validated against might be based on different constructs to the visual analogue scales (Ahearn, 1997). The comparison of these two scales, self rating screening tool and visual analogue scale according to Ahearn

(1997) may demonstrate good but not exceptional correlation, as these ratings might be measuring different aspects of an illness. Berg, Lönnqvist, Palomäki and Kaste (2009) did not recommend the Visual Analogue Mood Scale as it had poor sensitivity, 0.20 to 0.60 and did not have a correlation with the Beck Depression Inventory in stroke patients. Many validation studies for depression screening tools, according to Chorwe-Sungani and Chipps (2017) have been conducted in high income countries with a different culture and socio-economic context to low resource setting (Chorwe-Sungani & Chipps, 2017).

Visual analogue scales have not been developed and validated for depression and anxiety disorders in people living with hypertension and/or anxiety disorders. Moullec et al. (2010) argued that tools cannot be generalized to populations from other cultural or linguistic backgrounds different from those who participated in the development of the scales. According to Akena (2012) there has been limited work aimed at improving the previous modest performances of some visual analogue scales and include a broad range of symptoms of depression. Some of the recent improvements of non traditional screening tools have been conducted by Akena, Joska, Musisi and Stein (2013) who developed and validated a visual screening tool for depression in people living with Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS). Similarly to visual analogue scales, visual screening tools are non traditional instruments designed to measure or assess the presence of symptoms such as depression. However, screening tools, such as Akena's use a broad range of symptoms based on the Diagnostic Statistical Manual (DSM) criteria to demonstrate symptoms of depression using drawings/pictures. Akena et al. (2013) included images depicting loss of interest, poor appetite, suicidal ideation, crying spells and low energy. A symptom considered to be culturally appropriate was included, namely "worries/too many thoughts" by Akena et al. (2013). The aforementioned symptoms were graphically presented to illustrate depressive symptoms. These symptoms either had a face or action depicting a normal state or

one depicting an abnormal state. A score of 1 was allocated for a normal state and 2 for an abnormal state for the following items: sadness, loss of interest, poor appetite, crying spells and low energy, and attempted suicide was allocated a score of 3. Akena et al. (2013) found the tool to be accurate in screening for depression in people living with HIV/AIDS with low levels of education. However, the screening tool developed by Akena et al. (2013) does not screen for anxiety disorders. According to Katon, Lin and Kroenke (2007), anxiety disorders should be included when screening for depression as these often co-exist in patients living with chronic physical conditions. Also, Akena et al. (2013) included a Ugandan culturally appropriate symptom for depression.

With the shift towards integrating mental health care into primary health care, and the limitations of current screening tools including, language, education and available visual analogue scales, we identify a need to develop and validate a visual screening tool that appropriate, accurate across cultures, education levels and language, and does not require to be translated into different languages and be used in primary health care settings for people living with hypertension and/or diabetes. This would be a tool that is easy and simple to administer and score; and accurate in detecting depression and anxiety disorders in people living with hypertension and/or anxiety disorders.

Screening tools must also be acceptable to the person who screens and to the people who are screened. With the focus in South Africa on integrating mental health into primary care, simple, culture friendly and easy to use tools are required. These should require less intense training and inexpensive tools.

## **Central theme and aims of this study**

Visual screening tools for depression and anxiety disorders could possibly circumvent the current challenges experienced at primary care settings as posed by cultural, language, educational and resource factors. However, available visual screening tools either: (a) neglect other symptoms of depression, focussing on sadness as the only symptom, (b) consist of matching exercises in which words and definitions are matched but these are most likely only available in English, and (c) do not screen for both depression and anxiety symptoms. Screening should ideally include both depression and anxiety disorders since these disorders often co-exist in chronic physical conditions. Our study focused on the development and validation of a visual screening tool that could address all of these barriers and the tool is simple and easy to administer and score.

The study was divided into two phases. During phase one, as described in chapter two, we focused on investigating the accuracy of pictures in aiding individuals to describe emotions and thoughts associated with depression and anxiety disorders in order to develop a culturally appropriate and simple visual screening tool that could be applied across language groups and levels of education.

Phase two, as described in chapters three and four focuses on the validation of our newly developed tool, the Visual Screening Tool for Anxiety Disorders and Depression (VISTAD). For this we chose to recruit a primary care sample of people living with hypertension and/or diabetes due to the high prevalence of these illnesses as well as the high known co-morbidity with depression and anxiety disorders. In chapter three, the sample recruited is described with reference to psychiatric co-morbidity, quality of life and alcohol and drug use. In the last chapter of phase two, chapter four, we describe the VISTAD validation process.

## **Research aims and objectives**

The study was conducted in two phases, and the aims of these phases are presented according to the three different articles that make up this dissertation.

### **Phase one:**

*The development of the Visual Screening Tool for Anxiety Disorders and Depression*

#### *Chapter 2*

Hypertension and diabetes often coexists with depression and/or anxiety disorders. However, these disorders are often not detected in people diagnosed with hypertension and/or diabetes. The lack of screening tools that can be administered at primary health care level to a diverse group of people contributes to the non-detection of these disorders. During phase one we thus aimed to develop a visual screening tool for depression and anxiety disorders that could be used in a primary health care population diagnosed with hypertension and/or diabetes. For this process, the accuracy of the drawings across race, language and different levels of education was determined.

### **Phase two:**

*The validation of the Visual Screening Tool for Anxiety Disorders and Depression and the description of the sample recruited for this phase*

#### *Chapter 3*

Previous and current research has shown a high prevalence of depression and anxiety disorders in people diagnosed with hypertension and/or diabetes. This co-morbidity has been associated with poor quality of life and poor prognosis, increased alcohol and drug use. However, the available evidence is often from research conducted in high-income countries and there is little information regarding the prevalence of these common mental disorders in patients accessing the South African primary health care system. We thus aimed to describe the presence of depression, anxiety disorders; and the quality of life. In this chapter we describe the presence

of depression and anxiety disorders in the sample recruited for the validation of the visual screening tool for depression and anxiety disorders (VISTAD).

#### Chapter 4 (Article 3)

We aimed to validate the visual screening tool for anxiety disorders and depression against the Mini-International Neuropsychiatric Interview (M.I.N.I) in adults attending primary care in a group of participants living with hypertension and/or diabetes. For this purpose, a language, education level and culturally diverse group was recruited in the Eastern Cape Province of South Africa. In this chapter we describe the validation process for determining the accuracy of the VISTAD in detecting depression and anxiety disorders in these participants.

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## **CHAPTER TWO**

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# The development of the visual screening tool for anxiety disorders and depression: Addressing barriers to screening for depression and anxiety disorders in hypertension and/or diabetes

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**Background:** There is a lack of screening tools for common mental disorders that can be applied across cultures, languages and levels of education in people with diabetes and hypertension.

**Aim:** To develop a visual screening tool for depression and anxiety disorders that is applicable across cultures and levels of education.

**Setting:** Participants were purposively recruited from two not-for-profit organisations and two public health facilities – a maternal mental health unit and a primary health care centre.

**Method:** This was a qualitative cross-sectional study. Thirteen drawings based on the Hospital Anxiety and Depression Scale depicting symptoms of anxiety disorders and depression were drawn. Participants described emotions and thoughts depicted in the drawings. Data were analysed through content analysis.

**Results:** Thirty-one women (66%) and 16 men (34%) participated in the development of the visual screening tool. The mean age was 34 (standard deviation [SD] 12.46). There were 32 (68%) black participants, 11 (23%) mixed race participants and 4 (9%) white participants. Two participants (4%) had no schooling, 14 (31%) primary schooling, 8 (18%) senior schooling, 13 (29%) matric qualification and 8 (18%) had post-matric qualification. Participants correctly described 10 out of the 13 visual depiction of symptoms as associated with depression and anxiety disorders, with no differences between levels of education and cultural groups.

**Conclusion:** Ten drawings were appropriate for inclusion in the visual screening tool for anxiety disorders and depression (VISTAD). The VISTAD will be validated against the mini international neuropsychiatric interview (MINI) in a primary care population with hypertension and/or diabetes.

## Introduction

Diabetes and hypertension are often comorbid with depression and/or anxiety disorders.<sup>1,2,3,4,5</sup> This comorbidity with depression and anxiety disorders has been shown to decrease adherence to treatment regimens,<sup>6</sup> increase rates of poor quality of life,<sup>7</sup> increase mortality risk<sup>8</sup> and inflate financial burden associated with health care.<sup>9,10</sup> In spite of this co-existence and its effects being well known, mental disorders in patients with chronic physical illness largely remain undetected and untreated at primary health care.<sup>11,12,13,14</sup> Lecrubier<sup>15</sup> argues that the detection and treatment of depression and anxiety disorders can address the burden imposed by these disorders.

Jenkins et al.<sup>16</sup> and Van Oers and Schlebusch<sup>17</sup> identified the lack of appropriate screening tools as one of the barriers in detecting mental health problems. Multicultural societies, such as South Africa with its 11 official languages, lack screening tools that can be applied to a diverse range of cultural and language groups.<sup>18</sup> A number of screening tools fail to meet acceptability for sensitivity and positive predictive value in the South African population<sup>19</sup> and cannot be generalised to populations different from those who participated in their development.<sup>20</sup>

Screening tools are often translated into other languages for use by other cultural groups. In making screening tools available for use in people across different languages, research has documented the loss of meaning in translation.<sup>21,22</sup> Steele and Edwards<sup>23</sup> argue that the translation process is often plagued by practical and methodological difficulties that threaten the validity of

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the cross-cultural research projects. Hermanns et al.<sup>24</sup> argue that the translation of concepts across cultures is crucial in order to develop culturally appropriate measurement tools, diagnoses and services for people with depression and anxiety disorders. Language, according to Alexander et al.,<sup>25</sup> is a factor that contributes to the non-detection of mental health problems.

Educational status has been highlighted as a critical variable to be considered when developing a screening tool.<sup>18</sup> Screening tools for depression and anxiety disorders have been found to be less effective in individuals with lower levels of education.<sup>24,26,27</sup>

Researchers have developed screening tools using drawings for example, Puertas et al.<sup>28</sup> developed the FACES test which consisted of schematic faces representing mood states ranging from happy to sad face, and from one extreme to the other. The FACES test, according to Puertas et al.<sup>28</sup> is a visual analog scale representation of mood, consisting of seven graded faces from happiest mood to saddest mood. Puertas et al observed that participants with no education were significantly more likely not to be able to answer the FACES test.

Contrary to Puertas et al.<sup>28</sup> a visual screening tool for depression in people living with human immunodeficiency virus (HIV) has demonstrated good psychometric properties in people with high and low levels of education.<sup>29</sup> However, the tool neglects anxiety symptoms which often coexist with depression. In addition, it focuses on symptoms that often overlap with diabetes. Reddy et al.<sup>27</sup> argue that symptoms such as low energy complicate the diagnosis of depression in people with diabetes. They further argue that the hospital anxiety and depression scale (HADS) is an appropriate screening tool for depression and anxiety disorders in people with diabetes. However, tools developed in high-income countries written in English for people with higher levels of education might not be appropriate for use in a context such as South Africa, especially in resource-constrained primary health centres.

The identification of patients with mental health problems cannot be successful without culture-fair instruments and instruments free of language bias.

Our study aimed to develop a visual screening tool that can screen both depression and anxiety disorders in people with diabetes and/or hypertension using culture-friendly drawings while avoiding some of the limitations associated with screening tools.

## Methods

### Development of the visual screening tool

As a starting point, an artist, Mrs Jane Metelo-Liquito (Bachelor of Arts Honors, CDAT-I) was asked to make drawings depicting depression and anxiety symptoms before the recruitment for the study began. The drawings

were based on the HADS<sup>30</sup> which has been recommended for screening for depression and anxiety disorders in patients diagnosed with diabetes.<sup>27</sup> Figure 1 shows the depression and anxiety items included in the development of the visual screening tool. Each item consisted of two drawings: one drawing depicting an abnormal state and the other depicting a normal state. Most of the drawings used in the development of the visual screening tool focused more on the face. The face, according to Betts,<sup>31</sup> is predominantly associated with the expression of emotions and individual identity.

### Setting

The study was conducted in two not-for-profit organisations in Cape Town and two public health facilities. The not-for-profit organisations included a church in a predominantly white community and an organisation working with business and South African youth in predominantly black and mixed-race communities. The two public health facilities included a maternal mental health clinic unit and a primary health care centre in the Eastern Cape Province of South Africa. The multiple settings included in the study serve multicultural groups from urban and rural communities and this served to minimise bias towards a specific language and/or cultural group. South Africa is a diverse country with the majority of South Africans being black people followed by mixed race people, Indian people, Asian people and white people,<sup>32</sup> and the most spoken languages are isiZulu, isiXhosa, Afrikaans and English out of the 11 official languages.

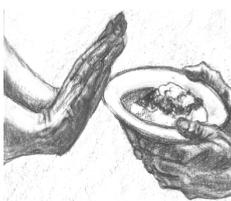
### Study design

This was a qualitative cross-sectional study that utilised semi-structured interviews to develop depression and anxiety disorder items for a new visual screening tool.

### Sampling strategy

Purposive sampling was utilised to recruit participants. Individuals were recruited while they were at the settings for a routine scheduled visit. The purpose of the study was explained, and individuals who expressed an interest to take part in the study were seen in a private room. The target study population excluded people with visual and hearing impairment and individuals with intellectual disability based on self-report.

Methodologists such as Morse<sup>33</sup> recommend 30–60 interviews when conducting semi-structured interviews. This is in agreement with our initial sample size calculation of 60 (at a 95% confidence interval and a precision of 12.75). However, according to Mason,<sup>34</sup> the most common sample sizes are between 20 and 30 as the necessary information is easily obtained in the interviews and thus fewer participants are needed.<sup>33</sup> This was also true for our study as themes were already established in a sample size of 47 and recruitment could be terminated after 3 months.

Item	Symptoms	N	%	Image
1	Sleep disturbance	38	81	
2	Frightened or panic feeling for no reason	47	100	
3	Sad and miserable	46	98	
4	Anxious when I go outside the house on my own	40	85	
5	Loss of interest	17	36	
6	Palpitation or sensations in chest	43	43	
7	Loss of appetite	46	98	
8	I feel life is not worth living	43	91	
9	I feel as if I have slowed down	0	0	

Source: Courtesy of artist Jane Metelo-Liquito.

**FIGURE 1:** The number of participants describing symptoms associated with depression and anxiety disorders.

Item	Symptoms	N	%	Image
10	Restlessness	0	0	
11	Irritability	45	96	
12	Worrying thoughts constantly go through my mind	46	98	
13	Depressed and sad	42	89	

Source: Courtesy of artist Jane Metelo-Liquito.

**FIGURE 1 (Continues...):** The number of participants describing symptoms associated with depression and anxiety disorders.

## Data collection

Data were collected over a period of 3 months through semi-structured interviews conducted by the principal researcher who is a clinical psychologist. The structured interviews were conducted in English and Xhosa. English-speaking participants were interviewed in English and Xhosa-speaking participants were interviewed in Xhosa. The demographic questionnaire was administered with all the participants after the completion of written informed consent. This questionnaire was utilised to collect socio-demographic variables such as age, race, sex, marital status, level of education, employment status, family income and medical conditions. Participants were then asked to describe the emotions and thoughts depicted in the 13 drawings, with each interview lasting between 20 and 50 min. The responses provided by the participants were captured on a spreadsheet designed by a statistician.

## Data analysis

The data were analysed through content analysis by coding the obtained data for words relating to symptoms of depression and anxiety disorders. Content analysis begins with predefined categories.<sup>35</sup> The predefined categories (Figure 1) in this study were based on the HADS. Themes were identified from the descriptions provided by the participants and matched against the HADS items. The number of instances in which participants provided descriptions in response to emotions and thoughts depicted in the drawings was counted.<sup>36</sup> The meaning of the themes

was interpreted, looking for correlation with the symptoms of depression and anxiety disorder as depicted in the drawings.

Trustworthiness of the obtained data was established through respondent validation.<sup>37</sup> This was done during the interview and at the end of the interview where the principal researcher restated, questioned and summarised the responses given by the participants. This allowed the participants an opportunity to affirm or reject the responses.<sup>38</sup>

Descriptive statistics was used to describe demographic data. Demographic data was summarised as frequencies, percentages, means with standard deviation (SD). STATA version 14 was used for descriptive statistics.

## Ethical considerations

Ethical approval was obtained from the Human Research Ethics Committee of the Faculty of Medicine and Health Sciences at the University of Stellenbosch (Reference number: S14/11/262) and permission was obtained from the Western Cape Department of Health and the Eastern Cape Department of Health to conduct the study. The not-for-profit organisations also granted permission to conduct the study.

## Results

Forty-seven participants participated in the development of the new visual screening tool for anxiety disorders and depression (VISTAD). The mean age of the participants was 34 with SD 12.46 (age range 18–60 years). Thirty-five (74%) of the 47 participants were unemployed and 12 (26%) were employed. The mean income per month was US \$487,70 with minimum salary less than US \$357,57 and maximum US \$4290,84 per month. Table 1 provides a descriptive overview of the demographics of the study participants.

Our study determined whether participants identified and described symptoms associated with depression and anxiety disorders correctly. Drawings that depicted symptoms of depression were easily identified and described by the participants. Items 1, 2, 6 and 7 recorded some of the highest frequencies in correct descriptions as symptoms of depression. The number of participants (*N*) who described symptoms of depression and anxiety disorders is presented in Figure 1.

As shown in Figure 1, 38 (81%) participants described item 1 as sleeping disturbance. This description was observed across race, gender and different levels of education. The other nine participants (19%) described item 1 as depicting sadness and depression. Some participants remarked that this is how they were when they were stressed, had too much on their minds and, as a result, struggled to sleep. Item 3 was described as depression, sadness and misery by 46 (98%) participants.

Similar to depression items, anxiety items were described correctly as depicting symptoms associated with anxiety disorders. For example, item 2 'frightened or panic feeling for no reason', was described as anxiety by all the 47 (100%) participants providing accurate descriptions.

**TABLE 1:** Description of the participants.

Variables	<i>N</i>	%
<b>Gender</b>		
Female	31	66
Male	16	34
<b>Race</b>		
Black people	32	68
Mixed race people	11	23
White people	4	9
<b>Language</b>		
isiXhosa	30	64
Afrikaans	14	30
English	1	2
Sotho	1	2
isiZulu	1	2
<b>Education†</b>		
No schooling	2	4
Primary schooling (Grade 1 and Grade 6)	14	31
Senior schooling (Grade 7 and Grade 11)	8	18
Matric	13	29
Post-matric qualification	8	18
<b>Employment</b>		
Employed	12	26
Unemployed	35	74

*N*, Number of participants; std dev, standard deviation.

†, There were two missing observations on education variable.

