Pilot study of an e-intervention for symptoms of depression among university students in South Africa

by
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DECLARATION

By submitting this thesis in hard copy and electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the sole author thereof (save to the extent explicitly otherwise stated), that reproduction and publication thereof by Stellenbosch University will not infringe any third party rights and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

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ABSTRACT

Background. Major Depressive Disorder (MDD) is associated with a range of adverse outcomes among university students, including academic failure, suicidal thoughts and behaviours, and severe role impairment. Despite the variety of effective treatments available, most university students do not seek or receive help. Evidence suggests that internet-based interventions (e-interventions) might be as effective as existing treatments available to treat MDD. Therefore, e-interventions have been suggested to address the treatment gap among university students. However, e-interventions have not been extensively used or evaluated in low- and middle-income countries (LMIC) like South Africa (SA). Therefore, I set out to pilot the use of an e-intervention, namely iCare, aimed at addressing depressive symptoms among SA university students.

Aims. This randomised external pilot study had two primary aims: (1) to assess the key feasibility aspects of iCare, namely (a) recruitment, (b) randomisation, and (c) implementation (utilisation, retention and follow-up rates, and the assessment of the outcome measures); and (2) to investigate students' experiences of using iCare and to document their suggestions on improving iCare and making it more culturally appropriate for use in the SA context.

Methods. All first-year university students (n=5094) were invited to complete a voluntary mental health survey. A total of 138 participants met the inclusion criteria and were randomised (according to a 2:1 ratio) to iCare (n=91) and treatment-as-usual (TAU) (n=47). iCare participants received one-month and three-month post-intervention follow-up assessments to monitor symptom change. Each iCare participant also received an email inviting them to participate in an individual in-depth post-intervention interview. The key feasibility aspects were quantified and assessed using various statistical analyses. A large proportion of the participants did not complete the follow-up assessments. The outcome measures were, therefore, assessed using three

approaches commonly used to handle missing data in clinical trials: (1) complete case analysis (CCA), (2) intention-to-treat analysis using multiple imputations (ITTA-MI), and (3) per-protocol analysis (PPA). Sample size estimations to scale this study to a randomised control trial were conducted based on the ITTA-MI, using (1) safeguard power analysis, and (2) the minimal clinically significant effect. The interviews were transcribed and analysed through thematic analysis following a data-driven approach.

Findings. Only 31.87% (n=29) of participants indicated their willingness to use iCare, of which 24.18% (n=22) started with iCare's first session. A substantial number (72.73%, n=16) of participants dropped out during treatment. Low follow-up rates were observed at the one-month (65.9%, n=60) and three-month (71.4%, n=65) post-intervention follow-up assessments. However, the ITTA-MI indicated a significant small to moderate decrease in iCare participants' depressive symptoms at these assessments. The PPA indicated that a large proportion (50%, n=3) of iCare completers achieved a successful treatment outcome. I identified seven superordinate themes and several sub-themes. The majority of participants felt the anonymity and accessibility of iCare enabled them to overcome the barriers they faced to traditional face-to-face therapy; others found the lack of direct human contact to be problematic, expecting iCare to mimic the responsiveness and reflectiveness of face-to-face therapy. The perceived time-consuming nature of iCare was put forward by some participants for their discontinuation of iCare; while others discontinued due to symptom improvement. The majority of participants indicated the need for more engaging and interactive content and suggested that iCare should be used in addition to, rather than replacing, traditional face-to-face therapy.

Conclusion. The findings of this study indicate that there is a proportion of students for whom e-interventions may provide the first step to accessing mental health services, although not

a replacement for traditional face-to-face therapy. A randomised control trial is needed to determine the efficacy of iCare. I also offer recommendations for addressing the key feasibility aspects that were identified, and for future research on e-interventions among university students in SA.

OPSOMMING

Agtergrond. Major Depressieversteuring word onder universiteitstudente geassosieer met ’n verskeidenheid nadelige effekte, insluitend akademiese mislukking, selfdoodgedagtes en -gedrag, en ernstige funksioneringsprobleme. Ten spyte van die verskeie effektiewe behandelings wat beskikbaar is, soek en ontvang die meeste universiteitstudente nie hulp nie. Navorsing bewys dat internet-gebaseerde intervensies (e-intervensies) net so effektief kan wees soos die bestaande depressiebehandelings. E-intervensies word dus aanbeveel om die gebrek aan behandeling onder universiteitstudente aan te spreek. In lae- en middelinkomstelande soos Suid-Afrika (SA) is e-intervensies egter nog nie in diepte gebruik of geëvalueer nie. Ek het dus onderneem om die gebruik van ’n e-intervensie genaamd iCare uit te toets, wat daarop gemik is om depressiesimptome onder SA universiteitstudente aan te spreek.