The participants' personal narratives were evident in items 2 and 3. Nine participants (19%) reflected on being diagnosed with HIV and associated anxiety symptoms. The participants responded in the first person when describing the emotions and thoughts depicted in the drawings. Also, it was observed that participants became emotional and tearful during the interviews. There were 4 participants who became tearful during the interviews. In responding to item 3, sad and miserable, participants related narrative life stories which were characterised by sadness. Item 4, 'anxious when outside on my own', included 'scared, hyperalert, fear of being attacked, fearful, cannot defend herself, shadow implies fear, abused, unsafe'. Participants with varying levels of education, different races and languages were able to understand the drawings and provided descriptions of symptoms associated with anxiety and depression.

Thirty participants (64%) described item 9 as portraying sadness and loneliness in a troubled person, and descriptions such as the person was praying were also mentioned. Some of the participants described the feeling of slowing down as a story of a depressed family member (item 9). Furthermore, participants empathised with the woman on the drawing reporting she was confused, on her own and lived below the poverty line (item 9). The feeling of slowing down (item 9) and restlessness (item 10) were not identified correctly by all the participants. Seven participants (15%) narrated their life stories in relation to the feeling of slowing down (item 9) and feeling restlessness (item 10). These stories were characterised by depression and anxiety. The picture depicting restlessness (item 10) was found to be the most unclear item. This was described as a group of angry people, poverty-stricken individuals, prisoners and sad individuals.

Participants expressed sadness at the person depicted in item 13, stating that the person was stressed and had many life problems. Some of the participants personally identified with the emotional state depicted in item 13. These participants began to describe issues that concerned them in life. The descriptions provided by the participants with varying levels of education and different races and languages were associated with symptoms of depression and anxiety as predefined in the HADS, and this showed that the items could be considered for inclusion in the visual screening tool.

The items that were frequently described correctly included depression items: sleep disturbance, feeling miserable and sad, appetite, feeling life is not worth living, and anxiety items; feeling frightened or having panic feelings for no reason, feeling frightened when going out of the house on my own, getting palpitations or sensations 'butterflies' in stomach or chest, irritable than usual and worrying thoughts. Items that were least understood by the participants and did not match the predefined categories were removed, both the normal and abnormal state drawings.

## Discussion

Forty-seven participants participated in the development of the VISTAD. The study confirmed that cultural and educational background had no bearing on the ability of participants to identify and describe symptoms associated with depression and anxiety disorders. Participants with low levels of education performed similarly to those with higher levels of education, and this was observed across cultures. Previous studies found visual screening tools to be valid for use as screening tools in people with low and high levels of education.<sup>29</sup> The participants identified symptoms associated with depression and anxiety disorders accurately. These findings are consistent with observations made by Vick and Strauss.<sup>39</sup> Also, when providing descriptions, participants gave reasons why people felt and thought the way did. For example, when the sleep disturbance item was identified, participants described reasons why the person on the drawing was not sleeping. Furthermore, descriptions of the items were connected to personal narratives of the participants. Drawings, according to Oster and Crone,<sup>40</sup> are often viewed as less threatening than direct verbal interaction.

The participants used their life stories in describing emotions and thoughts depicted in the drawings. The use of drawings potentially offers invaluable opportunities to explore emotional status across cultural boundaries. Similar to the Rorschach technique, individuals have tremendous freedom of response.<sup>41</sup> Individuals can report on what they are seeing instead of offering an either true or false response to a written statement.<sup>41</sup> The use of drawings depicting emotions can provide access to the emotions of patients suffering from chronic medical conditions. This study lays the groundwork for studying the ability of the drawings as a projective tool. The assumption of projective instruments is that the respondent will project onto an image, thus expressing unconscious needs that he or she is ordinarily unable or unwilling to report.<sup>42</sup>

The participants often responded in the first person and added statements such as 'that was me' when they identified with a specific drawing, such as sleep disturbance item. Projective drawings provide information that can enrich an individual's description of his or her own experience.<sup>43</sup> A projective test involves, amongst other stimuli, a drawing chosen because it will elicit hidden meanings and not because the tester has preconceived ideas of what it should mean.<sup>43</sup> In our study we held preconceived ideas about what the drawings mean as they were based on the HADS. However, it was not expected that participants would give personal stories in their responses to the drawings. The descriptions of the emotions and thoughts were accompanied by narratives offering unique material for understanding the participants' life stories.

The new screening tool was named the VISTAD. Of the 13 drawings depicting symptoms associated with depression and anxiety disorders, we selected 10 to be used in the validation study of the VISTAD. These included the normal state drawings. Items: 'feeling as if one's mind has slowed down', 'restlessness' and 'loss of interest' were excluded from the validation study. This included both the drawings portraying a normal and an abnormal state. The VISTAD will be validated against the mini international neuropsychiatric interview (MINI) for accuracy as a screening tool in a primary health care population diagnosed with hypertension or diabetes.

## Limitations

The research participants were predominantly of a low socio-economic status. However, the VISTAD is designed for primary health care, and primary health care predominantly services people of low socio-economic status. Furthermore, the study did not include all racial groups. There were no Indian, Asian and Mixed Race participants. The answers provided by the participants were captured on a spreadsheet during the interview and were not recorded as the participants described emotions and thoughts.

## Conclusions

The findings of this study demonstrate that the drawings are appropriate for use with people from different cultural backgrounds and varying educational levels to describe the same feelings and thoughts. As a next step, in order to establish the psychometric properties of the VISTAD, it should be validated against the MINI in a primary health care population with hypertension or diabetes.

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## Competing interests

The authors declare that they have no conflicts of interest to disclose. Neither personal nor financial relationship may have inappropriately influenced them in writing this article.

## Authors' contributions

This article is produced from a research paper that will be submitted for a PhD in Psychiatry. Z.O. is the principal researcher and collected data and produced the first draft of the article. L.K. is the research supervisor and reviewed the article. D.J.H.N. is the co-supervisor and reviewed the article.

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## **CHAPTER THREE**

This chapter presents a description of the presence of depression and anxiety disorders in the sample recruited for the validation of the VISTAD. It also describes the quality of life and patterns of alcohol and drug use in the study sample living with hypertension and/or diabetes.

## **Depression and anxiety disorders in primary health care patients living with hypertension and/or diabetes in the Eastern Cape, South Africa**

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### **ABSTRACT**

**Background:** Hypertension and diabetes have been associated with depression and anxiety disorders, poor quality of life and increased alcohol and drug use.

**Aim:** This study aimed to assess the number of patients with depression and anxiety disorders in a primary care population diagnosed with hypertension and/or diabetes. The study also aimed to describe the demographic and comorbid illness characteristics of the sample, including patterns of alcohol and drug use. The quality of life was measured and compared with the Visual Screening Tool for Anxiety Disorders and Depression (VISTAD) scores.

**Methods:** This cross sectional study using purposive sampling was conducted in five primary care centers in the Eastern Cape, South Africa. The Mini-International Neuropsychiatric Interview was utilized to diagnose depression and anxiety disorders. Fisher's exact test was used to determine the relationship between hypertension and hypertension with diabetes and depression and anxiety disorders. The WHOQOL-BREF was used to assess the quality of life. We used the Alcohol Use Disorders Identification Test and the Drug Use Disorders Identification Test to screen for alcohol and drug use respectively. The VISTAD scores was compared with selected illness and quality of life variables.

**Results:** The most common diagnosis was panic disorder (40%), followed by post-traumatic stress disorder (33%), depression (32%), generalized anxiety disorder (17%), social phobia (10%) and agoraphobia (10%). There was no statistically significant association observed between hypertension and/or diabetes and depression ( $p=.80$ ). There was a statistically significant association between hypertension and agoraphobia ( $p=.04$ ). The quality of life of people with hypertension and/or diabetes was found to be poor in all domains except for social domain (14.97), physical health (12.42), psychological health (14.17) and environment (12.71). There was also a statistically significant association between depression and poor quality of life ( $p<0.01$ ) across all quality of life domains, physical, psychological, social relationships and environment. Participants who endorsed depression and anxiety symptoms reported a poor quality of life. Of the sample, 69 (85%) scored between 0–7 on the AUDIT, indicating low risk drinking. Five (6%) reported possible dependence, two (3%) hazardous drinking and five (6%) harmful levels of drinking. On the DUDIT, 65 (83%) reported no drug related problems, 1 (1%) drug dependence and 13 (16%) drug related problems.

**Conclusion:** Depression was significantly associated with poor quality of life on physical, psychological, social relationships and environment domains whereas anxiety disorder had a statistically significant association with some of the quality of life domains. The study underscores the importance of detecting depression and anxiety disorders in people with hypertension and/or diabetes.

**Keywords:** hypertension, diabetes, depression, anxiety disorders, quality of life, alcohol, drug use

## INTRODUCTION

The burden of disease, including non communicable disease has increased globally. The global burden of mental, neurological and substance-use disorders increased by 41% between the year 1990 and 2010.<sup>1</sup> Hypertension and diabetes have emerged as major contributors to the world-wide burden of disease. According to the International Diabetes Federation Atlas (IDF),<sup>2</sup> there are approximately 450 million people world-wide living with diabetes. Similarly to the high prevalence of diabetes, over 1.3 billion people are living with hypertension.<sup>3</sup> Both hypertension and diabetes are highly prevalent in South Africa with 2.3 million people living with diabetes,<sup>2</sup> and 6.3 million with hypertension.<sup>4</sup> Individuals living with hypertension and diabetes have a higher prevalence of depression and anxiety disorders compared to those without these illnesses.<sup>5</sup> Alkhatami, Alamin, Alqahtani, Alsaeed, Alkhatami and Al-Dhafeeri (2017)<sup>6</sup> found a prevalence of 48.7% for depression and 38.4% anxiety in people living with hypertension and/or diabetes attending primary health care. Teixeira et al. (2015)<sup>7</sup> reported depression (severe) 35% and anxiety (severe) 26% in sample of 34 participants with hypertension and/or diabetes. In a sample of participants living with diabetes, Goldney, Phillips, Fisher, and Wilson<sup>8</sup> reported a prevalence of 24% for depression South Australia. Researchers in India reported a prevalence of 62% for depression and 49% for anxiety in people living with Type 2 diabetes.<sup>9</sup> There is less research reporting on the association between hypertension and depression<sup>10</sup> and association between depression and anxiety disorders in both hypertension and/or diabetes compared to depression and diabetes only.

Investigating the comorbidity between hypertension and/or diabetes and depression and anxiety disorders is crucial as this comorbidity has been associated with adverse consequences. These include poor adherence to treatment regimens and poor self-care behaviors.<sup>5,8</sup> Also, hypertension and diabetes often coexist<sup>11,12</sup> and both hypertension<sup>13,14</sup> and diabetes<sup>11</sup>, have been associated with a poor quality of life (QOL). Quality of life, according to Rubin and Peyrot (1999)<sup>11</sup> is an important health outcome for all health interventions and has also been

specifically shown to act as important indicator in the evaluation of hypertension treatment outcomes.<sup>15</sup> Quality of life can also serve as an important outcome measure for pharmacological or non-pharmacological interventions.<sup>16</sup> With the increase in hypertension and diabetes prevalence and the recorded negative medical impact on the lives of individuals, it is critical to understand the QOL of individuals diagnosed with these illnesses.

In addition to the association between hypertension and diabetes and QOL, previous research has demonstrated an association between hypertension, diabetes, mental disorders, alcohol and drug use.<sup>17-19</sup> The association between alcohol use and depression<sup>20</sup> and anxiety disorders<sup>21</sup> has consistently been reported. Collectively, these disorders, combined with hypertension and diabetes, contribute to a substantial burden of disease.<sup>22-24</sup>

Overall, the coexistence of hypertension and/or diabetes with depression and/or anxiety disorders presents a burden on health care resources. In addition to the negative impact, these conditions increase the mortality risk,<sup>9</sup> and inflate the financial burden associated with health care.<sup>25,26</sup> Studies have investigated the number of people living with depression and anxiety disorders who suffer from hypertension and/or diabetes. However, these studies have mostly been conducted in developed countries.<sup>27,28</sup> Furthermore, many of these studies have specifically focused on diabetes and depression excluding hypertension and anxiety disorders, with few studies investigating the association between depression (and anxiety disorders) and hypertension.<sup>28,29</sup>

The lack of research investigating depression and anxiety disorders in people living with hypertension and/or diabetes limits our ability to better understand and manage the implications of this burden. Especially, the dearth of locally conducted studies hinders our ability to allocate necessary resources and develop interventions for people living with diabetes and/or

hypertension comorbid with depression and anxiety disorders. Data from South Africa are needed in order to develop a full understanding of the prevalence of depression and anxiety disorders and for planning the provision of integrated mental health care for people living with hypertension and/or diabetes. We aimed to describe the presence of depression and anxiety disorders in a sample that was used to validate the Visual Screening Tool for Anxiety Disorders and Depression (VISTAD),<sup>30</sup> and to investigate the association between quality of life and hypertension and/or diabetes and depression and anxiety disorders. We also aimed to describe alcohol and drug use patterns of primary health care participants living with hypertension and/or diabetes.

## **METHODS**

### **Study design**

This cross sectional study using purposive sampling was conducted in five primary health care centers (two urban, one peri-urban, and two rural) in the Eastern Cape, South Africa. Participants diagnosed with hypertension and/or diabetes were recruited from these centres. This province has been identified to have a high prevalence of hypertension and diabetes.<sup>31,32</sup> Participants who potentially met the study criteria were either referred by primary health care workers or recruited by the researcher through purposive sampling. Thirty-one (38%) participants were from clinics in urban centers, 39 (48%) from rural and 11 (14%) from peri-urban centers in the Eastern Cape. Eighteen participants were Mixed Race, 13 White and 50 Black. The specific primary health care centres used as study sites were identified based on their accessibility and reduced interference due to service delivery protests that were ongoing at the time during the study period.

## **Study population**

Eighty-one participants diagnosed with hypertension and/or diabetes were recruited. Since hypertension and diabetes are frequently comorbid conditions, we recruited participants with either hypertension or diabetes or with both of these conditions. Purposive sampling which refers to the selection of a sample that the researcher perceives to be a “typical” sample based on selection criteria was utilized for this study. Primary health care staff at the study settings were requested to inform patients who had hypertension and/or diabetes and possibly met the inclusion criteria about the study, and then refer those who expressed an interest. The researcher also spoke to patients in the waiting area at the study setting and those who self-reported a diagnosis of hypertension and/or diabetes were informed of the study. Recruitment was done on the “chronic days”. “Chronic days” are days scheduled for treatment of people living with chronic medical conditions such as diabetes and hypertension, but excluding Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS). This allowed the researcher to easily identify possible participants. Participants who expressed an interest were invited to a separate room to meet with the researcher. Those who met criteria, were willing to participate and had capacity to consent were included. Individuals with intellectual disability, or visual and/or hearing impairment were excluded.

## **Questionnaires**

A demographic questionnaire was used to collect data such as age, race, gender, marital status, level of education, employment status, family income, dwelling type, number of people in household, history of mental illness, other medical conditions and disability. Depression and anxiety disorders were assessed according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria set out on the MINI International Neuropsychiatric Interview (M.I.N.I) version 5.0.<sup>33</sup> The M.I.N.I has been widely used as a diagnostic tool in people with diabetes only,<sup>34,35</sup> and diabetes and hypertension.<sup>36</sup> Whilst the M.I.N.I has not

specifically been validated for use at primary health in people living with diabetes and/or hypertension, it has been widely used in South Africa and found to be a valid and reliable tool.<sup>37</sup> The M.I.N.I has very good operating characteristic.<sup>38</sup> It is characterized by good and very good kappa values and higher specificities and negative predictive values of 0.85 or higher across all the diagnosis. Positive predictive values (PPV) for depression, panic disorder, post traumatic stress disorder are above 0.75 indicating very good (PPV). The M.I.N.I has been described as a gold standard in the validation of screening tools in the African context. Also, the M.I.N.I was used as a gold standard in the validation of a visual screening tool for depression<sup>39</sup> which is similar to the VISTAD.<sup>30</sup> Validation studies have reported AUC of ranging from 0.77<sup>37</sup> to 0.82<sup>39</sup> and 0.77 for post traumatic stress disorder, and 0.78 for generalized anxiety disorder.<sup>37</sup>

The WHO quality of life assessment instrument (WHOQOL-BREF), which was developed cross culturally by the WHO as a self-report questionnaire, was used to assess the QOL. This tool comprises 26 items with four different facets or domains of QOL, namely physical health (DOM 1), psychological health (DOM 2), social relations (DOM 3) and environment (DOM 4).<sup>40</sup> Each domain is scored, and then scores are transformed according to the WHOQOL-BREF manual.<sup>41</sup> Higher scores denote a higher QOL. The WHOQOL-BREF has not been validated for use in South African primary care patients living with hypertension and/or diabetes. However, the WHOQOL-BREF has shown good consistency and reliability in diverse groups and centers.<sup>42</sup>

The VISTAD<sup>30</sup> was developed as a screening tool for depression and anxiety disorders in a primary care population living with hypertension and/or anxiety disorders. The VISTAD has 10 items which screen for depression and anxiety disorders in people living with hypertension and/or diabetes. A score of 1 is allocated when a participant endorses an abnormal state drawing and 0 when none of the abnormal state symptoms are endorsed. The maximum score that could

be obtained on the VISTAD is 10. A score of 6 or more on the VISTAD indicates a positive screen for depression and anxiety disorders.

### **Statistical analyses**

Descriptive statistics were used to describe the study sample and the prevalence of depression and anxiety disorders. Fisher's exact test was used to determine the relationship between hypertension and diabetes and depression and anxiety disorders. An analysis for the diabetes only group was not conducted as there was only one participant who fell in this group. The participant was not removed in the overall data analysis as our study sample was relatively small. We compared hypertension only with hypertension comorbid with diabetes to determine if a comorbid diagnosis was associated with being diagnosed with depression and anxiety disorders. Cronbach's alpha was used to estimate the reliability of the WHOQOL-BREF. Cronbach's alpha values of 0.80 and above were regarded to be acceptable.<sup>40</sup> We used the Mann-Whitney U Test to compare mean scores between people with and without medical conditions (HIV and diabetes were also analyzed as separate variables given the prevalence in the sample and clinical features of these disorders). The level of significance was set at  $p < 0.05$  for all analyses which were performed using STATA, version 14.

### **Ethical considerations**

Ethical considerations were the same as those in the main/parent study as this was one study with different aims and aspects. Ethical approval was granted by the University of Stellenbosch Faculty of Medicine and Health Sciences Human Research Ethics Committee (Reference number: S14/11/262) (Addendum 1). Permission to conduct the study was obtained from the Eastern Cape Department of Health, South Africa. The study was conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical

Guidelines for Research.

## RESULTS

Eighty-one participants were recruited and interviewed, but only 79 participants completed the demographic questionnaire and thus represent the sample described in Table 1. Two participants had incomplete demographic data and their data was used in the analysis of WHOBREF-QOL. The mean age of the participants was 49 years, with standard deviation 8.7 and a range of 22–60 years. The majority of the participants interviewed were female 69 (87%). Most of the participants were Black 50 (63%), 16 (20%) Mixed Race, and 13 (17%) White. The majority were unemployed 58 (73%) with the minimum monthly income \$15,12 and the median \$143,39. The highest monthly income was \$3018,80. Forty-seven of the participants had a diagnosis of hypertension (59%), followed by hypertension co-morbid with diabetes in 31 participants (39%) and a single participant with diabetes only. The total of 81 participants were recruited from clinics in Port Elizabeth, 23 from Algoa Park Clinic and 8 from kwaMagxaki Clinic. Eleven participants were recruited from Uitenhage clinic; 19 from Wentzel Park Clinic and 20 from kwaNonkqubela Clinic, the last two sites being in Alexandria.