Doelstellings. Hierdie ewekansige eksterne toetsstudie het twee primêre doelstellings gehad: (1) om die lewensvatbaarheid van iCare te assesseer in terme van (a) werwing, (b) ewekansige verdeling, en (c) implementering (benutting, retensie- en opvolgkoerse, en die assessering van die uitkomste); en (2) om die studente se ervaring van iCare te ondersoek en hul voorstelle te dokumenteer oor hoe om iCare te verbeter en dit meer kultureel toepaslik vir die SA konteks te maak.

Metodologie. Alle eerstejaarstudente (n=5094) is uitgenooi om ’n vrywillige geestesgesondheidsvraelys in te vul. ’n Totaal van 138 deelnemers het aan die insluitingskriteria voldoen en is ewekansig verdeel (in die verhouding 2:1) tussen iCare (n=91) en gewone behandeling (n=47). Die iCare-deelnemers het een maand asook drie maande ná die intervensie opvolg-assesserings ontvang om simptoomveranderinge te monitor. Elke iCare-deelnemer het ook ’n e-pos ontvang wat hom/haar uitnooi om aan ’n individuele in-diepte post-intervensie onderhoud

deel te neem. Die lewensvatbaarheidsaspekte van só ’n intervensie is gekwantifiseer en geassesseer deur die gebruik van verskeie statistiese ontledings. ’n Groot proporsie van die deelnemers het nie die opvolg-assesserings voltooi nie, dus is die uitkomste geassesseer met behulp van drie benaderings wat algemeen gebruik word om vermiste data in kliniese toetse te hanteer: (1) volledige gevalsontleding (CCA), (2) veelvuldige imputasies (ITTA-MI), en (3) per-protokol-ontleding (PPA). Om te bepaal wat nodig sal wees om hierdie studie na ’n ewekansige kontroletoets uit te brei, is steekproefskattings op grond van die ITTA-MI bereken met behulp van (1) ontleding met magsbeskerming, en (2) die minimaal klinies beduidende effek. Die onderhoude is getranskribeer en ontleed met tematiese analise, in ooreenkoms met ’n datagedrewe benadering.

Bevindinge. Slegs 31.87% (n=29) van die deelnemers het hul bereidwilligheid aangedui om iCare te gebruik. Hiervan het 24.18% (n=22) iCare se eerste sessie begin. ’n Aansienlike aantal deelnemers (72.73%, n=16) het tydens behandeling onttrek. Lae opvolgkoerse is een maand (65.9%, n=60) en drie maande (71.4%, n=65) ná die intervensie tydens opvolg-assesserings waargeneem. Die ITTA-MI het egter tydens hierdie assesserings ’n beduidende klein tot middelmatige afname in die iCare-deelnemers se depressiesimptome getoon. Die PPA het getoon dat ’n groot proporsie (50%, n=3) van die iCare-voltooiers (n=6) ’n suksesvolle behandelingsuitkoms bereik het. Ek het sewe hooftemas en verskeie subtemas geïdentifiseer. Die meerderheid deelnemers het gevoel dat die anonimiteit en toeganklikheid van iCare hulle in staat stel om die hindernisse te oorkom wat hulle verhoed om tradisionele een-tot-een-terapie te gebruik. Ander het die gebrek aan direkte menslike kontak problematies gevind omdat hulle verwag het dat iCare die responsiwiteit en refleksiwiteit van een-tot-een-terapie sou deel. Party deelnemers het nie met iCare voortgegaan nie omdat hulle dit as tydrowend gesien het, terwyl ander as gevolg van simptoomverbetering onttrek het. Die meerderheid deelnemers het daarop gewys dat meer

boeiende en interaktiewe inhoud nodig is, en voorgestel dat iCare aanvullend tot tradisionele terapie gebruik word, eerder as in plaas daarvan.

Gevolgtrekking. Die bevindinge van hierdie studie dui daarop dat daar ’n proporsie studente is vir wie e-intervensies moontlik ’n eerste stap kan bied om ’n geestesgesondheidsdiens te begin gebruik, alhoewel dit nie ’n plaasvervanger vir tradisionele terapie is nie. ’n Ewekansige kontroletoets sal nodig wees om die doeltreffendheid van iCare te bepaal. Ek maak aanbevelings oor hoe om die lewensvatbaarheidsaspekte wat in hierdie studie geïdentifiseer word, aan te spreek, asook vir toekomstige navorsing oor e-intervensies onder universiteitstudente in SA.

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DEDICATION

I dedicate this thesis to everyone struggling with depression; a daily battle.

"... then some become strong at the broken places."

- Ernest Hemingway

CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1: Introduction

Major Depressive Disorder (MDD) is one of the most prevalent common mental disorders (CMDs) among university students (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018). Rates of MDD are typically higher among university students (Auerbach et al., 2016; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018) compared to the general population, both globally (Lim et al., 2018) and in South Africa (SA) (Bantjes, Lochner, et al., 2019; Tomlinson, Grimsrud, Stein, Williams, & Myer, 2009). Studies suggest that the weighted mean rates of MDD are as high as 30.6% in university students (Ibrahim, Kelly, Adams, & Glazebrook, 2013). MDD is associated with a range of adverse outcomes, including academic failure (Bruffaerts et al., 2018), suicidal thoughts and behaviours (STB) (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Cuijpers, et al., 2018), and severe role impairment (Alonso, Mortier, et al., 2018; Alonso,Vilagut, et al., 2018). Despite the range of effective treatments available, there is a significant treatment gap; most university students do not receive help (Auerbach et al., 2016). Authors have suggested that internet-based interventions (e-interventions) might be appropriate in helping to close this treatment gap for students (Alonso, Vilagut, et al., 2018; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018). Evidence suggests that e-interventions might be as effective as existing treatments in high-income countries (Cuijpers, Donker, Van Straten, Li, & Andersson, 2010; Cuijpers, Donker, et al., 2011; Spek et al., 2007). However, e-interventions have not been extensively used or evaluated in low- and middle-income countries (LMIC) like SA. Therefore, I set out to (1) pilot the use of an e-intervention (iCare-Prevent) for symptoms of MDD among university students at Stellenbosch University, and (2) investigate the students' experiences of utilising iCare-Prevent and document their suggestions on how to adapt iCare-Prevent to make it more culturally acceptable in SA.

In this chapter, I set out the context of the study with a brief discussion of the clinical features of MDD, the epidemiology of MDD among university students, and the adverse outcomes associated with MDD in this population. I go on to discuss the treatment gap and the possible contributing factors among university students. I present e-interventions as a possible solution to address the treatment gap, describe the proposed e-intervention (iCare-Prevent), and discuss the role of pilot studies. I conclude this chapter with the aims of this study and give an overview of the chapters to follow.

Context of the study

Clinical features and epidemiology of MDD

MDD is a mood disorder characterised by two main symptoms: (1) depressed mood (dysphoria) and (2) loss of interest or pleasure in nearly all activities (anhedonia) (LeMoult, Gastonguay, Joorman & McAleavey, 2013). MDD will be the leading cause of disability worldwide by the year 2020 (Murray & Lopez, 1997). High rates of MDD are common among adult populations (Herman et al., 2009; Lim et al., 2018). Globally, the 12-month and lifetime prevalence of MDD was found to be 7.2% and 10.8%, respectively (Lim et al., 2018). In SA, these rates were found to be lower: 4.9% (12-month) and 9.8% (lifetime) (Herman et al., 2009). The rates of MDD are higher among the student population (Auerbach et al., 2017, Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018; Bantjes, Lochner, et al., 2019). Internationally, the 12-month prevalence of MDD for first-year university students is 18.5%, while lifetime prevalence is 21.2% (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018). In SA, the 12-month MDD prevalence is lower (13.62%), although the lifetime prevalence of MDD (25.61%) is higher than international rates (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018; Bantjes, Lochner, et al., 2019). Similarly, Bantjes, Kagee, McGowan, and Steel (2016) reported high rates of depressive

symptoms (measured by the Beck Depression Inventory) among SA university students: 63.4% scored in the Minimally Depressed range; 24.2 % scored in the Mild Depression range; 9% scored in the Moderate Depression range and 3.4% scored in the Severe Depression range.

MDD may appear abruptly or gradually, at any age (Malhi & Mann, 2018). Early onset has been associated with more significant impairment and comorbidity (Zisook et al., 2007). Internationally, the majority (83.1%) of first-year students with a 12-month CMD reported having a pre-matriculation onset (Auerbach et al., 2016). An age of onset for MDD of 14.3 [95% CI (14.1, 14.5)] is reported (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018). Similarly, in SA, the majority of students (84.77%) with a CMD reported a median age of onset for MDD of 15 [95% CI (15.00, 16.00)] (Bantjes, Lochner, et al., 2019).

The majority of first-year university students with a CMD had an onset before entering university. However, the age at which students begin university (18 to 25 years of age, which is known as ‘emerging adulthood’) is a period of psychological transition marked by emotional, educational and social changes and challenges (Prendergast, 1994; Sussman & Arnett, 2014); including difficulty in adjusting and coping to university life (Dyson & Renk, 2006). The lifestyle maintained by most students during this time may lead to a higher risk of disorder onset. This lifestyle includes an increase in experimental substance use, increased levels of interpersonal stress, and irregular sleep patterns (Sussman & Arnett, 2014). This lifestyle might partially explain the disorder onset of 16.9% of students who did not report pre-matriculation onset in the study by Auerbach et al. (2017).