**Table 1: Demographic characteristics of participants (N=79)**

Variable	N	%
<b>Gender</b>		
Female	69	87
Male	10	13
<b>Education</b>		
No education	2	3
Primary level (grade 1 to grade 6)	25	32
Senior level (grade 7 to grade 11)	33	42
Matric	15	19
Post-Matric qualification	4	5
<b>Employment</b>		
Yes	21	27
No	58	73
<b>Chronic Illness</b>		
Hypertension only	47	59
Hypertension and diabetes	31	39

Diabetes	1	1
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*N*, Number of participants who completed the demographic questionnaire

Forty-three (54%) of the participants reported that they had other existing medical conditions including HIV/AIDS (25%), asthma (28%), arthritis (25%), and high cholesterol (21%). Only ten (13%) participants reported they had previously been informed that they suffered from a mental disorder.

### Substance and alcohol patterns in the sample

In our study sample (85%) scored between 0–7 on the AUDIT, indicating low risk drinking, 3 association between the VISTAD and a positive AUDIT score. However, participants who screened positively with drug related problems on the DUDIT endorsed the suicide item more often (42% versus 15.6%, Chi sq .033) and irritability (64% versus 28%, Chi sq .014).

### Major Depressive and Anxiety Disorders in the sample

Panic disorder was the most commonly diagnosed mental disorder during our study, followed by post-traumatic stress disorder (PTSD), depression, generalized anxiety disorder (GAD), social phobia and agoraphobia, as shown in Table 2.

**Table 2: Anxiety disorders and depression in hypertension only and hypertension and diabetes**

Comorbid mental disorder	Overall, n (%)	Hypertension and diabetes, n (%)		
		Hypertension only	Hypertension & diabetes	p-value
Depression	24 (33)	14 (30%)	10 (33%)	0.80
Panic disorder	32 (40)	18 (38%)	11 (37%)	1.00
PTSD	27 (33)	14 (30%)	11 (37%)	0.62
Social phobia	8 (10)	6 (13%)	2 (7%)	0.47
Agoraphobia	8 (10)	7 (15%)	0 (0.00%)	0.03*
GAD	14 (17)	7 (15%)	6 (20%)	0.75

\*indicates statistically-significant Fisher exact test

Seventeen percent of the total sample of 81 had been diagnosed with one mental disorder, whilst 25% of the total sample had 2 comorbid mental disorders, 11% had 3 comorbid mental disorders. There were 6 (7%) of the total sample with 4 comorbid mental disorders and only 2 (2%) with 5 comorbid mental disorders. Agoraphobia was likely to coexist with panic disorders with Cohen's kappa of 0.29. Depression and generalized anxiety were likely to coexist with Cohen's kappa of 0.29.

Ten (33%) participants with hypertension and diabetes met diagnostic criteria for depression compared to 14 (30%) participants with hypertension only who met diagnostic criteria for depression (Table 2). A total of 18 (38%) participants with hypertension only met diagnostic criteria for panic disorder, and 11 (37%) with hypertension and diabetes met diagnostic criteria for panic disorder. There was no statistically significant difference in the prevalence of depression or panic disorder between participants with only hypertension and those with hypertension and diabetes. The diagnosis of hypertension only and hypertension comorbid with diabetes was not significantly associated with a diagnosis of PTSD. The diagnosis of hypertension only had a statistically significant association with agoraphobia.

### Quality of Life in the study sample

The internal consistency of the domains was assessed through the Cronbach reliability coefficient. Cronbach's alpha values for psychological health, physical health, social relationships and environment are presented in Table 3.

**Table 3: Quality of life: Descriptive statistics**

	<b>DOM1:Physical health</b>	<b>DOM2: Psychological</b>	<b>DOM3:Social relationships</b>	<b>DOM4: Environment</b>
<b>Mean</b>	12.42	14.17	14.97	12.71
<b>Std. dev.</b>	3.8669	3.4185	3.1289	2.9453
<b>Cronbach alpha</b>	0.82	.80	.60	.79

Cronbach's alpha for internal consistency reliability was shown to be acceptable for different WHOQOL-BREF domains (Table 3). DOM 1, physical health had a low mean score (12.42) indicative of poor physical health suggesting impairments in activities of daily living, low energy and fatigue, pain and discomfort and dependence on medicinal substances and medical aids. Similar to the physical health domain, DOM 4, environment had a low mean score indicative of poor QOL in the environment domain. This suggested poor financial resources, a poor sense of freedom, physical safety and security, home environment, health and social care and a poor physical environment. The social relationships domain, DOM 3, had a higher mean score 14.97 compared to all the domains. This result suggests good personal relationships, social support and sexual activity amongst adults living with hypertension and/or diabetes.

### **Quality of life and the endorsement of Major depressive disorder and/or an Anxiety disorder**

The results show a statistically significant association between depression and quality of life  $p < 0.01$  (Table 4). Panic disorder had a statistically significant association with quality of life, physical domain. Post traumatic stress disorder had a statistically significant association with quality of life and psychological domain.

**Table 4: WHOQOL-BREF scores associated with common mental disorders**

Effect	Physical domain		Psychological domain		Social domain		Environmental domain	
	Mean ( $\pm$ SD)	p-value	Mean ( $\pm$ SD)	p-value	Mean ( $\pm$ SD)	p-value	Mean ( $\pm$ SD)	p-value
<b>Depression</b>								
No (n=55)	13.23 (3.67)	<0.01*	15.77 (2.17)	<0.01*	15.95 (2.60)	<0.01*	13.56 (2.57)	<0.01*
Yes (n=26)	10.73 (3.79)		10.79 (3.13)		12.92 (3.19)		10.92 (2.92)	
<b>Panic disorder</b>								
No (n=49)	13.36 (3.65)	<0.01*	14.27 (3.59)	0.49*	15.02 (3.40)	0.75	13.09 (3.01)	0.15
Yes (n=32)	10.98 (3.80)		14.02 (3.19)		14.92 (2.72)		12.14 (2.72)	
<b>PTSD</b>								
No (n=54)	12.66 (4.20)	0.33	14.91 (3.26)	<0.01*	15.31 (3.26)	0.10	13.04 (3.00)	0.10

Yes (n=27)	11.96 (3.12)		12.69 (3.29)		14.32 (3.22)		12.07 (2.78)	
<b>GAD</b>								
No (n=67)	12.90 (3.85)	<0.01*	14.53 (3.23)	0.05	15.40 (2.83)	0.01*	13.24 (2.86)	<0.01*
Yes (n=14)	10.12 (3.13)		12.48 (3.90)		12.95 (3.79)		10.21 (1.90)	
<b>Agoraphobia</b>								
No (n=73)	12.44 (4.05)	0.63	14.19 (3.55)	0.58	12.65 (2.95)	0.07	12.45 (3.97)	0.63
Yes (n=8)	12.29 (1.59)		14.00 (1.94)		13.31 (1.41)		12.14 (2.88)	
<b>Social phobia</b>								
No (n=73)	12.45 (3.97)	0.62	14.25 (3.52)	0.31	14.98 (3.11)	0.83	12.67 (2.93)	0.45
Yes (n=8)	12.14 (2.88)		13.50 (2.33)		15.00 (3.5)		13.13 (3.26)	

\* indicates a statistically-significant Mann-Whitney test at  $p < 0.05$

PTSD, posttraumatic stress disorder; GAD, generalised anxiety disorder

DOM 1, physical health had a low mean score indicative of poor physical health suggesting impairments in activities of daily living, low energy and fatigue, pain and discomfort and dependence on medicinal substances and medical aids. Similar to DOM 1 (physical health), DOM 4 (environment) had a low mean score indicative of poor QOL in the environment domain. This indicated poor financial resources, a poor sense of freedom, physical safety and security, home environment, health and social care and a poor physical environment. The social relationships domain, DOM 3, had a higher mean score 14.97 compared to all the domains. This result suggests good personal relationships, social support and sexual activity amongst adults living with hypertension and/or diabetes.

### Quality of life and comorbid medical conditions

DOM 1 (physical health) and DOM 4 (environment) have the lowest mean scores in participants living with other co-morbid medical conditions (Table 5). The other medical conditions included HIV/AIDS (25%), asthma (28%), arthritis (25%) and high cholesterol (21%).

**Table 5: Relationship between quality of life scores and the presence of other medical conditions in patients with hypertension and/or diabetes**

WHOQOL-BREF domains	Other medical conditions		p value
	Yes (n=43)	No (n=36)	
Physical	11.26 (3.85)	13.76 (3.57)	<0.01*
Psychological	13.58 (3.49)	14.76 (3.32)	0.09
Social	14.45 (3.28)	15.67 (2.89)	0.18
Environment	12.07 (3.04)	13.50 (2.69)	0.03*

\*indicates a statistically-significant ( $p < 0.05$ ) Mann-Whitney U test

### VISTAD and Quality of life

The minimum score for the VISTAD was 0 and maximum was 10 with a mean of 3.96 and a Std. Deviation of 3.401.

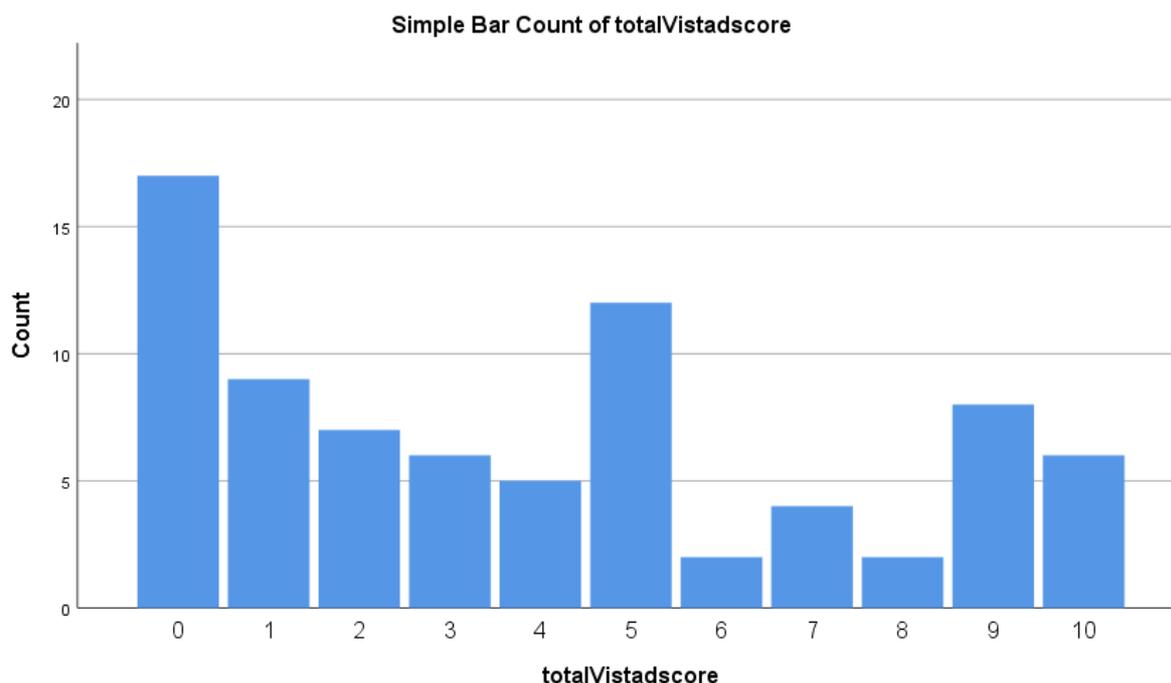
**Figure 1: Simple bar count of total VISTAD score**

Table 6 shows that participants who endorsed VISTAD items had lower mean scores on all domains compared to participants who did not endorse VISTAD items. Table 6 shows that participants who endorsed VISTAD items had poor quality of life compared to participants who did not endorse VISTAD items. Participants who endorsed the sleep disturbance item on the

VISTAD had lower mean scores (Table 6) on the physical, psychological, social and environment domain compared to participants who did not endorse sleep disturbance.

**Table 6: WHOQOL-BREF Domains and VISTAD items**

Item	Physical domain		Psychological domain		Social domain		Environmental domain	
	Mean (±SD)	p-value	Mean (±SD)	p-value	Mean (±SD)	p-value	Mean (±SD)	p-value
<b>Sleep disturbance</b>								
Yes (n=45)	10.71 (3.40)	.0000	12.56 (3.47)	.0000	14.10 (3.12)	.0000	11.66 (3.04)	.0000
No (n=36)	14.55 (3.34)		16.18 (2.00)		16.07 (2.81)		14.02 (2.23)	
<b>Frightened for no reason</b>								
Yes (n=31)	11.07 (3.52)	.013	12.88 (3.78)	.007	14.53 (2.71)	.320	11.98 (3.02)	.078
No (n=50)	13.25 (3.86)		14.97 (2.93)		15.25 (3.35)		13.17 (2.82)	
<b>Sad</b>								
Yes (n=32)	10.83 (3.23)	.002	11.75 (3.59)	.000	13.54 (2.93)	.001	11.48 (2.84)	.002
No (n=49)	13.45 (3.92)		15.75 (2.15)		15.91 (2.91)		13.52 (2.74)	
<b>Frightened when going out on my own</b>								
Yes (n=42)	11.87 (3.83)	.156	13.41 (3.76)	.026	14.34 (2.82)	.038	12.02 (2.70)	.020
No (n=38)	13.11 (3.86)		15.10 (2.76)		15.78 (3.27)		13.55 (3.03)	
<b>Palpitations</b>								
Yes (n=38)	11.27 (3.84)	.008	12.85 (3.82)	.001	14.21 (2.94)	.023	11.85 (2.70)	.009
No (n=42)	13.53 (3.61)		15.44 (2.45)		15.77 (3.10)		13.56 (2.95)	
<b>Loss of appetite</b>								
No (n=21)	10.55 (3.33)	.008	11.90 (4.35)	.000	12.95 (3.07)	.000	11.04 (2.92)	.003
Yes (n=59)	13.14 (3.85)		15.03 (2.59)		15.77 (2.79)		13.35 (2.73)	
<b>Life is not worth living</b>								
Yes (n=16)	10.85 (3.23)	.063	10.87 (3.78)	.000	14.08 (2.79)	.174	11.09 (2.81)	.011
No (n=64)	12.86 (3.93)		15.05 (2.77)		15.27 (3.15)		13.16 (2.85)	
<b>Depression</b>								
Yes (n=27)	10.77	.005	11.72	.000	13.82	.012	11.74	.028

	(3.77)		(3.37)		(3.24)		(3.12)
No (n=53)	13.32		15.48		15.64		13.26
	(3.66)		(2.68)		(2.87)		(2.74)
<b>Irritability</b>							
Yes (n=27)	10.89	.009	11.50	.000	13.92	.022	11.75
	(3.57)		(3.74)		(3.03)		(2.93)
No (n=53)	13.26		15.59		15.59		13.25
	(3.80)		(2.23)		(3.02)		(2.85)
<b>Worrying thoughts constantly go through my mind</b>							
Yes (n=38)							
	11.17	.004	12.64	.000	14.10	.010	12.30
No (n=42)	(3.40)		(3.74)		(3.26)		(2.87)
	13.63		15.63		15.87		13.15
	(3.93)		(2.34)		(2.74)		(2.99)

## VISTAD scores and other comorbid medical conditions

There was no statistically significant association between medical conditions and the VISTAD (Table 7).

**Table 7: Other medical conditions and VISTAD scores**

Medical conditions	VISTAD Score	N	Mean	Std. Dev	Mann-Whitney p
HIV	no	67	3.84	3.401	p=.424
	yes	11	4.73	3.467	
Asthma	no	66	3.83	3.404	p=.439
	yes	12	4.67	3.447	
Arthritis	no	66	3.79	3.422	p=.293
	yes	12	4.92	3.260	
<b>Other medical conditions together</b>	no	42	4.50	3.445	p=.132
	yes	36	3.33	3.286	

## DISCUSSION

We found a prevalence of depression 32% for depression which is lower than previously reported by Alkhatami et al.<sup>6</sup> of 48.7 in a primary health population living with hypertension and/or diabetes. Our findings were consistent with a South African study conducted by

Andersson et al.<sup>43</sup> which found a prevalence of 31% in the South African province where our study was conducted.

In a study sample of 40 patients with hypertension, Rubio-Guerra et al.<sup>44</sup> reported that 23 patients (57%) had depression which is higher than the number reported in our study. A systematic review and meta-analysis by Li et al.<sup>45</sup> reported a summarized depression prevalence of 26.8% in people living with hypertension with prevalence rates ranging from 4.8% to 73.3%. Mahmood et al.<sup>46</sup> reported higher prevalence rate to ours in a cross sectional study with a 40.1% prevalence rate of depression in hypertension.

We found a statistically significant association between the diagnosis of depression and poor QOL. This was observed across the four domains; physical, psychological, social relationships and environment in participants living with hypertension and/or diabetes. This is consistent with findings by Goldney et al.<sup>8</sup> who observed that people living with diabetes comorbid with depression have poor quality of life on all domains compared to those who have diabetes only without depression. Higher quality of life, according to Goldney et al.<sup>8</sup> is experienced by people without diabetes, without depression compared to those with depression and diabetes. Overall, the sample of our study had poor quality of life across domains (physical, psychological, environment) except for the social relationships domain which was found to be higher. This is indicated satisfaction with personal relationships and social support.

Agoraphobia had a statistically significant association with the diagnosis of hypertension, but not hypertension co-morbid with diabetes. Whilst few participants (10%) were diagnosed with agoraphobia, this was similar to 10.4% in an older population previously reported by Ritchie et al.<sup>47</sup> Low prevalence rates of agoraphobia were also reported by the American Psychiatric Association (APA),<sup>48</sup> noting that about 1.7% of adults and adolescents are diagnosed with agoraphobia every year.

Similarly to agoraphobia, 10% of the study participants had a diagnosis of social phobia. Social phobia in adolescents has a prevalence of approximately 9% according to Burstein et al.<sup>49</sup>

According to the APA,<sup>48</sup> the 12-month prevalence rates of social phobia in children and adolescents are comparable to those in adults. Based on this we could argue that the number reported in our study is consistent to with current reports on the prevalence of social phobia. Leichsenring and Leweke reported a higher prevalence rate (13%) in the American population.<sup>50</sup> We found no association between the diagnosis of social phobia and hypertension and/or diabetes. This is consistent with findings made by Edwards and Mezuk who observed no evidence between a history of anxiety disorders, including social phobia and Type 2 diabetes.<sup>51</sup> Anxiety and depression, as reported by Edwards and Mezuk, have different biological mechanisms which may explain the difference in the relationship between these disorders (anxiety disorders and depression) and diabetes.<sup>51</sup>

Panic disorder was the most observed diagnosis in this study sample with 32 (40%) participants diagnosed. Research evidence shows that panic disorder is also highly prevalent in other medical conditions. Reported rates include 40% in tinnitus<sup>52</sup> 29% in HIV,<sup>53</sup> and 25% in chest pain patients.<sup>54</sup> In hypertension, panic attacks and panic disorder are extremely common in patients receiving treatment in hospital settings.<sup>55</sup> Li et al. reported a prevalence rate of panic disorder of 26.8% in patients diagnosed with hypertension.<sup>45</sup> We found no statistically significant association between these conditions and hypertension in our study. This is consistent with previous research.<sup>55</sup>

Post-traumatic stress disorder was the second most observed anxiety disorder in this study. Posttraumatic stress disorder, according to Seedat,<sup>56</sup> is among the most prevalent compared to other anxiety disorders in terms of lifetime and 12-month prevalence rates documented in epidemiological studies.<sup>56</sup> The authors recognize that people in South Africa are exposed to high levels of violence,<sup>57</sup> which contributes to the development of PTSD. Balint et al. found a 9% prevalence for PTSD in 70% of hypertensive patients who have had at least one traumatic event.<sup>58</sup> In primary care, studies have recounted a prevalence of PTSD ranging from 2.0%–39.1% in hypertensive patients.<sup>59</sup> Also there is an increased prevalence of PTSD in Type 2

diabetes; and the relationship between PTSD and Type 2 diabetes remains significant when depression, depressive mood or exhaustion, anxiety, and somatization have been adjusted for, and also controlling for socio-demographic characteristics.<sup>60</sup> The relationship between hypertension and/or diabetes and PTSD was not statistically significant in our study.

Generalized anxiety disorder (GAD) was observed in 14 (17%) of the study participants. Grigsby et al. reported that GAD was present in 14% of their study sample of people living with diabetes,<sup>61</sup> and Whitworth et al. reported a current prevalence of 6.5% and a lifetime prevalence of 23%.<sup>48</sup> Revicki et al.<sup>62</sup> reported that GAD is highly prevalent but under-diagnosed. Generalised anxiety disorder requires early identification and treatment in order to reduce the extent of impairment and disability.<sup>63</sup> Consistent with our findings, previous studies found no statistically significant association between GAD symptoms and hypertension.<sup>64</sup>

People living with hypertension and/or diabetes comorbid with anxiety disorders had poor quality of life compared to participants without anxiety disorders. There was a statistically significant association with PTSD and impairment on the psychological domain. This indicates poor satisfaction with bodily appearance, presence of negative feelings and low self-esteem. Furthermore, this could suggest impairments with ability to think, poor memory and concentration. Previous studies have established that people living with hypertension and/or diabetes have an increased prevalence of psychological health problems.<sup>65,25,63,66</sup> Different factors can influence the results on the psychological domain. These factors include trauma and violence,<sup>57</sup> post-traumatic stress disorder,<sup>67</sup> and the generally high prevalence of mental disorders in South Africa. Also, environmental or social factors in poverty stricken communities might increase psychological distress.<sup>66</sup> Generalized anxiety disorder had significant association with poor physical, social relationships and environment domain.

Chronic medical conditions such as type 2 diabetes are known to influence, the social and psychological domain as a result of the nature of the disease and its associated complications.

This imposes demands on patients and families which can be burdensome.<sup>68</sup> A study with an elderly population found low scores on physical, psychological and environment domain compared to participants with diabetes.<sup>69</sup> The relationship between hypertension, diabetes and quality of life was not statistically significant in the study by Kumar et al.<sup>69</sup> Some of the research findings using the on QOL amongst people living with hypertension has been conflicting. In our study, we found that overall, the study participants had higher satisfaction in the social relationships domain compared to physical, psychological and environment domain; whereas, Oza et al.<sup>16</sup> reported the social domain to be the lowest with hypertension. Consistent with previous some research, people living with hypertension and/or diabetes have poor quality life on the physical<sup>70,71</sup> psychological<sup>70</sup> and environment domains.<sup>72</sup> Consistent with the findings on M.I.N.I based diagnosis of depression and anxiety disorders, participants who endorsed depression and anxiety items on the VISTAD reported poor QOL compared to participants who did not endorse any depression or anxiety disorder items. This finding showed that the VISTAD has significant correlation with the WHOQOL-BREF which shows that the VISTAD has acceptable psychometric properties.

A relatively small number of participants in our study reported possible dependence and harmful or hazardous levels of drinking. The relatively low levels of alcohol use found in our study are inconsistent with findings of previous studies in other countries and South Africa which reports much higher levels.<sup>73,74</sup> A South African study conducted by Bhana, Rathod, Selohiwe, Kathree, and Petersen<sup>75</sup> found high levels of abstinence from alcohol amongst patients with diabetes (65%) and this is consistent with observations of our study. Whilst alcohol and drug use seemed to be relatively low, more than 15% admitted use of drugs or problematic use of alcohol, future studies can further investigate in larger samples, the patterns of alcohol and drug use and the association with hypertension and/or diabetes and depression and anxiety disorders.

We found a statistically significant association between two VISTAD items, irritability and

suicidal ideation and drug related problems. The additional eight VISTAD items had no association with alcohol and/ drug related problems. From this finding, we can conclude that the VISTAD only screens for depression and anxiety disorders symptoms and not drug and alcohol related problems.

Our findings of no significant association between anxiety disorders and hypertension are consistent with other reports.<sup>76,77</sup> However, it is worth noting the conflicting findings on the association between hypertension and anxiety disorders.<sup>78</sup> Rigorous data on larger samples are needed in order to validate the growing body of research reporting on this association.<sup>79,80</sup>

## **STUDY STRENGTHS AND LIMITATIONS**

We used a valid and reliable diagnostic tool, the M.I.N.I to diagnose and report the number of people living with depression and anxiety disorders rather than screening tools only which might over-estimate the prevalence of depression.<sup>81</sup> However, the M.I.N.I has not been specifically validated for use at primary care with people living with hypertension and/or diabetes. It is also important to acknowledge that patients could have difficulty in distinguishing between hypoglycemia and anxiety symptoms such as dizziness, shakiness, lack of coordination and heart palpitations,<sup>82</sup> which might lead to over-reporting of anxiety, perhaps explaining the high number of participants meeting criteria for panic disorder. The data presented in this study pertains to the diagnosis of hypertension and/or diabetes, and the type of diabetes is not differentiated. Future studies could differentiate prevalence rates according to the type of diabetes and have two separate groups, diabetes only and hypertension only in order to compare prevalence of depression in the conditions. As a result of the small sample, findings of this study cannot be generalized to individuals attending primary health care. Furthermore, with reference to race, gender and level of education the sample of our study was not a nationally representative sample of primary health care patients living with hypertension and/or diabetes.

It is worth noting that Eastern Cape is a predominantly black province and that the sample is fairly representative of this region.

## **CONCLUSION**

Depression and anxiety disorders influence quality of life of people living with hypertension and anxiety disorders. Whilst alcohol and drug use seemed to be relatively low, more than 15% admitted use of drugs or problematic use of alcohol. The findings of this study underscore the need to have mental health care integrated into primary health for people living with hypertension and/or diabetes.

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## **CONFLICT OF INTEREST**

The authors declare that there is no conflict of interest regarding the publication of this paper.

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## **CHAPTER FOUR**

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# The validation of the visual screening tool for anxiety disorders and depression in hypertension and/or diabetes

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**Background:** Depression and anxiety disorders remain poorly detected at primary health care, particularly in patients with hypertension and/or diabetes. A visual screening tool for anxiety disorders and depression (VISTAD) has been developed, but not validated.

**Aim:** To validate the VISTAD in primary health care participants diagnosed with hypertension and/or diabetes.

**Setting:** Participants were recruited from five primary health care centres in the Eastern Cape, South Africa (urban, peri-urban and rural).

**Methods:** The study used a cross-sectional study design to validate the VISTAD. The VISTAD was validated against the International Neuropsychiatric Interview (M.I.N.I) using field testing. A demographic questionnaire was used to collect data on socio-economic variables.

**Results:** Sixty-nine (87%) females and 10 (13%) males with a mean age of 49 (SD 8.6844) participated in the study. Fifty black people (63%), 16 mixed race people (20%) and 13 white people (16%) participated in the study. The majority of the participants (77%) did not complete high school. The area under curve score (AUC) for the VISTAD in screening for depression was 0.91, and for anxiety disorders, 0.87 post-traumatic stress disorder, 0.87 panic disorder, 0.85 social phobia, 0.88 agoraphobia, and 0.83 generalised anxiety disorder revealing acceptable psychometric properties.

**Conclusion:** The use of the VISTAD as a screening tool at primary health care in people living with hypertension and/or diabetes is recommended. The VISTAD could, therefore, play a key role in the prevention and early treatment of individuals diagnosed with hypertension and/or diabetes across cultures and levels of education. The VISTAD needs to be validated in a large population representative of primary care patients diagnosed with hypertension and/or diabetes.

## Background

Current literature demonstrates that hypertension and diabetes have emerged as a major medical and public burden globally.<sup>1,2,3,4</sup> South Africa is burdened with a high prevalence of hypertension and diabetes. There are 2.3 million people living with diabetes in South Africa,<sup>5</sup> and 30% of the adult population is living with hypertension.<sup>6</sup> Furthermore, hypertension and diabetes account for 17 million visits to health facilities in South Africa every year.<sup>1</sup>

The diabetes and hypertension burden is further complicated by the increasingly high comorbidity with depression and anxiety disorders. Kumar and Clark<sup>7</sup> argue that chronic diseases have psychological sequelae; however, these remain largely undetected and untreated at primary health care.<sup>8,9,10</sup> Patients may be aware of their emotional state; however, they may be unable to describe accurately their subjective experience, according to Aitken.<sup>11</sup> In addition, inadequate levels of mental health literacy, for both health care workers<sup>12</sup> and patients, have been well established in research.<sup>13</sup>

When clinicians do attempt to screen for mental disorders in patients with hypertension and/or diabetes, primary health care facilities are faced with barriers such as insufficient human and material resources, lack of assessment instruments that can be appropriately applied to the diverse range of cultural and language groupings in South Africa, and communication difficulties which lead to misunderstandings, misdiagnosis and/or inappropriate treatment. In addition to the above-mentioned barriers, pencil and paper tests are often not available or have to be read aloud

to illiterate patients.<sup>14</sup> Availability of appropriate tools at primary health care could therefore contribute to the quality of detection and management of mental disorders, particularly in developing countries. Visual screening tools for depression and anxiety disorders could possibly circumvent the challenges posed by cultural, language, educational and time factors. This has been shown by Akena et al.<sup>15</sup> who developed a visual screening tool for depression in patients living with HIV and/or AIDS in Uganda. However, the screening tool developed by Akena et al.<sup>15</sup> does not screen for anxiety disorders. Screening for depression, according to Katon et al.,<sup>16</sup> should also include anxiety disorders as these often coexist in patients living with chronic physical conditions.

The use of pictures in aiding patients to describe emotions and thoughts has been well established in psychology. Psychological tests, referred to as projectives, such as the thematic apperception test (TAT),<sup>17</sup> make use of drawings in order to allow access to unconscious thoughts, emotional life and internal dynamics – revealing hidden materials that clients are unable to disclose or unwilling to disclose. Ogle, Koen and Niehaus developed a visual screening tool for anxiety disorders and depression (VISTAD) using drawings based on the hospital anxiety and depression scale (HADS). The visual screening tool is referred to as the VISTAD. It includes depression items such as sleep disturbance, feeling miserable and sad, appetite and feeling life is not worth living, as well as anxiety items such as feeling frightened or having panic feelings for no reason, feeling frightened when going out of the house alone, getting palpitations or sensations ‘butterflies’ in stomach or chest, more irritable than usual and worrying thoughts. The VISTAD, however, has not been validated for use in primary health care.

The aim of the study was to validate the VISTAD as a screening tool for use in primary health care in individuals diagnosed with hypertension and/or diabetes and as a tool that can be used effectively in a time- and resource-constrained environment and with people with low levels of education.

## Methods

### Study design

The study used a cross-sectional study design for validating the newly developed VISTAD.

### Setting

The study was conducted in five primary health care centres in the Eastern Cape, South Africa. These primary health care centres provide health care services to two urban areas, KwaMagxaki, a predominantly black suburb, and Algoa Park, a mixed suburb, mixed race and white population, in Port Elizabeth; one peri-urban area in Uitenhage, predominantly black population; and two rural communities, KwaNonqubela, a black community, and Wentzel Park, a mixed race community in Alexandria, Eastern Cape.

### Sampling strategy

Purposive sampling was utilised to recruit participants who were able to provide informed consent. Individuals were recruited while they were at the settings for their routine scheduled visit. Individuals between the ages of 18 and 60, diagnosed with diabetes and/or hypertension, were eligible for the study. Individuals known to have visual and hearing impairments, and intellectual disability were excluded from the study.

The principal researcher explained the purpose of the study and requested individuals who were interested in participating in the study to indicate their interest. Those who indicated an interest or wanted to get more information were interviewed in a private setting and provided with more details on the study.

### Data collection

A demographic questionnaire was utilised to gather information about gender, age, race, marital status, level of education, employment status, family income and medical conditions. A short structured diagnostic interview, the International Neuropsychiatric Interview (M.I.N.I.),<sup>18</sup> was used as a gold standard in the validation of the VISTAD. It covers 17 Axis I disorders that include mood, anxiety, substance use, psychotic and eating disorders, and it also has a suicidality module and one Axis-II disorder, antisocial personality disorder.<sup>18</sup> Sheehan et al.<sup>18</sup> found the M.I.N.I. to be a reliable and valid diagnostic tool, and it has been used in South African studies.<sup>19,20,21,22</sup> The development of the VISTAD is discussed in detail in Ogle, Koen and Niehaus.<sup>23</sup> In the VISTAD, a score of 1 is allocated when a participant endorses an abnormal state drawing and 0 when none of the abnormal state symptoms are endorsed. The maximum score that could be obtained on the VISTAD is 10.

### Data analysis

Descriptive statistics were used to describe demographic data. The M.I.N.I. was used to categorise cases and non-cases of depression (major depressive episode) and anxiety disorders, that is, agoraphobia, generalised anxiety disorder (GAD), panic disorder, post-traumatic stress disorder (PTSD) and social phobia, excluding obsessive-compulsive disorder. The impact of education, employment and gender on the performance of VISTAD was investigated. Coefficient of correlation (coef.) indicated the correlation between the above-mentioned variables. The sensitivity and specificity and likelihood ratios (LR) were estimated. Sensitivity and specificity was calculated based on leave-one-out cross validation. Cut-off scores were informed by high specificity scores and moderate sensitivity scores. With a high specificity, the truly positives represent the mental disorder being screened for and not another condition, such as diabetes or hypertension.

The plot of sensitivity versus specificity is referred to as the receiver operating characteristics (ROC).<sup>24</sup> The area under the

curve (AUC) which is an effective measure of diagnostic test accuracy<sup>24</sup> was used for interpretations of the data. An AUC value of 0.50–0.70 is considered low accuracy, 0.70–0.90 is considered moderate accuracy and 0.90 is considered high accuracy.<sup>25</sup> Linear discriminant analysis was used to predict the disorder outcomes with the VISTAD drawing outcomes as predictors. All data analyses were done with STATA, version 14.

## Ethical considerations

Ethical approval was granted by the University of Stellenbosch's Faculty of Medicine and Health Sciences Human Research Ethics Committee (Reference number: S14/11/262). Permission to conduct the study at the primary care centres was obtained from the Eastern Cape Department of Health, South Africa

## Results

### Demographics

Eighty-one participants from primary health care participated in the validation of the VISTAD. All the participants consented and participated in this study. However, out of the 81 participants, one declined to continue with completing the interview reporting that the VISTAD depicted his life, and it was painful to look at the images.

In this study, we used demographic data of 79 participants as there was missing information from two participants. The majority of the participants were females, 69 (87%), with 10 (13%) males. Race distribution on the basis of gender showed that there were 43 black females, 15 mixed race females and 11 white females, and seven black males, two white males and one mixed race male. The mean age of the participants was 49, with standard deviation 8.6844 and minimum age 22 and maximum 60. Socio-demographic variables and related factors are set out in Table 1.

### Accuracy of the visual screening tool for anxiety disorders and depression

The AUC determined the accuracy of the VISTAD. The AUC in screening for depression is shown in Figure 1, PTSD in Figure 2, panic disorder in Figure 3, GAD in Figure 4, social phobia in Figure 5 and agoraphobia in Figure 6. The AUC score for depression shows a high accuracy of 0.91.

The best cut-off scores were based on high specificity and moderate sensitivity. At a cut-off score of 6, the specificity was 90.91, and sensitivity was 72.00%, with 85% correctly classified cases. The specificity was 90.91 and sensitivity was 60.00%, with 81.25% correctly classified cases at a cut-off score of 7.

The area under curve for PTSD was 0.87. At a cut-off point of 6 for PTSD, there were 68% correctly classified cases with a specificity of 72.22% and a sensitivity of 37%. Similar to PTSD, the area under curve for panic disorder was 0.87,

**TABLE 1:** Demographic and clinical characteristics of participants (*N* = 79).

Variables	<i>n</i>	(%)
<b>Gender</b>		
Female	69	87
Male	10	13
<b>Language</b>		
isiXhosa	48	61
Afrikaans	29	37
English	1	1
Shona	1	1
<b>Race</b>		
Black people	50	63
Mixed race	16	20
White people	13	17
<b>Education</b>		
No education	2	3
Primary level of education (Grades 1–6)	25	32
Senior level of education (Grades 7–11)	33	42
Matric (Grade 12)	15	19
Post-matric qualification	4	5
<b>Employment</b>		
Yes	21	27
No	58	73
<b>Hypertension or diabetes</b>		
Hypertension only	47	59
Diabetes only	1	1
Hypertension and diabetes	31	39
<b>Other medical conditions</b>		
Yes	43	54
No	36	46
<b>Existing mental disorder</b>		
Yes	10	13
No	69	87
<b>M.I.N.I. diagnosis</b>		
Depression	26	32
Panic disorder	32	40
Agoraphobia	8	10
Social phobia	8	10
Post-traumatic stress disorder	27	33
Generalised anxiety disorder	14	17

which indicated moderate accuracy. The specificity of the VISTAD at a cut-off point of 6 was 81.25%, with a sensitivity of 43.75%.