MDD has a variable course and prognosis (Malhi & Mann, 2018). Naturalistic cohort studies from primary care and specialist mental healthcare settings (Penninx et al., 2008; Penninx et al., 2011; Verduijn et al., 2017) found that in a two-year period the median duration of an MDE

is six months, with 79.5% of individuals achieving remission (defined as symptom-free for a period of three consecutive months). Of these individuals, 21.5% experienced a reoccurring episode within a median period of six months from remission (Penninx et al., 2011). Steinert, Hofmann, Kruse and Leichsenring's systematic literature review (2014) suggested that between one-third and two-thirds of patients experience recovery, with between 10% and 17% experiencing a chronic course; the remainder of patients experiencing an intermittent course.

Adverse outcomes associated with MDD among university students

Suicidal ideation is common among university students (Eisenberg, Hunt, & Speer, 2013). MDD has been found to be an important risk factor of suicide ideation among this group (Arria et al., 2009), where between 35.5% and 42.8% of those with suicidal ideation also screen positive for MDD (Eisenberg, Gollust, Golberstein, & Hefner, 2007; Eisenberg et al., 2013). Students with MDD were almost five times more likely to engage in suicidal ideation (odds ratio or OR=4.7; 95% CI [4.0, 5.4]) (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Cuijpers, et al., 2018) Similarly, Bantjes et al. (2016) found that MDD is an important predictor of suicidal ideation among university students in SA.

Internationally, students with internalising mental health problems, such as MDD, had significantly lower academic functioning (on average a 2.9% decrease of their average year percentage) compared to students without these CMDs (Bruffaerts et al., 2018). In SA, controlling for other CMDs, academic failure was associated with MDD (aOR=3.69) and attention deficit hyperactivity disorder (ADHD) (aOR=2.05). Population Attributable Risk analysis suggests that effectively treating MDD and ADHD would yield a 23.0% proportional reduction in the prevalence of academic failure (Bantjes, Saal, et al., 2019).

Internationally, 51.2% of students with 12-month prevalent MDD reported severe role impairment in one or more domains (home management/chores, college-related work, close relationships and social life). Twelve-month prevalent MDD was associated with the highest likelihood of impairment in any domain [(OR=4.0 [95% CI: 3.3, 4.8]). A similar rate (48.6%) was found in SA; the likelihood of impairment in specific domains of those with 12-month prevalent MDD ranged from OR=4.4 (95% CI: 3.4, 5.5) in close personal relationships to OR=2.2 (95% CI: 1.6, 3.0) in home management. Northern Ireland specifically, but also SA and Germany showed a higher likelihood of reporting severe role impairment. The reasons for this remain unclear (Alonso, Mortier, et al., 2018).

Treatment gap among university students: barriers to effective treatments

The high prevalence rates and deleterious outcomes associated with MDD mentioned above (Alonso, Vilagut, et al., 2018; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018; Bruffaerts et al., 2018) highlight the need to provide accessible and well-resourced student counselling services which provide evidence-based treatments for CMDs (Bantjes, Lochner, et al., 2019). However, a large proportion (83.6%) of university students with CMDs do not receive treatment; only 16.4% of these students received minimally adequate treatment in the past 12 months (Auerbach et al., 2016).

This gap in treatment has been attributed to barriers preventing individuals from seeking and receiving help (Corrigan, 2004; Corrigan, Druss, & Perlick, 2014; Kazdin & Blase, 2011; Mowbray et al., 2006). The stigma associated with mental disorders and seeking treatment is considered one of the common barriers (Corrigan, 2004; Corrigan et al., 2014; Eisenberg, Downs, Golberstein, & Zivin, 2009; Link, Yang, Phelan, & Collins, 2004; Vogel, Wade, & Hackler, 2007). Self-stigma, the internalisation of perceived public stigma, is an important predictor of the

willingness to seek help (Vogel et al., 2007). Furthermore, among university students, self-stigma was significantly and negatively associated with help-seeking, while perceived public stigma was not (Eisenberg et al., 2009).