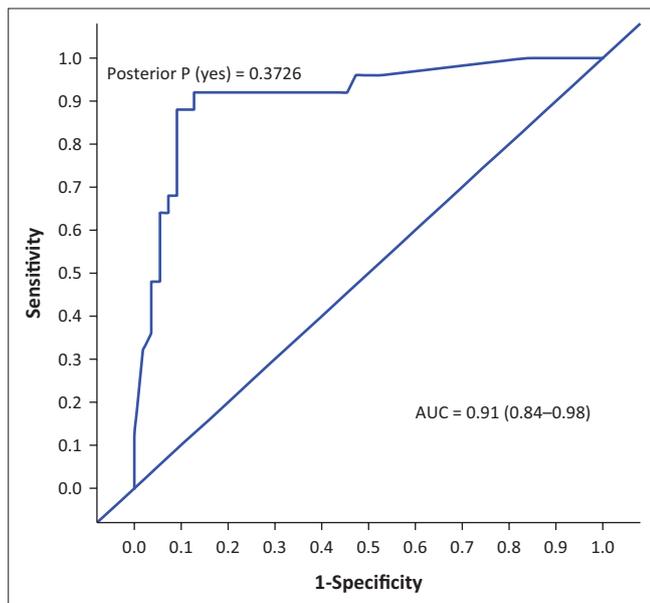
Agoraphobia had a specificity of 73.61%. Social phobia had a specificity of 72.22% at a cut-off score of 6. Generalised anxiety disorder had a specificity of 74.63%, with 70% correctly classified cases.

Fundamental to the validation of the VISTAD is the investigation of whether education levels, socio-economic status and gender have an impact on the performance of the VISTAD. Table 2 presents the impact of level of education, gender and employment status on the performance of the VISTAD.

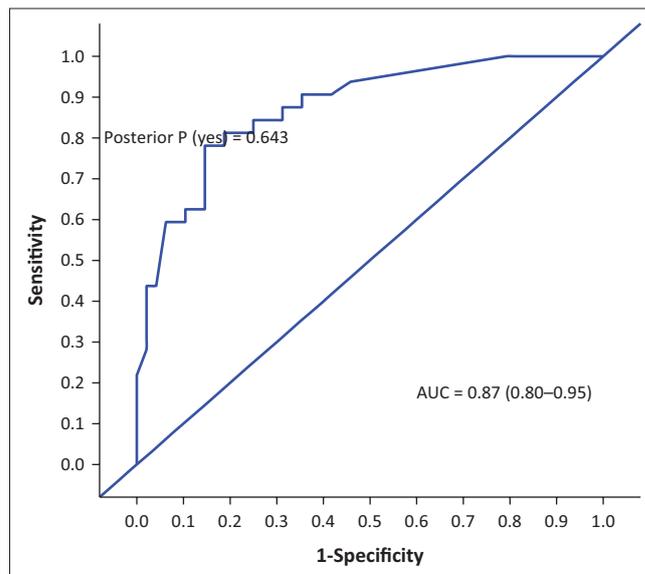
## Discussion

### Findings

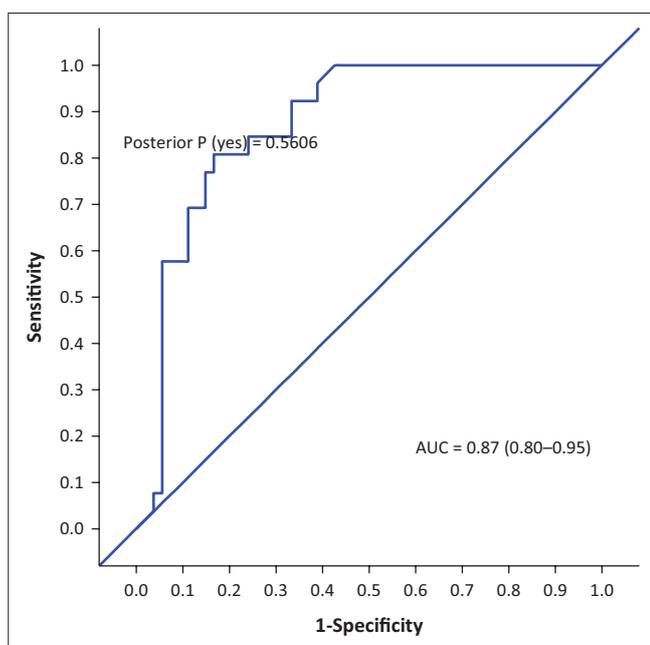
In this study, we validated the VISTAD against the M.I.N.I. at primary health care in participants diagnosed with hypertension and/or diabetes. The VISTAD demonstrated



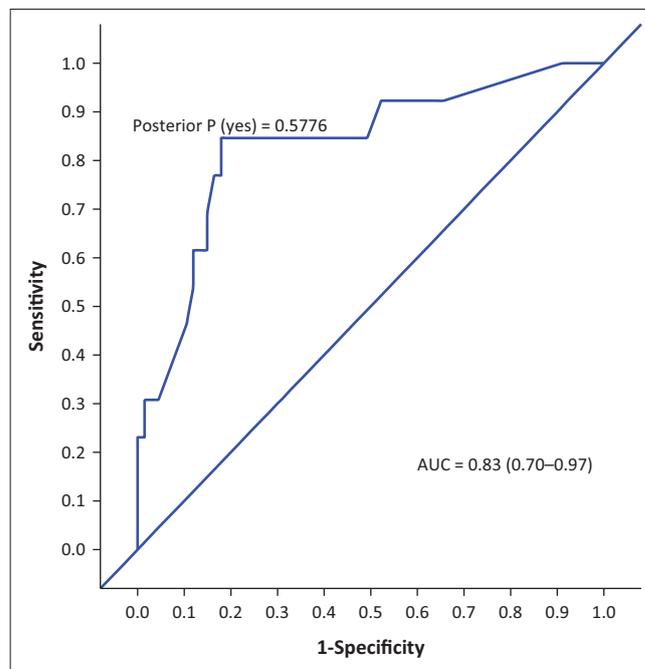
**FIGURE 1:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for depression.



**FIGURE 3:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for panic disorder.



**FIGURE 2:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for post-traumatic stress disorder.

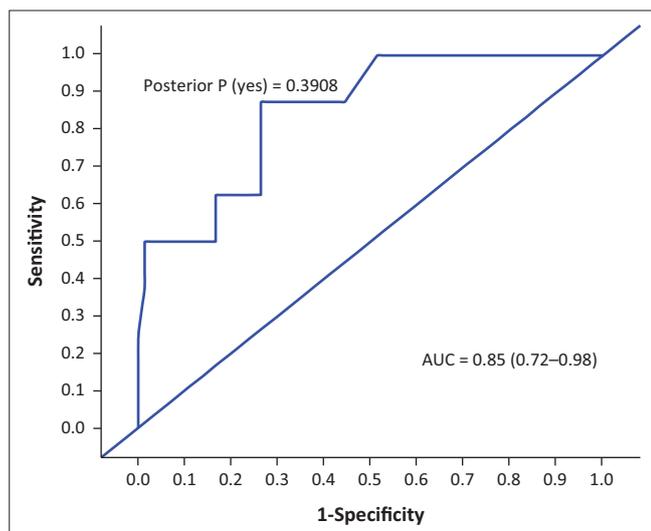


**FIGURE 4:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for generalised anxiety disorder.

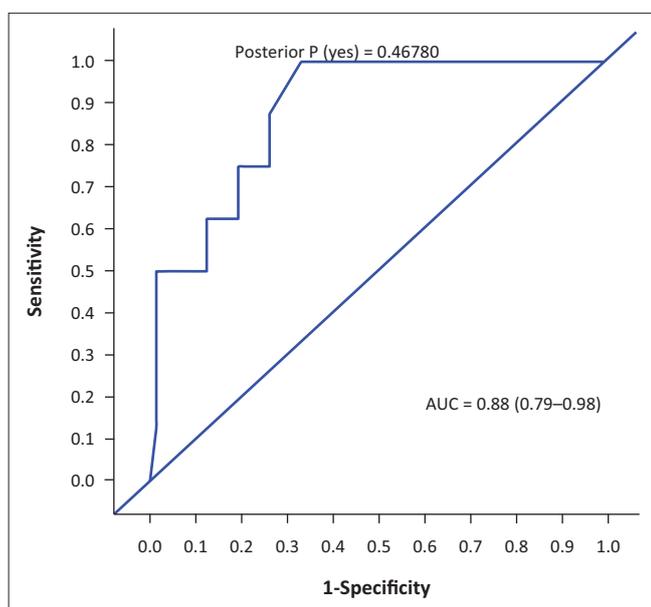
high accuracy in detecting depression in participants with hypertension and/or diabetes. The AUC of the VSTAD was 0.91 in screening for depression. At a cut-off score of 6, the VISTAD had satisfactory accuracy in classifying cases. This is similar to that of the HADS which the VISTAD is based on. At a cut-off score of 7, the HADS depression subscale provided the best balance between a sensitivity of 0.86 and a specificity of 0.81 in cancer patients.<sup>26</sup> In our study, the best balance was at a cut-off score of 6 with a sensitivity of 0.72 and a specificity of 0.91, with 85% of the cases classified correctly. The accuracy of the VISTAD is also similar to that of other widely used traditional screening tools, such as the Patient Health Questionnaire (PHQ), with an AUC of 0.88 at a higher cut-off score in patients with type II diabetes and/or coronary heart

disease in primary care,<sup>27</sup> and the Kessler Scale (K10) for either anxiety or depression<sup>28</sup> and CES-D, K-10 and PHQ-9 and with AUC ranging from 0.82 to 0.96<sup>15</sup> in people living with HIV.

The VISTAD had a higher AUC score compared to the recently validated WHO-5 for use in screening for depression in adults with diabetes. The AUC scores for WHO-5 in the validation study by Halliday et al.<sup>29</sup> ranged between 0.85 and 0.88, which demonstrated that the WHO-5 has moderate accuracy in screening for depression. This demonstrates that the VISTAD is a valuable tool for detecting depression. The optimal cut-off score chosen for depression was 6 in this study. This is in line with the current practice of selecting higher cut-off scores to indicate the presence of depression.<sup>28,29</sup> Similar to screening for



**FIGURE 5:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for social phobia.



**FIGURE 6:** Receiver operating curves of the visual screening tool for anxiety disorders and depression for agoraphobia.

depression, the optimal cut-off score chosen for anxiety disorders was 6. The AUC for anxiety disorders was in the moderate range. This indicates that the accuracy of the VISTAD was better for depression than for anxiety. This is consistent with findings made in the meta-analysis conducted by Vodemaier and Millman<sup>26</sup> on other screening tools. Previous research has also established a similar pattern. For example, GAD 7 showed lower sensitivity and specificity levels when compared to screening tools for depression.<sup>28</sup> Makanjuola et al.<sup>30</sup> also reported lower AUC values in Nigeria for K-6 and the General Health Questionnaire (GHQ-12). K-6 and GHQ-12 are sensitive and specific screening tools widely used and recommended for use in the screening for depression and/or anxiety disorders in primary health care and community samples.

Newly developed screening tools have also been recommended for use in patients with chronic medical

**TABLE 2:** Impact of education, gender and employment status on the performance of the visual screening tool for anxiety disorders and depression.

Variable	Coef.	SE	T	p >  t	95% CI
<b>Level of education</b>					
Primary	-0.7505694	3.557147	-0.21	0.833	-7.841612–6.340473
Senior	-0.6239653	3.507459	-0.18	0.859	-7.615957–6.368026
Matric	-2.326809	3.619307	-0.64	0.522	-9.541764–4.888147
Post-matric	0.0663401	4.089943	0.02	0.987	-8.086812–8.219493
<b>Gender</b>					
Male	-3.715155	1.795807	-2.07	0.042	-7.295031– -0.1352794
<b>Employment</b>					
Yes	0.4993359	1.26012	0.40	0.693	-2.012668–3.01134
_cons	4.808826	3.425357	1.40	0.165	-2.019499–11.63715
/sigma	4.344278	0.4488455			3.449521–5.239035

CI, confidence interval; SE, standard error; coef., coefficient of correlation; cons, coefficient estimate; sigma, standard deviation.

conditions. A Ugandan study recommended the use of a visual screening tool for depression.<sup>15</sup> This was based on its accuracy in detecting depression in people living with HIV. However, a study by Puertas<sup>31</sup> did not recommend the use of visual screening tools as it found the FACES test to have low accuracy. The FACES test, according to Puertas, is a visual analogue scale representation of mood, consisting of seven graded faces from happiest mood to saddest mood. Akena<sup>15</sup> argues that screening tools, such as the FACES test, have often depended on a single facial picture depicting emotions ranging from a happy face to an extremely sad face. Participants with lower literacy levels struggle to comprehend the FACES screening tool according to Puertas<sup>31</sup> Previous research has established that education has an impact on people's ability to comprehend and complete screening tools.<sup>32,33</sup> Some, according to Snaith,<sup>34</sup> are ashamed and pretend to answer questions and respond in a haphazard manner. This study demonstrated that education had no impact on the participants' ability to comprehend and complete the VISTAD. The findings on the education and performance of the VISTAD are consistent with previous research by Akena et al.<sup>15</sup> Furthermore, the socio-economic status had no impact on the participants' ability to understand and complete the VISTAD. The majority of participants in this study were of low socio-economic status.

Based on the M.I.N.I, we noted a high prevalence of common mental disorders in this study. For example, depression had a prevalence of 32%. This is consistent with the findings of Jacob and Kostev's study,<sup>35</sup> which reported a prevalence of 33.7% in women and 26.8% in men diagnosed with diabetes. Cols-Sagarra et al.<sup>36</sup> reported a higher prevalence of 43.4% in women with diabetes at primary health care. A prevalence of 31.4% was reported in a study conducted in rural and urban parts of the Eastern Cape, South Africa,<sup>37</sup> and this finding is consistent with the prevalence observed in our study.

Anxiety disorders such as panic disorder and PTSD had a high prevalence, with panic disorder at 40% and PTSD at 33%. Other studies have found a significantly higher prevalence of panic disorder in hypertensive patients.<sup>38</sup> Also, in primary care, studies have observed a prevalence of PTSD ranging from 2.0% to 39.1% in hypertensive patients.<sup>39</sup> Post-traumatic stress disorder, according to Seedat<sup>40</sup> is among the

most prevalent compared to other anxiety disorders in terms of lifetime and 12-month prevalence rates documented in epidemiological studies. The number of participants who had a positive diagnosis of a common mental disorder was high. This observation is consistent with previous research findings.<sup>39,41,42</sup> Data on larger samples are needed to determine the prevalence of depression and anxiety disorders in primary care patients with hypertension and/or diabetes.

## Strengths and limitations

This is the first study to develop and validate a visual screening tool for both depression and anxiety disorders in primary health care participants diagnosed with hypertension and/or diabetes in South Africa. Furthermore, the use of the M.I.N.I in the study was not limited to the depression module, and the anxiety disorder module was also administered, except for obsessive-compulsive disorder module. The administration of the M.I.N.I depression module only might artificially inflate the extent of the correlations as some participants with depression might have been better diagnosed with another disorder, such as anxiety disorders.<sup>15</sup> Also, this could lead to a false accuracy of the visual screening tool. The strength of the study was enhanced by the inclusion of five different primary health care sites, which serve urban, peri-urban and rural population.

Because of the small size of the sample, we cannot generalise the findings of the study to all individuals attending primary health care. Thus, future research is needed to validate the VISTAD in a large primary health care population. Furthermore, the use of the VISTAD in primary health care with speech impairments and intellectual impairments needs further investigation. A further limitation is that this study was informed by the DSM-IV nosology. For example, PTSD is no longer described as an anxiety disorder in the current DSM-V, but as a trauma- and stressor-related disorder.

## Conclusion

The visual screening tool is referred to as the VISTAD. The VISTAD is accurate in detecting depression and anxiety disorders in primary health care participants diagnosed with diabetes and/or hypertension. The use of the VISTAD is recommended as a screening tool for depression and anxiety disorders at primary care level in patients with hypertension and/or diabetes. However, the VISTAD needs to be validated in a large population of primary care patients diagnosed with hypertension and/or diabetes.

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## Competing interests

The authors declare that they have no conflicts of interest to disclose. Neither personal nor financial relationship may have inappropriately influenced them in writing this article.

## Authors' contributions

This article is produced from research that will be submitted for a PhD in Psychiatry. Z.O. is the principal researcher. Z.O. collected data and produced the first draft of the article. L.K. is the research supervisor and contributed to the article review. D.J.H.N. is the co-supervisor and contributed to the article review.

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Chapter four described the validation of the visual screening tool for anxiety disorders and depression (VISTAD) in primary care patients living with hypertension and/or diabetes. This section presents additional data on the validation of the VISTAD.

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## The validation of the visual screening tool for anxiety disorders and depression in hypertension and/or diabetes

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### ABSTRACT

**Background:** Depression and anxiety disorders remain poorly detected at primary health care, particularly in patients with hypertension and/or diabetes. A visual screening tool for anxiety disorders and depression (VISTAD) has been developed, however not validated.

**Aim:** To validate the VISTAD in primary health care participants diagnosed with hypertension and/or diabetes.

**Setting:** Participants were recruited from five primary health care centres in the Eastern Cape, South Africa (urban, peri-urban and rural).

**Methods:** The study used a cross-sectional study design to validate the VISTAD. The VISTAD was validated against the MINI International Neuropsychiatric Interview (M.I.N.I) using field testing. A demographic questionnaire was used to collect data on socio-economic variables.

**Results:** Sixty-nine (87%) females and ten (13%) males with a mean age of 49 (SD 8.6844) participated in the study. Fifty black people (63%), 16 mixed ancestry people (20%) and 13 white people (16%) participated in the study. The majority of the participants (77%) did not complete high school. The area under curve score (AUC) for the VISTAD in screening for depression was 0.91, and for anxiety disorders, 0.87 post-traumatic stress disorder, 0.87 panic

disorder, 0.85 social phobia, 0.88 agoraphobia, and 0.83 generalised anxiety disorder revealing acceptable psychometric properties.

**Conclusion:** The use of the VISTAD as a screening tool at primary health care in people living with hypertension and/or diabetes is recommended. The VISTAD could therefore play a key role in the prevention and early treatment of individuals diagnosed with hypertension and/or diabetes across cultures and levels of education. The VISTAD needs to be validated in a large population representative of primary care patients diagnosed with hypertension and/or diabetes.

**Keywords:** Screening; Visual Screening Tool; Depression; Anxiety; Hypertension; Diabetes

## **BACKGROUND**

Current literature demonstrates that hypertension and diabetes have emerged as a major medical and public burden globally.<sup>1-4</sup> South Africa is burdened with a high prevalence of hypertension and diabetes. There are 2.3 million people living with diabetes in South Africa,<sup>5</sup> and 30% of the adult population is living with hypertension.<sup>6</sup> Furthermore, hypertension and diabetes account for 17 million visits to health facilities in South Africa every year.<sup>1</sup>

The diabetes and hypertension burden is further complicated by the increasingly high co-morbidity with depression and anxiety disorders. Kumar and Clark<sup>7</sup> argue that chronic diseases have psychological sequelae; however, these remain largely undetected and untreated at primary health care.<sup>8-10</sup> Patients may be aware of their emotional state; however, they may be unable to describe accurately their subjective experience, according to Aitken.<sup>11</sup> In addition, inadequate levels of mental health literacy, for both health care workers<sup>12</sup> and patients, have been well established in research.<sup>13</sup>

When clinicians do attempt to screen for mental disorders in patients with hypertension and/or diabetes, primary health care facilities are faced with barriers such as insufficient human and

material resources, lack of assessment instruments that can be appropriately applied to the diverse range of cultural and language groupings in South Africa and communication difficulties which lead to misunderstandings, misdiagnosis and/or inappropriate treatment. In addition to the above-mentioned barriers, pencil and paper tests are often not available or have to be read aloud to illiterate patients.<sup>14</sup> Availability of simple, accurate and appropriate tools at primary health care could therefore contribute to the quality of detection and management of mental disorders, particularly in developing countries. Visual screening tools for depression and anxiety disorders could possibly circumvent the challenges posed by cultural, language, educational and time factors. This has been shown by Akena et al.<sup>15</sup> who developed a simple visual screening tool for depression in patients living with HIV and AIDS in Uganda that can also be used by non specialists. However, the screening tool developed by Akena et al.<sup>15</sup> does not screen for anxiety disorders. Screening for depression, according to Katon et al.,<sup>16</sup> should also include anxiety disorders as these often coexist in patients living with chronic physical conditions.