The traditional model of delivery of mental health services may in itself be a barrier to treatment (Kazdin & Blase, 2011). A model of delivery refers to the various characteristics of how an intervention is administered, in what context, under which circumstances and by whom. The dominant model in psychology follows from a medical patient care model – face-to-face individual patient care – which has a limited reach (Kazdin & Blase, 2011). This is reflected by the number of students who do not receive treatment (Auerbach et al., 2016) and the high prevalence rates of CMDs (38.5% lifetime and 31.4% 12-month), especially MDD (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018; Bantjes, Lochner, et al., 2019). It is argued that this dominant model is unlikely to be a feasible or affordable way to reach a large number of students, address the treatment gap and reduce the burden of mental disorders among students in SA (Bantjes, Lochner, et al., 2019). The critical use of technology may provide the means to overcome the barriers mentioned above and reach a large number of the students in need (Kazdin & Blase, 2011).

The potential for e-interventions to bridge the treatment gap

With internet access and use on the rise, the internet has become part of the daily lives of a large part of the population. In SA, it is expected that the number of smartphone users will reach over 25 million by 2022; every second adult in SA will have access to the internet (Holst, 2019). It was estimated that 21 million South Africans would be able to access the internet by the end of 2018 (Shapshak, 2019). The internet provides anonymity and accessibility, making it highly suitable for offering and receiving help with psychological problems, which opens up new treatment opportunities (Spek et al., 2007). The use of information and communication technology (ICT)

specifically related to the internet, to support and improve mental health conditions and care is generically called e-mental health. Interventions within this field are referred to as e-interventions (Riper et al., 2010). These represent a new way of delivering evidence-based treatments (Berger, 2017; Kazdin & Blase, 2011).

An overview of e-interventions

In e-interventions, the internet is used as a model to deliver an evidence-based treatment protocol through which clients work, relatively independently, either with or without guidance by a therapist or coach (Cuijpers, Kleiboer, Karyotaki & Riper, 2017). E-interventions are defined according to (1) the amount and intensity of contact/support provided during the treatment; (2) the mode of communication used during guidance: asynchronous or synchronous; (3) the specific treatment modality which is delivered; and (4) how the e-intervention is implemented (Berger, 2017). E-interventions are typically defined as guided or unguided self-help interventions (Cuijpers et al., 2017). Berger (2017) also refers to 'internet-based psychotherapies' as a form of e-intervention where the internet is used exclusively as a communication method and the purpose of contact is purely therapeutic. However, in this thesis, when referring to e-interventions, I am not referring to 'internet-based psychotherapies', but rather to the definition given at the start of this section.

In guided e-interventions, the purpose of contact is facilitative and supportive; feedback is aimed at acknowledging and encouraging the client's independent work through the protocol (Berger, 2017; Cuijpers et al., 2017). The amount of support provided in guided e-interventions should be viewed along a continuum as this varies between different interventions (Cuijpers et al., 2017), although the majority of guided e-interventions require minimal therapist or administrative involvement in the form of providing guidance and feedback on homework assignments through

secure e-mail (Andersson, Cuijpers, Carlbring, Riper & Hedman., 2014). The iCare-Prevent intervention used in this study is an example of this.

Studies indicate that e-interventions, primarily guided e-interventions (Spek et al., 2007), appear to be as effective as face-to-face therapy (Andersson et al., 2014; Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018; Cuijpers, Donker, et al., 2011). It is essential to identify the students who are more likely to respond to e-interventions as this would enable clinicians to target this cost-effective treatment at these individuals. This allows more intensive treatments to be reserved for patients who would not respond to e-interventions (Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Ebert, et al., 2018). Screening for MDD is necessary to provide targeted interventions such as e-interventions (Bantjes et al., 2016), although screening is controversial (see Kagee, Tsai, Lund, and Tomlinson, 2013 for a review). To date, no attempts have been made to pilot the use of e-interventions for MDD among university students in SA. It is therefore essential to fill this gap in the literature.

ICare-Prevent: e-intervention used in this study

ICare-Prevent is a trans-diagnostic cognitive behavioural therapy (CBT) based e-intervention (iCBT) for MDD. Trans-diagnostic treatments focus on the psychological processes that are common among disorders, rather than psychological constructs specific to particular disorders (Clark, 2009). iCare-Prevent is based on prior work on e-interventions in diverse samples of adults with MDD (e.g. Buntrock et al., 2015; Buntrock et al., 2016; Ebert et al., 2016) and university students (Weisel et al., 2019). iCare-Prevent (from here on referred to as ‘iCare’), its theoretical underpinnings and its trans-diagnostic features are discussed in more detail in Chapter 3.