The use of pictures in aiding patients to describe emotions and thoughts has been well established in psychology. Psychological tests, referred to as projectives, such as the thematic apperception test (TAT),<sup>17</sup> make use of drawings in order to allow access to unconscious thoughts, emotional life and internal dynamics – revealing hidden materials that clients are unable to disclose or unwilling to disclose. Ogle, Koen and Niehaus<sup>18</sup> developed a visual screening tool for anxiety disorders and depression (VISTAD) using drawings based on the Hospital Anxiety and Depression Scale (HADS). The visual screening tool is referred to as the VISTAD. It includes depression items such as sleep disturbance, feeling miserable and sad, appetite and feeling life is not worth living, as well as anxiety items such as feeling frightened or having panic feelings for no reason, feeling frightened when going out of the house on my own, getting palpitations or sensations ‘butterflies’ in stomach or chest, irritable than usual and

worrying thoughts. The VISTAD, however, has not been validated for use in primary health care.

The aim of the study was to validate the VISTAD as a screening tool for use in primary health care in individuals diagnosed with hypertension and/or diabetes and as a tool that can be used effectively in a time- and resource-constrained environment and with people with low levels of education.

## **METHODS**

### **Study design**

The study used a cross-sectional study design for validating the newly developed VISTAD.

### **Setting**

The study was conducted in five primary health care centres in the Eastern Cape, South Africa. These primary health care centres provide health care services to two urban areas, KwaMagxaki, a predominantly black suburb, and Algoa Park, a mixed suburb, mixed race and white population, in Port Elizabeth; one peri-urban area in Uitenhage, predominantly black population; and two rural communities, KwaNonqubela, a black community, and Wentzel Park, a mixed race community in Alexandria, Eastern Cape.

### **Sampling strategy**

Purposive sampling was utilised to recruit participants who were able to provide informed consent. Individuals were recruited while they were at the settings for their routine scheduled visit. Individuals between the ages of 18 and 60, diagnosed with diabetes and/or hypertension, were eligible for the study. Individuals known to have visual and hearing impairments, and intellectual disability were excluded from the study.

The principal researcher explained the purpose of the study and requested individuals who were interested in participating in the study to indicate their interest. Those who indicated an interest or wanted to get more information were interviewed in a private setting and provided with more details on the study.

### **Data collection**

A demographic questionnaire was utilised to gather information about gender, age, race, marital status, level of education, employment status, family income and medical conditions. A short structured diagnostic interview, the MINI International Neuropsychiatric Interview version 5.0 (M.I.N.I),<sup>19</sup> was used as a gold standard in the validation of the VISTAD. It covers 17 Axis I disorders that include mood, anxiety, substance use, psychotic and eating disorders, and it also has a suicidality module and one Axis-II disorder, antisocial personality disorder.<sup>19</sup> The symptoms on the M.I.N.I are based on the Diagnostic and Statistical Manual of Mental Disorders. Sheehan et al.<sup>19</sup> found the M.I.N.I to be a reliable and valid diagnostic tool, and it has been used in South African studies.<sup>20-23</sup> The M.I.N.I has good psychometric properties; positive predictive values (PPV) are above 0.75 for depression, panic disorder, agoraphobia and post traumatic stress disorder.<sup>19</sup> The PPV for generalized anxiety disorder agoraphobia are between 0.60-0.74 which is indicative of good values.<sup>19</sup> Traditional screening tools such as the Centre for Epidemiological Surveys for Depression (CES-D),<sup>22</sup> and the Kessler-10 (K-10)<sup>23</sup> have been validated against the M.I.N.I.<sup>24</sup> The M.I.N.I has also been used as a gold standard in the validation of a visual screening tool for depression in people living with HIV in an environment with high illiteracy rates.<sup>15</sup> There was a significant agreement between the visual screening tool for depression with receiver operating characteristic indicating an area under the curve of 0.82 for identifying depression. In a South African study, there was a significant agreement between the Kessler and depression (0.77) and anxiety disorders, 0.77

for post traumatic stress disorder, and 0.78 for generalized anxiety disorder (0.78).<sup>23</sup> A study by Azevedo-Marques and Zuardi<sup>24</sup> reported kappa coefficients ranging from 0.65 to 0.85, sensitivity was between 0.75 and 92, and specificity ranged from 0.90 to 0.99 for the M.I.N.I. Accuracy of the M.I.N.I ranged from 0.83 to 0.98. Taken together, the available data supports the notion that the M.I.N.I. provides reliable and valid diagnoses for mental disorders.

The development of the VISTAD is discussed in detail in Ogle, Koen and Niehaus.<sup>18</sup> In the VISTAD, a score of 1 is allocated when a participant endorses an abnormal state drawing and 0 when none of the abnormal state symptoms are endorsed. The minimum score is 0 and the maximum score that could be obtained on the VISTAD is 10. A total score of 6 and above indicates a positive screen for depression and anxiety disorders on the VISTAD.

### **Data analysis**

Descriptive statistics were used to describe demographic data. The M.I.N.I was used to categorise cases and non-cases of depression (major depressive episode) and anxiety disorders, that is, agoraphobia, generalised anxiety disorder (GAD), panic disorder, post-traumatic stress disorder (PTSD) and social phobia, excluding obsessive–compulsive disorder. The impact of education, employment and gender on the performance of VISTAD was investigated. Coefficient of correlation (coef.) indicated the correlation between the above-mentioned variables. The sensitivity and specificity and likelihood ratios (LR) were estimated. Sensitivity and specificity was calculated based on leave-one-out cross validation. Cut-off scores were informed by high specificity scores and moderate sensitivity scores. With a high specificity, the truly positives represent the mental disorder being screened for and not another condition, such as diabetes or hypertension.

The plot of sensitivity versus specificity is referred to as the receiver operating characteristics

(ROC).<sup>25</sup> The area under the curve (AUC) which is an effective measure of diagnostic test accuracy<sup>26</sup> was used for interpretations of the data. An AUC value of 0.50–0.70 is considered low accuracy, 0.70–0.90 is considered moderate accuracy and 0.90 is considered high accuracy.<sup>26</sup> Linear discriminant analysis was used to predict the disorder outcomes with the VISTAD drawing outcomes as predictors.

Correspondence analysis was utilized to provide a two-dimensional graphical representation of the categorical data, the M.I.N.I. diagnoses and VISTAD items. This applies to categorical rather than continuous data. All data analyses were done with STATA, version 14.

## **Results**

Eighty-one participants from primary health care participated in the validation of the VISTAD. All the participants consented and participated in this study. However, out of the 81 participants, one declined to continue with completing the interview reporting that the VISTAD depicted his life, and it was painful to look at the images.

In this study, we used demographic data of 79 participants as there was missing information from two participants. The majority of the participants were females, 69 (87%), with 10 (13%) males. Race distribution on the basis of gender showed that there were 43 black females, 15 mixed ancestry females and 11 white females; and 7 black males, 2 white males and 1 mixed ancestry male. The mean age of the participants was 49, with standard deviation 8.6844 and minimum age 22 and maximum 60. Socio-demographic variables and related factors are set out in Table 1.

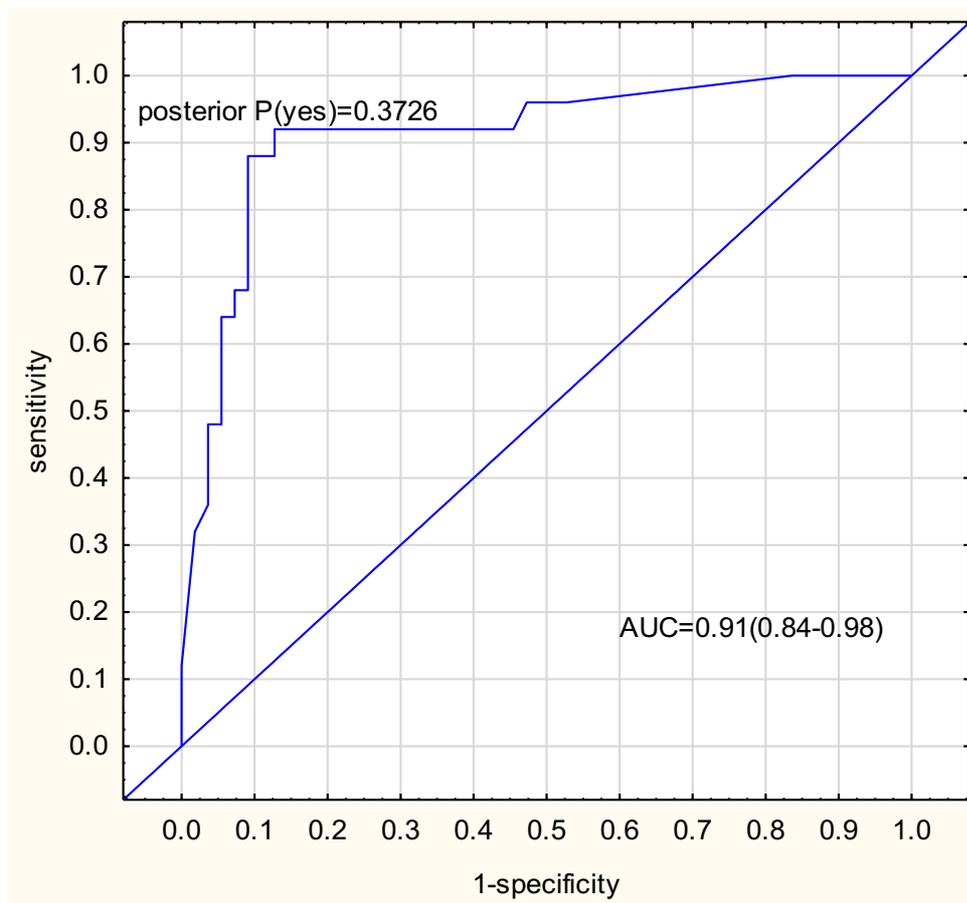
**Table 1: Demographic and clinical characteristics of participants (N = 79).**

<b>Variables</b>	<b>n (%)</b>
Gender	
Female	69(87)
Male	10(13)
Language	
Xhosa	48(61)
Afrikaans	29(37)
English	1 (1)
Shona	1 (1)
Race	
Black	50(63)
Mixed ancestry	16(20)
White	13(17)
Education	
No education	2 (3)
Primary level of education (Grades 1–6)	25(32)
Senior level of education (Grades 7–11)	33(42)
Matric (Grade 12)	15(19)
Post-matric qualification	4 (5)
Employment	
Yes	21(27)
No	58(73)
Hypertension or diabetes	
Hypertension only	47(59)
Diabetes only	1(1)
Hypertension and diabetes	31(39)
Other medical conditions	
Yes	43(54)
No	36(46)
Existing mental disorder	
Yes	10 (13)
No	69 (87)
MINI diagnosis	
Depression	26 (32)
Panic disorder	32 (40)
Agoraphobia	8 (10)
Social phobia	8 (10)
Post-traumatic stress disorder	27 (33)
Generalised anxiety disorder	14 (17)

*Source:* Authors' own work

### Accuracy of the visual screening tool for anxiety disorders and depression

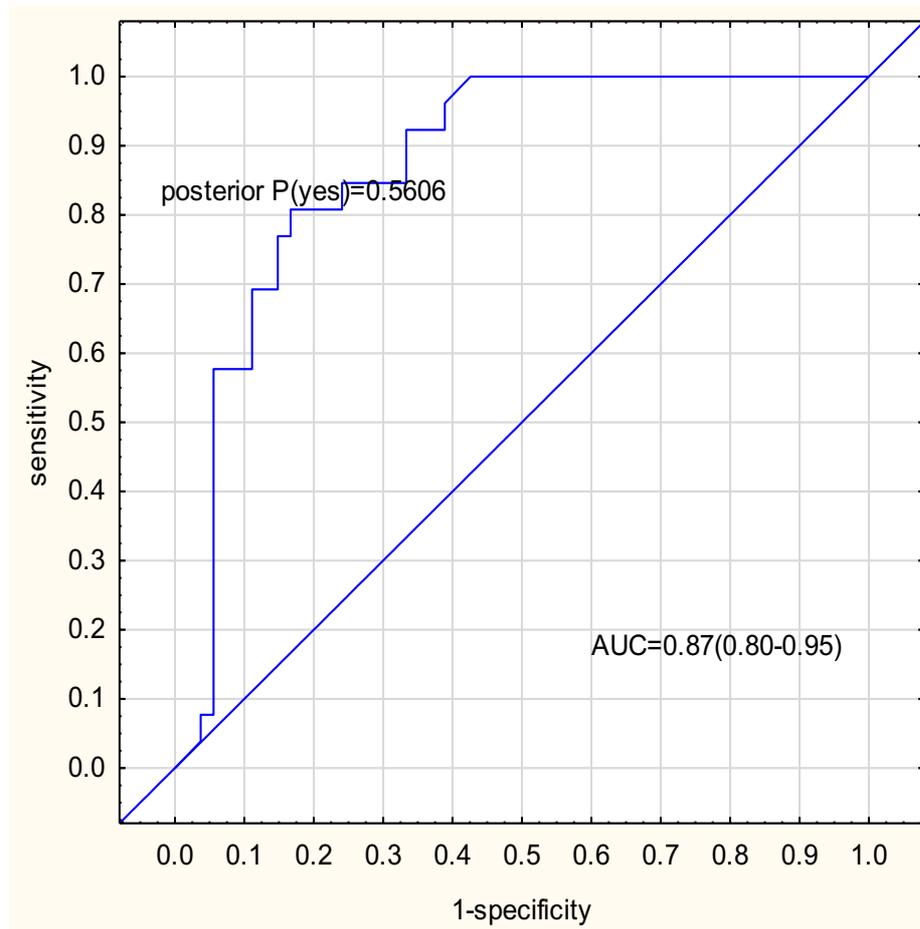
The AUC determined the accuracy of the VISTAD. The AUC in screening for depression is shown in Figure 1, PTSD in Figure 2, panic disorder in Figure 3, GAD in Figure 4, social phobia in Figure 5 and agoraphobia in Figure 6. The AUC score for depression shows a high accuracy of 0.91.



**Figures 1: Receiver operating curves of the visual screening tool for anxiety disorders and depression for depression.**

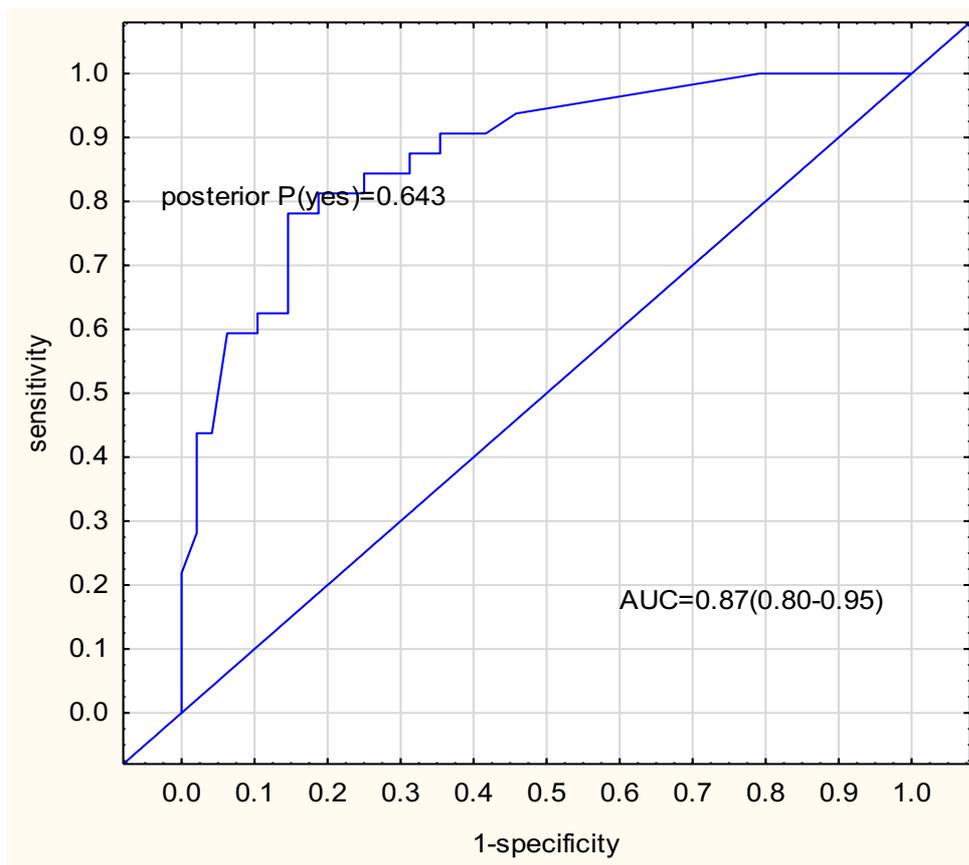
*Source:* Authors' own work

The best cut-off scores were based on high specificity and moderate sensitivity. At a cut-off score of 6, the specificity was 90.91, and sensitivity was 72.00%, with 85% correctly classified cases. The specificity was 90.91 and sensitivity was 60.00%, with 81.25% correctly classified cases at a cut-off score of 7.



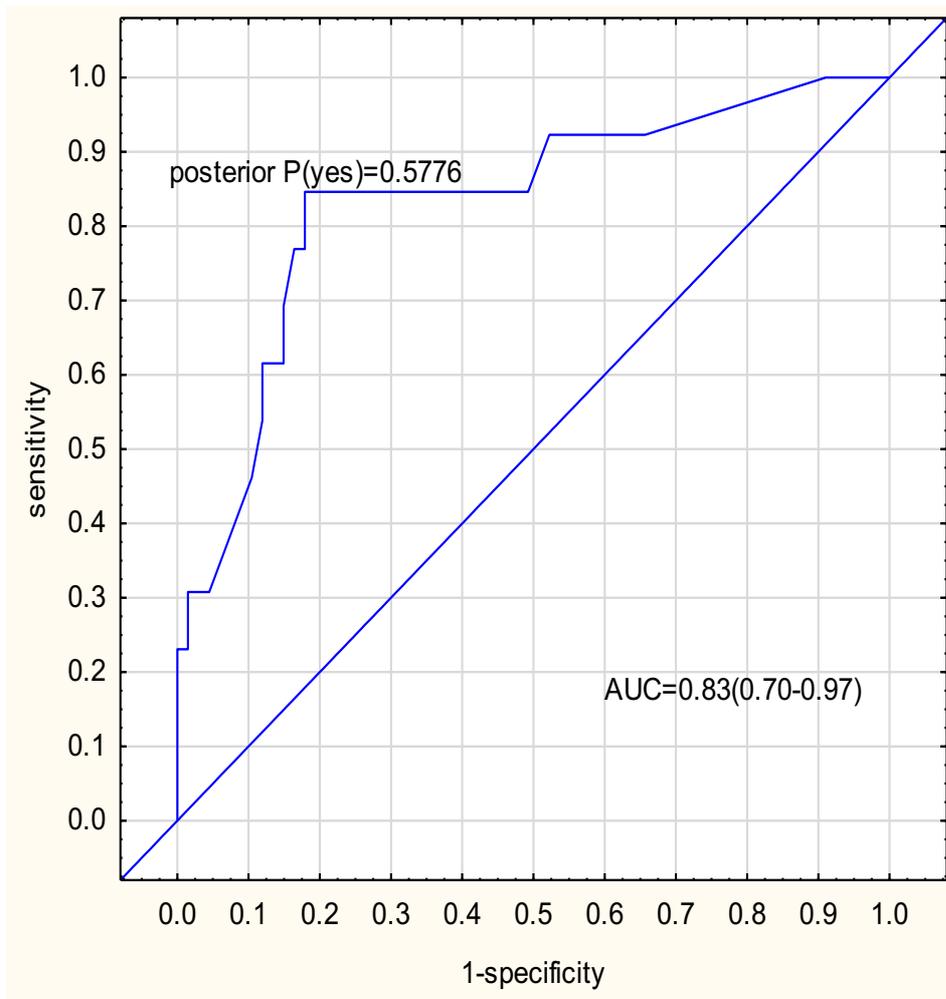
**Figure 2: Receiver operating curves of the visual screening tool for anxiety disorders and depression for post-traumatic stress disorder.**

*Source:* Authors' own work



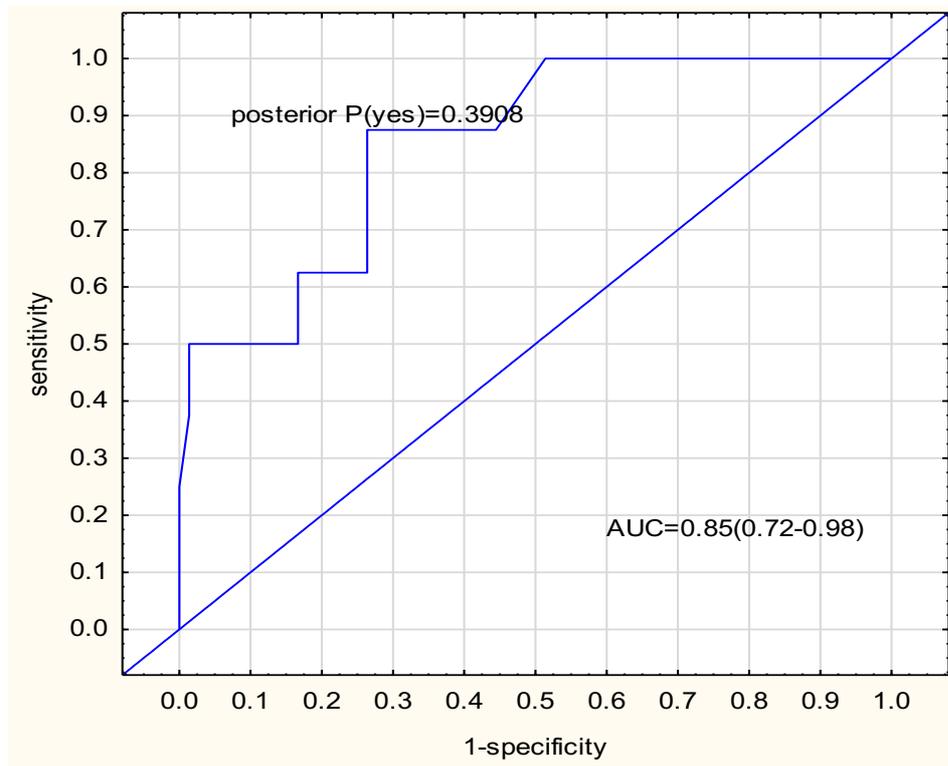
**Figure 3: Receiver operating curves of the visual screening tool for anxiety disorders and depression for panic disorder.**

*Source:* Authors' own work



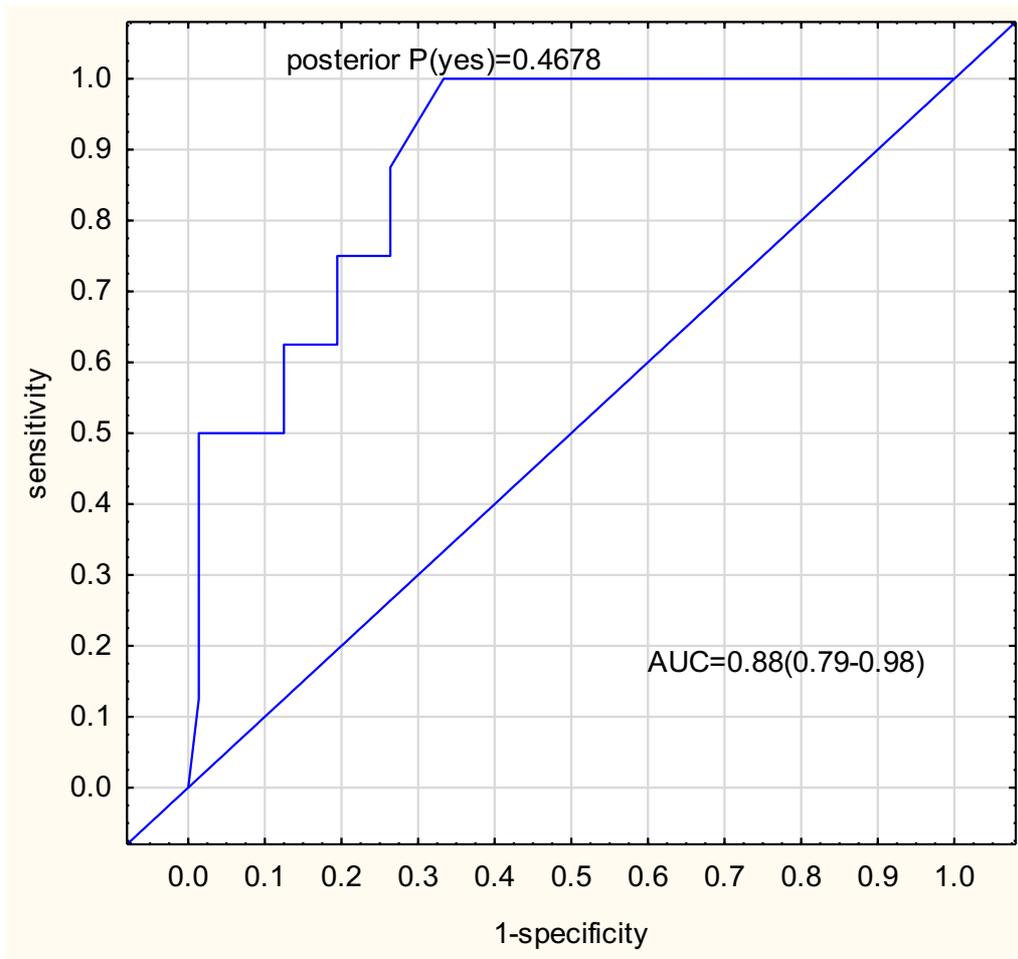
**Figure 4: Receiver operating curves of the visual screening tool for anxiety disorders and depression for generalised anxiety disorder.**

*Source:* Authors' own work



**Figure 5: Receiver operating curves of the visual screening tool for anxiety disorders and depression for social phobia.**

*Source:* Authors' own work



**Figure 6: Receiver operating curves of the visual screening tool for anxiety disorders and depression for agoraphobia.**

*Source:* Authors' own work

The area under curve for PTSD was 0.87. At a cut-off point of 6 for PTSD, there were 68% correctly classified cases with a specificity of 72.22% and a sensitivity of 37%. Similar to PTSD, the area under curve for panic disorder was 0.87, which indicated moderate accuracy. The specificity of the VISTAD at a cut-off point of 6 was 81.25%, with a sensitivity of 43.75%. Agoraphobia had a specificity of 73.61%. Social phobia had a specificity of 72.22% at a cut-off score of 6. Generalised anxiety disorder had a specificity of 74.63%, with 70% correctly classified cases.

### Response pattern

In table 2, we analyzed the response patterns to the VISTAD. We compared participants with depression to those without depression, and participants with anxiety to those without anxiety. There was a statistically significant association between the diagnosis of depression, anxiety disorder and the majority of VISTAD items, excluding one. There was no statistically significant association between all items and between the item, “feeling frightened when going out on my own” and a M.I.N.I diagnosis of major depression.

**Table 2: VISTAD Response Patterns**

VISTAD Item	No Depression N=55	Yes Depression N=26	Fisher Exact p	No Anxiety N=50	Yes Anxiety N=31	Fisher Exact p
 Sleep disturbance	21 (38%)	24 (92%)	p<0.01	8 (25%)	37 (76%)	p<0.01

**Feeling frightened for no reason**



16 (29%) 15 (58%) p=0.02 7 (22%) 24 (49%) p=0.02

**Sad and miserable**



12 (22%) 20 (77%) p<0.01 6 (19%) 26 (53%) p<0.01

**Feeling frightened when going out on my own**



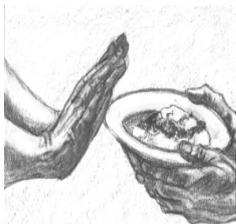
26 (47%) 16 (64%) p=.22 10 (31%) 32 (67%) p<0.01

**Palpitations**



18 (33%) 20 (80%) p=0.0010 4 (13%) 34 (71%) p<0.01

**Loss of appetite**



8 (15%) 13 (52%) p=0.0081 4 (13%) 17 (35%) p=0.04

**Life not worth living**



3 (5%) 13 (52%) p=.00001 2 (6%) 14 (29%) p=0.02

**Depressed**



9 (16%)      18 (72%)       $p < 0.01$       5 (16%)      22 (46%)       $p < 0.01$

**Irritability**



9 (16%)      18 (72%)       $p < 0.01$       9 (16%)      18 (72%)       $p < 0.01$

**Worrying thoughts constantly go through my mind**



19 (35%)      19 (76%)       $p = .00072$       8 (25%)      30 (63%)       $p < 0.01$

**Correspondence analysis results**

Correspondence analysis was used to collapse the complex matrix of data (Figure 7). The spatially plotted data reduced the amount of information expressed in the response patterns of the participants (Table 2), while better expressing the associations present in the data.

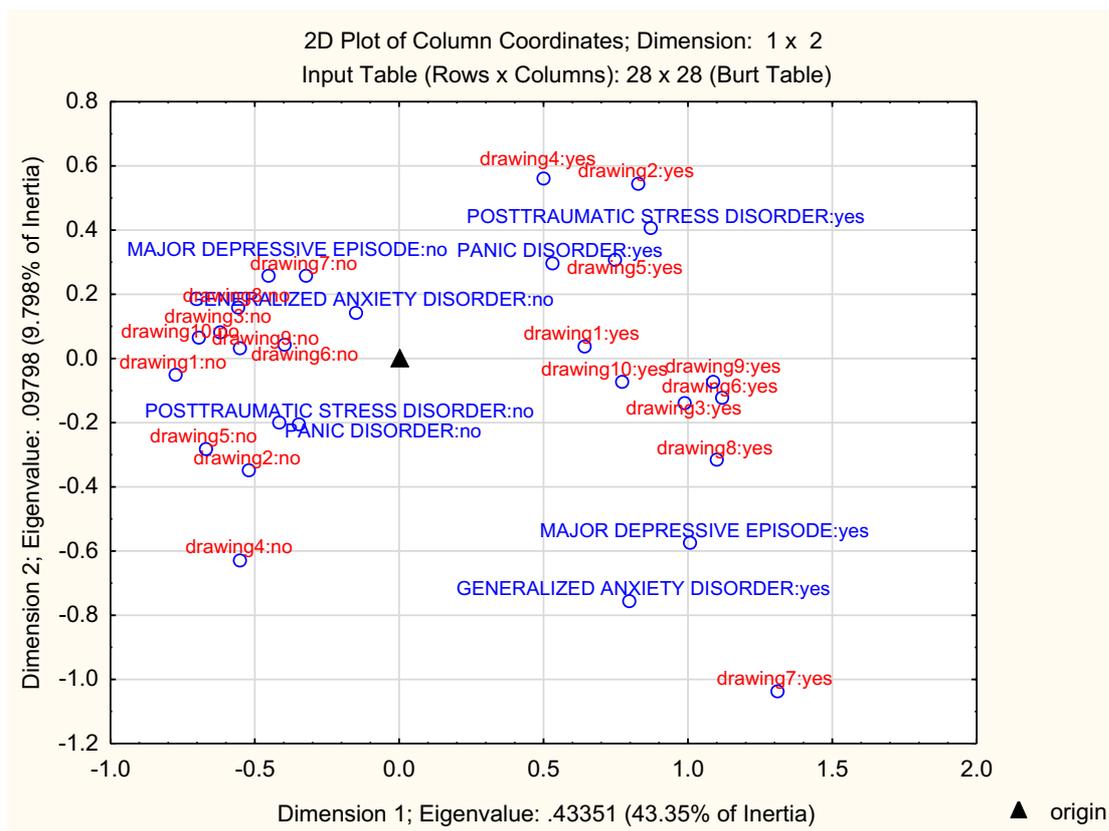


Figure 7: VISTAD performance against M.I.N.I

This plot illustrates some important aspects of the VISTAD' performance in the study. Drawing 2 (Feeling frightened for no reason) and 4 (Feeling frightened when going out on my own) relates spatially to the diagnosis of PTSD. On a conceptual level this spatial association makes clinical sense in terms of the symptoms of PTSD. Drawing 5 (Palpitations or sensations in chest) related to panic disorder more closely and again makes sense in terms of the clinical features of this disorder. Drawing 8 (Depressed) related spatially most closely with a diagnosis of major depressive episode, while the rest of the items clustered between Major Depressive Episode and Panic Episode (MDE). The exception is drawing 7 (Life is not worth living); if this item is not endorsed it is closely related to the absence of MDE, but endorsement of the item was not spatially closely related to the presence of MDE. There were 12 out of the 81 participants who reported on the M.I.N.I. interview that they repeatedly consider hurting yourself, feel suicidal, or wish they were dead.

## Demographic variables and the VISTAD items

Fundamental to the validation of the VISTAD is the investigation of whether education levels, socio-economic status and gender have an impact on the performance of the VISTAD. Table 3 presents the impact of level of education, gender and employment status on the performance of the VISTAD. There was a significant association between gender and performance on VISTAD, 0.042.

**Table 3: Impact of education, gender and employment status on the performance of the visual screening tool for anxiety disorders and depression.**

Variable	Coef.	SE	<i>t</i>	<i>p</i> >   <i>t</i>	95% CI
Level of education					
Primary	-0.7505694	3.557147	-0.21	0.833	-7.841612 to 6.340473
Senior	-0.6239653	3.507459	-0.18	0.859	-7.615957 to 6.368026
Matric	-2.326809	3.619307	-0.64	0.522	-9.541764 to 4.888147
Post-matric	0.0663401	4.089943	0.02	0.987	-8.086812 to 8.219493
Gender					
Male	-3.715155	1.795807	-2.07	0.042	-7.295031 to -0.1352794
Employment					
Yes	0.4993359	1.26012	0.40	0.693	-2.012668 to 3.01134
_cons	4.808826	3.425357	1.40	0.165	-2.019499 to 11.63715
/sigma	4.344278	0.4488455			3.449521 to 5.239035

*Source:* Authors' own work

CI, confidence interval; SE, standard error; coef., coefficient of correlation.

## DISCUSSION

### Findings

In this study, we validated the VISTAD against the M.I.N.I. at primary health care in participants diagnosed with hypertension and/or diabetes. The VISTAD demonstrated high accuracy in detecting depression in participants with hypertension and/or diabetes. The AUC of the VISTAD was 0.91 in screening for depression. This is higher than the previously AUC of 0.82 established by the visual screening for depression established in people living with HIV/AIDS.<sup>15</sup> At a cut-off score of 6, the VISTAD had satisfactory accuracy in classifying cases. This is similar to that of the HADS which the VISTAD is based on. At a cut-off score of 7, the HADS depression subscale provided the best balance between a sensitivity of 0.86 and a specificity of 0.81 in cancer patients.<sup>26</sup> In our study, the best balance was at a cut-off

score of 6 with a sensitivity of 0.72 and a specificity of 0.91, with 85% of the cases classified correctly. The AUC of VISTAD for both depression and anxiety is higher than that of the HADS. In study of 79 study patients with heart disease, Bambauer et al.<sup>27</sup> reported AUC for HADS depression subscale of 0.81 and 0.70 for the HADS anxiety subscale against the M.I.N.I. The accuracy of the VISTAD is also similar to that of other widely used traditional screening tools such as the Patient Health Questionnaire (PHQ), with an AUC of 0.88 at a higher cut-off score in patients with type II diabetes and/or coronary heart disease in primary care,<sup>28</sup> and the Kessler Scale (K10) for either anxiety or depression<sup>23</sup> and CES-D, K-10 and PHQ-9 and with AUC ranging from 0.82 to 0.96 in people living with HIV.<sup>29</sup>

The VISTAD had a higher AUC score compared to the recently validated WHO-5 for use in screening for depression in adults with diabetes. The AUC scores for WHO-5 in the validation study by Halliday et al.<sup>30</sup> ranged between 0.85 and 0.88, which demonstrated that the WHO-5 has moderate accuracy in screening for depression. This demonstrates that the VISTAD is a valuable tool for detecting depression. The optimal cut-off score chosen for depression was 6 in this study. This is in line with the current practice of selecting higher cut-off scores to indicate the presence of depression.<sup>31</sup> Similar to screening for depression, the optimal cut-off score chosen for anxiety disorders was 6.<sup>32</sup> The AUC for anxiety disorders was in the moderate range. This indicates that the accuracy of the VISTAD was better for depression than for anxiety. This is consistent with findings made in the meta-analysis conducted by Vodemaier and Millman<sup>32</sup> on other screening tools. Previous research has also established a similar pattern. For example, GAD 7 showed lower sensitivity and specificity levels when compared to screening tools for depression.<sup>31</sup> Makanjuola et al.<sup>33</sup> also reported lower AUC values in Nigeria for K-6 and the General Health Questionnaire (GHQ-12). K-6 and GHQ-12 are sensitive and specific screening tools widely used and recommended for use in the screening for depression and/or depression in primary health care and community samples. The VISTAD demonstrated good performance

against the M.I.N.I, and its performance is consistent with widely used screening tools such as the HADS and PHQ-9. It provides valid screening of depression and anxiety. According to Kaufman and Charney,<sup>34</sup> people living with depression also have a comorbid diagnosis of an anxiety disorder. We found that participants who endorsed symptoms of depression were also likely to endorse symptoms of anxiety on the VISTAD.