The importance of pilot studies

Eldridge, Lancaster, et al. (2016) constructed a conceptual framework to aid in the correct use of the terms 'feasibility study' and 'pilot study'. Their framework states that feasibility studies refer to an overarching concept of all studies done in preparation for a larger randomised control trial (RCT), whereas pilot studies form a specific subset of these studies. These two terms are, therefore, not mutually exclusive (Eldridge, Lancaster, et al., 2016). Similar to feasibility studies, pilot studies assess whether or not something can be done, and if so, whether one should proceed with it and how one should do so. However, pilot studies also include a specific design feature(s) of the intended future RCT, such as the randomisation procedure (Eldridge, Lancaster, et al., 2016). Due to pilot studies' exploratory nature, they represent a crucial stage in the research of novel interventions (Leon, Davis, & Kraemer, 2012) and aim to assist researchers in overcoming commonly faced problems in scaling an intervention. These include the inability to recruit the proposed sample size and excessive attrition due to ill-conceived methods of increasing retention or intolerable procedures. These are common problems which lead to a reduction in the statistical power needed to detect a treatment effect (Altman & Bland, 2005; Leon et al., 2012).

As RCTs tend to be costly, it is vital to consider the feasibility of a treatment before conducting the trial (Anguera, Jordan, Castaneda, Gazzaley, & Areán, 2016; Speich et al., 2018). This is especially true in LMICs such as SA, which have limited financial and human resources (Saxena, Thornicroft, Knapp, & Whiteford, 2007). Since this study will be the first on an e-intervention conducted in SA, a randomised pilot study is needed to evaluate the feasibility of participant recruitment, randomisation and the implementation of iCare within this context. I discuss the strengths and limitations of pilot studies in Chapter 4.

Study aims

This pilot study was designed to test the feasibility of e-treatment for university students reporting moderate or moderately severe symptoms of MDD. University students from Stellenbosch University (SU) were screened for MDD, after which eligible participants were randomised to either iCare or TAU. The study had two primary aims.

1. To assess the key feasibility aspects of iCare, namely:
    a. recruitment,
    b. randomisation, and
    c. implementation (utilisation, retention, the assessment of the outcome measures and the follow-up rates).
2. To investigate the students' experiences of using iCare and document their suggestions on improving iCare and making it more culturally appropriate for use in the SA context.

Overview of thesis

In Chapter 2, I discuss the importance of and issues surrounding the evidence-based practice in psychology (EBPP) in planning a student mental health service. Following this, I provide evidence in support of e-interventions as a means to address the treatment gap among university students. I conclude the chapter with a critique of the use of e-interventions, and I evaluate the advantages and limitations of implementing e-interventions to treat MDD among university students. In Chapter 3, I present iCare. I discuss the theory underlying its development, format and content. I conclude the chapter by examining the evidence in support of iCare. In Chapter 4, I describe the methodology which guided this research and the strengths and limitations thereof. In Chapter 5, I report and discuss the quantitative results of this study. In Chapter 6, I present and discuss the qualitative findings of this study. In both Chapters 5 and 6, I draw on existing literature in e-mental

health to discuss the results. I conclude this thesis with Chapter 7, where I discuss the strengths of and limitations to my research and provide recommendations for future research in the domain of e-interventions in SA.

Conclusion

This chapter highlighted the need for evidence-based treatments for university students in light of the high prevalence rates and deleterious outcomes associated with MDD. It showed that the traditional model of delivery is unlikely to be a feasible or affordable means to address the need among university students. This is reflected in the large proportion of students in need who are not receiving treatment. The chapter concluded by pointing out the means to, and the potential of, exploring alternative models to deliver evidence-based treatments, such as e-interventions, in SA.

CHAPTER 2: Literature review

I begin this literature review with a discussion of the available evidence-based treatments for treating MDD and the implications of the so-called Dodo bird verdict for e-interventions among students. I also critique the methodology used to establish evidence-based treatments and discuss the impact of these critiques. Following this, I provide a clarification of what evidence-based practice in psychology (EBBP) entails, including the need for practice-based evidence (PBE), routine outcome measures, and considering various forms of evidence when planning student counselling services. I then describe the existing literature supporting the use of CBT-based e-interventions (iCBT) for MDD. I conclude the chapter with a critique of the use of e-interventions with regard to (a) the role of the working alliance (WA); (b) their possible adverse effects; and (c) the limitations of their application in the SA context. I conclude this chapter with a discussion of the advantages and potential barriers to implementing e-interventions to address the treatment gap among SA university students.

The need for evidence-based treatments and the EBM

As indicated in Chapter 1, there is a need for effective delivery of evidence-based treatments among university students in light of the high prevalence rates and the harmful impact of MDD. The importance of utilising treatments with a sound evidence base is referred to as the EBPP (Goodheart et al., 2006). EBPP emerged from the evidence-based medicine movement (EBM) (Spring, 2007) and is defined by Sackett, Rosenberg, Gray, Haynes & Richardson (1996) as "…the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research" (p.71).

The EBM argues that the evidence (efficacy results) provided by RCTs (Bower, 2003) should inform the treatments used in practice (Margison et al., 2002). In EBPP (Goodheart et al., 2006), numerous efficacious psychotherapies to treat MDD exist. These are called empirically supported therapies (ESTs) (Chambless & Ollendick, 2001) or evidence-based psychotherapies (Kazdin, 2014).

Evaluating the use of ESTs to treat MDD among university students

In Chapter 1 I argued that the traditional model of delivering ESTs is unlikely to be a feasible way to address the treatment gap among university students (Bantjes, Lochner, et al., 2019; Kazdin & Blase, 2011). Furthermore, e-interventions represent a model of delivering ESTs (Kazdin, 2015; Kazdin & Blase, 2011) and not a therapeutic approach in and of itself (Berger, 2017). It is therefore essential to consider the available ESTs that can be delivered through e-interventions. I start this section with a discussion of the available ESTs for treating MDD. Following this, I present the Dodo bird verdict: a debate regarding the most efficacious ESTs in treating MDD. I conclude this section by discussing the implications of this debate for e-interventions.

Over 350 RCTs have been conducted to establish ESTs for treating MDD (Cuijpers, van Straten, Warmerdam, & Andersson, 2008). There are several primary forms of ESTs to treat mild to moderate MDD in adults (Cuijpers, van Straten, Andersson, & van Oppen, 2008). These are: CBT (e.g. Butler, Chapman, Forman, & Beck, 2006; Cuijpers, Berking, et al., 2013), non-directive supportive therapy (e.g. Cuijpers et al., 2012), behavioural activation treatment (e.g. Cuijpers, van Straten, & Warmerdam, 2007a; Ekers, Richards, & Gilbody, 2008), short-term psychodynamic psychotherapy (STPP) (e.g. Driessen et al., 2010; Driessen et al., 2015; Leichsenring, 2001), problem-solving therapy (e.g. Cuijpers, van Straten, & Warmerdam, 2007b; Malouff,

Thorsteinsson, & Schutte, 2007); and interpersonal psychotherapy (e.g. Cuijpers, Geraedts, et al., 2011; De Mello, De Jesus, Bacaltchuk, Verdeli, & Neugebauer, 2005).

The Dodo bird verdict: equally efficacious treatments

The argument that all ESTs are equally efficacious in treating MDD, due to common factors such as the therapeutic alliance (TA), is known as the Dodo bird verdict (Luborsky, 1975). However, there have been those who oppose this verdict, critiquing the methodology used to determine it. For example, Beutler (2002) argued that the Dodo bird verdict has been reached prematurely.

A comprehensive meta-analysis conducted by Cuijpers, van Straten, Andersson et al., (2008) indicated comparable efficacy between CBT, psychodynamic psychotherapy, behavioural activation therapy, problem-solving therapy; and social skills training. However, they found that non-directive supportive counselling was slightly less efficacious than the other ESTs in treating MDD (d=-0.13; 95% CI [-0.24, -0.03]), while interpersonal therapy was slightly more efficacious (d=0.20; 95% CI [0.02, 0.38]), concluding that CBT was not more efficacious than other ESTs (Cuijpers, van Straten, Andersson et al., 2008) as was argued by others (e.g. Dobson, 2005). These authors and others (Barth et al., 2013) have pointed to the methodological limitations of this meta-analysis. Firstly, not all of the studies were of optimal quality (Cuijpers, van Straten, Andersson et al., 2008). Secondly, they had to pool the studies comparing interpersonal and psychodynamic therapies, as only a limited number of studies with within-study comparisons of these therapies were available. This complicated the results of the meta-analysis, as the pooled comparator interventions consisted of different ESTs (Barth et al., 2013).

Barth et al. (2013) attempted to overcome these methodological issues by conducting a network meta-analysis, also referred to as a mixed trail comparison (MTC) meta-analysis (Lu & Ades, 2004). Similarly to Cuijpers, van Straten, Andersson, et al. (2008), they found that most

major forms of ESTs had comparable efficacy, with small non-significant differences ranging from d=0.01 to d=-0.31 (Barth et al., 2013). However, supportive therapy was significantly less efficacious than interpersonal therapy (d=-0.30; 95% CI [-0.54, -0.05]). Most of the ESTs were more beneficial than TAU (d=-0.29 to d=-0.59), except for social skills training. However, comparing ESTs to TAU is not without its limitations (Freedland, Mohr, Davidson, & Schwartz, 2011; Kazdin, 2014), as will be discussed later. Thus, the majority of ESTs for MDD, as analysed in this network meta-analysis, had comparable moderate-to-large effects, and the relative differences between these ESTs were small (Barth et al., 2013). CBT was not more efficacious than other ESTs, as only small and non-significant ESs were found between CBT and interpersonal therapy (d=-0.14; 95% CI [-0.03, 0.07]), CBT and behavioural activation (d=-0.02; 95% CI [-0.29, 0.25]), CBT and supportive counselling (d=-0.13; 95% CI [-0.30, 0.03]), CBT and psychodynamic psychotherapy (d=-0.22; 95% CI [-0.59, 0.06]), CBT and social skills training (d=0.11; 95% CI [-0.66, 0.84]); and CBT and problem-solving therapy (d=-0.02; 95% CI [-0.50, 0.36]) (Barth et al., 2013).