Newly developed screening tools have also been recommended for use in patients with chronic medical conditions. A Ugandan study recommended the use of a visual screening tool for depression.<sup>15</sup> This was based on its accuracy in detecting depression in people living with HIV. However, a study by Puertas et al.<sup>35</sup> did not recommend the use of visual screening tools as it found the FACES test to have low accuracy. Akena et al.<sup>15</sup> argues that screening tools, such as the FACES test, have often depended on a single facial picture depicting emotions ranging from a happy face to an extremely sad face. Participants with lower literacy levels struggle to comprehend the FACES screening tool according to Puertas et al.<sup>35</sup> Previous research has established that education has an impact on people's ability to comprehend and complete screening tools.<sup>36,37</sup> Some, according to Snaith,<sup>38</sup> are ashamed and pretend to answer questions and respond in a haphazard manner. This study demonstrated that education had no impact on the participants' ability to comprehend and complete the VISTAD. The findings on the education and performance of the VISTAD are consistent with previous research by Akena et al.<sup>15</sup> Furthermore, the socio-economic status had no impact on the participants' ability to understand and complete the VISTAD. The majority of participants in this study were of low socio-economic status. We found that gender had a significant association with performance on the VISTAD. This is due to one VISTAD item, sleep disturbance item. The observed gender difference on the sleep disturbance item is consistent with previous research. Sleep related disorders such as insomnia are more common in women than men.<sup>39-41</sup> Screening tools also have gender biases. Kerr and Kerr<sup>42</sup> added that self-reporting screening tools for depression

have limitation with respect to gender, somatic symptoms and culture.

Based on the M.I.N.I, we observed a depression prevalence of 32%. This is consistent with the findings of Jacob and Kostev's study,<sup>43</sup> which reported a prevalence of 33.7% in women and 26.8% in men diagnosed with diabetes. Cols-Sagarra et al.<sup>44</sup> reported a higher prevalence of 43.4% in women with diabetes at primary health care. A prevalence of 31.4% was reported in a study conducted in rural and urban parts of the Eastern Cape, South Africa,<sup>45</sup> and this finding is consistent with the prevalence observed in our study.

Anxiety disorders such as panic disorder and PTSD had a high prevalence, with panic disorder at 40% and PTSD at 33%. Other studies have found a significantly higher prevalence of panic disorder in hypertensive patients.<sup>46</sup> Also, in primary care, studies have observed a prevalence of PTSD ranging from 2.0% to 39.1% in hypertensive patients.<sup>47</sup> Post-traumatic stress disorder, according to Seedat<sup>48</sup> is among the most prevalent compared to other anxiety disorders in terms of lifetime and 12-month prevalence rates documented in epidemiological studies. The number of participants who had a positive diagnosis of a common mental disorder was high. This observation is consistent with previous research findings.<sup>49,50</sup> Data on larger samples are needed to determine the prevalence of depression and anxiety disorders in primary care patients with hypertension and/or diabetes.

## **STRENGTHS AND LIMITATIONS**

This is the first study to develop and validate a visual screening tool for both depression and anxiety disorders in primary health care participants diagnosed with hypertension and/or diabetes in South Africa. Furthermore, the use of the M.I.N.I in the study was not limited to the depression module, and the anxiety disorder module was also administered, except for obsessive-compulsive disorder module. The administration of the M.I.N.I depression module

only might artificially inflate the extent of the correlations as some participants with depression might have been better diagnosed with another disorder, such as anxiety disorder(s).<sup>15</sup> Also, this could lead to a false accuracy of the visual screening tool. The strength of the study was enhanced by the inclusion of five different primary health care sites, which serve urban, peri-urban and rural population.

The validity of the VISTAD is based on the ten items used in its validation. In order to shorten the VISTAD, a process evaluation would need to be conducted to explore the experiences of using the VISTAD. This process will also determine how primary health care workers are using the VISTAD and whether a shorter tool would be effective and why. We would then need to devise criteria for performance for a shortened VISTAD. Future studies will also be needed to determine this criteria degrades as items are removed.

Because of the small size of the sample, we cannot generalise the findings of the study to all individuals attending primary health care. Thus, future research is needed to validate the VISTAD in a large primary health care population. Furthermore, the use of the VISTAD in primary health care with speech impairments and intellectual impairments needs further investigation. A further limitation is that this study was informed by the DSM-IV nosology. For example, PTSD is no longer described as an anxiety disorder in the current DSM-V, but as a trauma- and stressor-related disorder.

## **CONCLUSIONS**

The visual screening tool is referred to as the VISTAD. The VISTAD is accurate in detecting depression and anxiety disorders in primary health care participants diagnosed with diabetes and/or hypertension. The use of the VISTAD is recommended as a screening tool for depression and anxiety disorders at primary care level in patients with hypertension and/or diabetes.

However, the VISTAD needs to be validated in a large population of primary care patients diagnosed with hypertension and/or diabetes.

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### **COMPETING INTERESTS**

The authors declare that they have no conflicts of interest to disclose. Neither personal nor financial relationship may have inappropriately influenced them in writing this article.

### **AUTHORS' CONTRIBUTIONS**

This article is produced from a research paper that will be submitted for a PhD in Psychiatry. Z.O. is the principal researcher and collected data and produced the first draft of the article. L.K. is the research supervisor and reviewed the article. D.J.H.N. is the co- supervisor and reviewed the article.

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## **CHAPTER FIVE**

### **General Discussion**

The primary objective of this PhD was to develop and validate a simple and accurate visual screening tool for depression and anxiety disorders for adults attending primary health care centers with a diagnosis of hypertension and/or diabetes. The project was conceptualized against the realization as to the lack of availability of appropriate mental health screening tools that can be applied across language, education and resource barriers in a multi-cultural society such as South Africa.

Thus we developed and validated the Visual Screening Tool for Anxiety Disorders and Depression (VISTAD). The VISTAD consists of ten culturally appropriate drawings depicting symptoms of depression and anxiety disorders. The study was borne from a need in the South African context where there is a lack of culturally appropriate and sensitive screening tools for common mental disorders that can be applied to diverse population groups and people with low and high levels of education.

This study was divided into two phases. Phase one was the development of the VISTAD (chapter 2), and phase two (chapter 3 and 4) was the validation of the VISTAD. For the first phase of the study, we recruited adults attending primary health care, a maternal mental health clinic and from the general public. All the participants were asked to describe emotions and thoughts depicted in the drawings that represented symptoms of depression and anxiety disorders. Independent of culture, language, and level of education the participants demonstrated the ability to correctly identify and describe symptoms as associated with depression and anxiety disorders for ten of the thirteen proposed drawings. Our findings were

instrumental in identifying the drawings that were accurate enough to be included for the validation of the VISTAD in phase two of our study.

In addition to the participants' ability to describe the symptoms correctly, we also found that they referred to their lived experiences as they described emotions and thoughts depicted in the drawings. We concluded that these descriptions were connected to personal narratives of the participants and that the use of drawings offered an invaluable opportunity to explore emotional status across cultural and language boundaries. As participants narrated their life stories, they had a freedom of response where unconscious needs that they would ordinarily be unable or unwilling to report were expressed. The possible use of the VISTAD as a projective tool needs further exploration that falls beyond the scope of this study.

For the second phase of the study, a sample of primary care patients with hypertension and/or diabetes were recruited. This sample was then used to validate the VISTAD. This sample is fully elucidated on in chapter three. Firstly, we described the presence of depression and anxiety disorders as determined using the Mini International Neuropsychiatric Interview (M.I.N.I.), quality of life (QOL) and patterns of alcohol and drug use. In our sample, panic disorder was the most common disorder at 40%, followed by post-traumatic stress disorder (PTSD) (33%), depression (32%) and generalised anxiety disorder (GAD) (17%). Social phobia (10%) and agoraphobia (10%) were the least prevalent anxiety disorders.

The prevalence of depression in our study is consistent with findings from studies previously conducted in our study setting, Eastern Cape (Andersson et al., 2013). The Eastern Cape is a province where people are exposed to high levels of poverty and economic distress which has a negative impact on their health. This is consistent with our findings with the majority of

participants in our study unemployed and mostly reliant on state support, in the form of pensions and grants.

International studies have reported a wide ranging prevalence of depression in people living with diabetes. These include 2%–84% (Naskar, Victor, & Nath, 2017), 32.7% (Calvin, Gaviria, & Rios, 2015) 33.7% in women and 26.8% in men (Jacob & Kostev, 2016) and 43.4% in women (Cols-Sagarra et al., 2016). Li, Li, Chen, Chen and Hu (2015) reported a prevalence of 26.8% of depression among patients with hypertension. We found a higher prevalence of depression in patients diagnosed with both hypertension and diabetes compared to patients diagnosed with hypertension only. The diagnosis of depression was associated with a poor QOL in our study.

Generally, there is limited published literature on the prevalence of anxiety disorders in people living with hypertension and/or diabetes. From the data available, it is clear GAD is one of the highly prevalent but under-diagnosed anxiety disorders (Revicki et al., 2012). Whitworth et al. (2016) reported a prevalence of 6.5% for GAD, current, and a lifetime prevalence of 23%. Both these rates are higher than 17% found in our study.

Agoraphobia and social phobia were less prevalent in our study. Both these having a prevalence of 10% which is consistent with previous research. According to the National Institute of Mental Health, 0.8% of American adults suffer from agoraphobia whilst Stein et al. (2009) reported a lifetime prevalence of agoraphobia of 9.8% in South Africa. In our study only patients diagnosed with hypertension had a diagnosis of agoraphobia with no association demonstrated between diabetes and agoraphobia.

One of the costs associated with hypertension and diabetes is poor QOL. This was confirmed in our sample with participants demonstrating poor QOL in the physical health, psychological

and environmental domains. Based on this, we can conclude that our study participants were experiencing pain, low energy and fatigue and impairments in activities of daily living. They were also experiencing negative feelings, low self-esteem and poor concentration. We found a statistically significant association between diagnosis of depression, anxiety and poor QOL. Participants who had other medical conditions had a significantly poor QOL compared to participants without other medical conditions, and this shows that multimorbidity is associated with a poor QOL.

An interesting finding from our study was that a significant number of participants did not engage in hazardous and harmful use of alcohol and drugs. Possibly, this finding could be related to primary health care staff focusing on early identification and appropriate intervention. However, we observed that participants who reported or endorsed irritability and suicidal ideation on the VISTAD were more likely to report drug related problems.

The overarching goal of phase two was the validation of the VISTAD which was developed in phase one (chapter 4). The VISTAD showed it was highly accurate in detecting depression with an Area Under Curve (AUC) of 0.91 showing that the tool can be used to screen for depression in South African primary health care centers in adults living with hypertension and/or diabetes. Although the sample size was small, our findings are consistent with findings of studies with larger samples. We found the VISTAD to be valid in screening for depression with accuracy higher than that demonstrated in the validation of the Akena's Visual Depression Inventory (AVIDI) (Akena et al., 2013) and within the same range as that of other widely used screening tools, including the Patient Health Questionnaire (PHQ) in patients with Type II diabetes and/or coronary heart disease in primary care (van der Zwaan et al., 2016), the Kessler Psychological Distress Scale 10 (K10) for either anxiety or depression (Conway et al., 2016) and Center for Epidemiologic Studies Depression Scale (CES-D), as well as K-10 and PHQ-9 in a group of

people diagnosed with HIV (Akena et al., 2013). The recently validated World Health Organization Wellbeing Index (WHO-5) for use in screening for depression in adults with diabetes had AUC ranging between 0.85–0.88. (Halliday et al., 2017) which is lower than the AUC 0.91 established in our study.

We not only investigated the accuracy of the VISTAD in screening for depression, but also its accuracy in screening for anxiety disorders. Moderate accuracy was demonstrated with an AUC of 0.87 for panic disorder, 0.88 for agoraphobia, 0.85 for social phobia, 0.87 for PTSD and 0.83 for GAD. Our findings are consistent with findings by Vodemaier and Millman (2011). Screening tools, including the Generalised Anxiety Disorder 7 (GAD 7), have acceptable sensitivity and specificity levels in screening for anxiety. However, as in our study these are lower when compared to screening tools for depression (Conway et al., 2016). Makanjuola et al. (2014) also reported lower AUC in Nigeria for Kessler Psychological Distress Scale 6 (K-6) and General Health Questionnaire 12 (GHQ-12).

Our findings showed that the VISTAD has high accuracy in detecting depression and moderate accuracy in detecting anxiety disorders in adults attending primary health care centers with a diagnosis of hypertension and/or diabetes.

Our aim was not to elucidate the pathways between hypertension and/or diabetes and depression and anxiety disorders but rather to describe the presence thereof and determine the VISTAD's accuracy in positively identifying these illnesses. The high number of participants diagnosed with depression and anxiety disorders in primary health care adults living with hypertension and/or diabetes does not imply causality. Rather, it highlights the importance of detecting and treating depression and anxiety disorders in these patients. The high prevalence of these disorders presented in this study highlights the urgent need for preventative action to minimize suffering and costs to society. The data should be of particular interest to governing structures,

clinicians and researchers as available information is in many cases limited and outdated information (Tomlinson et al., 2009). Our study results could contribute to processes with regards to planning and allocation of resources, particularly for mental health care at a primary health care level. Conway et al. (2016) argued that the generalizability of their findings were supported as they were consistent with previous research. Similarly our findings on the prevalence of depression and anxiety disorders are consistent with the available literature. However, they should be interpreted with caution as our study sample was small. We believe that the VISTAD represents an important contribution towards furthering the integration of the management of mental health conditions into the primary health care system.

Firstly, it addresses the challenges posed by cultural, language, educational and time factors when attempting to screen for common mental disorders. Secondly, the VISTAD includes symptoms of depression and anxiety disorders in one screening tool. Katon, Lin, and Kroenke (2007) have argued that the assessment of depressive disorders should include anxiety disorders since these disorders often co-exist in chronic physical conditions.

It is well known and widely reported in the literature that primary health care access to mental health specialists is severely limited. Thus, the true integration of mental health care into primary health will improve the early identification and management of depression and anxiety disorders in people living with chronic illnesses. The availability of simple to use and culturally appropriate tools such as the VISTAD brings this goal much closer to becoming a reality.

### **Conclusions and reflective assessment of contribution**

In conclusion, we report on the successful development of the VISTAD. To the best of our knowledge, this is the first study to develop and validate a visual screening tool, for both depression and anxiety disorders in primary health care patients with hypertension and/or

diabetes in a developing world setting. The VISTAD is self-administered and any primary health care worker can easily be trained to score it. We demonstrated that it can be administered to patients irrespective of level of education, language and cultural background. The findings from the developmental phase of the VISTAD provide an opportunity for further exploration of the VISTAD as a projective tool as it supported that drawings can be used to describe emotions and thoughts associated with depression and anxiety disorders.

We found a high prevalence of depression and anxiety disorders in adults diagnosed with hypertension and/or diabetes in our study when compared to other studies. Socioeconomic factors are a contributor to this high prevalence and this emphasizes the importance of having a health care system providing care that is beneficial to all. With simple to use and culturally appropriate tools such as the VISTAD, the detection of depression and anxiety disorders could be improved. This study highlights the urgency for the integration of health care services in order to address the impact of depression, and anxiety disorders coexisting with chronic illnesses such as diabetes and/or hypertension. This study showed that hypertension and diabetes can compromise the QOL of patients, if left undetected.

In order to pursue a more comprehensive role-out of the VISTAD, it needs to be validated in a larger sample. Furthermore, the VISTAD only assesses the likelihood of the presence of depression and anxiety disorders symptoms and not severity in categories such as mild, moderate and severe. A follow-up study is recommended to explore the symptomatology of depression and anxiety disorders in people living with hypertension and/or diabetes in order to investigate the particular burden and management of these illnesses. The use of the VISTAD as a projective tool is another avenue for future research.



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## **ADDENDUM 1**



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## Approval Notice New Application

11-Feb-2015  
Ogle, Zimbini Z

**Ethics Reference #: S14/11/262**

**Title: The development of a visual screening sale for depression and anxiety in patients with hypertention and/or diabetes.**

Dear Miss Zimbini Ogle,

The **New Application** received on **14-Nov-2014**, was reviewed by Health Research Ethics Committee 1 via Committee Review procedures on **04-Feb-2015** and has been approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: **04-Feb-2015 -04-Feb-2016**

**Present Committee Members:**

Weber, Franklin CFS  
Unger, Marianne M  
Sprenkels, Marie-Louise MHE  
Els, Petrus PJJS  
Kearns, Elaine E  
Barsdorf, Nicola N  
Botha, Paul JP  
Decloedt, Eric EH  
Hall, David DR  
Hendricks, Melany ML  
Ferris, William WF  
Welzel, Tyson B

Please remember to use your **protocol number (S14/11/262)** on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

**After Ethical Review:**

Please note a template of the progress report is obtainable on [www.sun.ac.za/rds](http://www.sun.ac.za/rds) and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372  
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

**Provincial and City of Cape Town Approval**

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel:

+27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: [www.sun.ac.za/rds](http://www.sun.ac.za/rds)

If you have any questions or need further assistance, please contact the HREC office at 219389156.

**Included Documents:**

Checklist

Protocol Synopsis

The Alcohol Use Disorders Identification Test

Declaration D Niehaus

Letter regarding consent forms

Eastern Cape Dept of Health Permission Letter-1

Maternal Mental Health Outpatient Clinic Permissio

Demographic questionnaire

Cape Mental Health Permission Letter

PhD Evaluation committee report

Western Cape Dept of Health Permission Letter

Application form

CV L Koen

CV Z Ogle

Declaration Z Ogle

WHO\_BREF\_QOL

Drug Use Disorders Identification Test

Declaration L Koen

Western Cape Clinic Permission Letter

Visual Screening Scale for Depression and Anxiety

Mini International Neuropsychiatric Interview

Protocol

CV D Niehaus

Eastern Cape Clinic Permission Letter

Sincerely,

Franklin Weber

HREC Coordinator

Health Research Ethics Committee 1

# Investigator Responsibilities

## Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1. Conducting the Research. You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.
2. Participant Enrolment. You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.
3. Informed Consent. You are responsible for obtaining and documenting effective informed consent using **only** the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.
4. Continuing Review. The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period**. Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur**. If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.
5. Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.
6. Adverse or Unanticipated Events. Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HREC's requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch University Health Research Ethics Committee Standard Operating Procedures [www.sun025.sun.ac.za/portal/page/portal/Health\\_Sciences/English/Centres%20and%20Institutions/Research\\_Development\\_Support/Ethics/Application\\_package](http://www.sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package) All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.
7. Research Record Keeping. You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC
8. Reports to the MCC and Sponsor. When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.
9. Provision of Emergency Medical Care. When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.
10. Final reports. When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.
11. On-Site Evaluations, MCC Inspections, or Audits. If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.