Similarly, Cuijpers, Berking, et al. (2013) found that CBT was not more or less efficacious than non-directive supportive therapy (g=0.1; 95% CI [-0.06, 0.25]), behavioural activation (g=-0.02; 95% CI [-0.25; 0.21]), psychodynamic psychotherapy (g=0.25; 95% CI [-0.07, 0.58]), interpersonal psychotherapy (g=-0.09; 95% CI [-0.39, 0.02]), or problem-solving therapy (g=-0.13; 95% CI [-0.39, 0.13]). In contrast, Goldstone (2017) found that CBT and Short-Term Psychodynamic Psychotherapy (STPP) are the most efficacious forms of therapy, although equally efficacious for treating MDD. Thus, in line with Barth et al. (2013), Cuijpers, Berking, et al. (2013) and Cuijpers, van Straten, Andersson, et al (2008), CBT is not more efficacious than other forms of psychotherapy. Furthermore, it has been argued that providing any of the main ESTs to treat

MDD over and above TAU could lead to an improvement in remission and response rates, although small (14%) (Cuijpers et al., 2014). Despite the popularity of CBT in treating MDD (Andersson, 2018; Andersson & Cuijpers, 2009; Johansson & Andersson, 2012; Schröder, Berger, Westermann, Klein, & Moritz, 2016), CBT is therefore not more or less efficacious than other ESTs (Barth et al., 2013; Cuijpers, Berking, et al., 2013; Cuijpers, van Straten, Andersson et al., 2008).

The Dodo bird verdict: implications for e-interventions among university students

Cuijpers et al. (2016) found that ESTs used to treat MDD among university students (pooled overall effect size: g=0.89; 95% CI [0.66, 1.11]) showed comparable efficacy to those used in adult populations (pooled overall effect size: g=0.79; 95% CI [0.69, 0.88]) and did not differ significantly (p=0.38). Therefore, various ESTs developed for adults can be used among students (Cuijpers et al., 2016) and delivered through e-interventions. For example, e-interventions based on psychodynamic and interpersonal psychotherapy have been developed and tested (Andersson, Paxling, Roch-Norlund, et al., 2012; Donker et al., 2013).

However, specific subgroups may benefit more from or prefer particular equally efficacious ESTs over others, which is known as differential efficacy (Driessen et al., 2016). Driessen et al. (2016) found that short-term psychodynamic supportive psychotherapy (SPSP) was more efficacious among patients who reported having a depressive episode for a year or longer. Also, they received antidepressant medication and psychotherapy (d=-0.31) and had low-baseline comorbid anxiety with moderate symptoms of depression. They only received psychotherapy. On the other hand, CBT was found to be more efficacious if the patient had a depressive episode for less than one year. These findings were observed despite the minimal difference (d=0.04) found between CBT and SPSP in treating MDD in the total sample (Driessen et al., 2016), highlighting

the critical role that moderators, mediators and mechanisms of change play in determining which EST works best for whom and under which conditions. These findings also highlight the limits of efficacy results when generalising to routine clinical practice (Kazdin, 2009, 2014).

Critique of RCT methodology and the implications of efficacy results

RCTs are considered the gold standard for amassing evidence for the efficacy of psychotherapies due to their highly controlled conditions, which minimise threats to internal validity, i.e. ensuring that the difference observed between the intervention and the control group is due to the treatment provided and not as a result of confounding variables (Bower, 2003). However, the RCT design is not without its limitations (Kazdin, 2014; Shean, 2016). There are four main criticisms against the idealisation of RCTs. The first is the sampling practices used. The second is the use of various control groups: (a) the no-treatment and waitlist control groups; (b) the attention placebo and credible procedures control groups; and (c) the treatment as usual (TAU) control groups. Thirdly, there is the use of arbitrary measures, and the selective analysis and reporting of these measures. Finally, there is the evaluation of the data and the criteria used to establish efficacy (Kazdin, 2014; Shean, 2016). In essence, these issues question the generalisability of efficacy results to routine clinical settings, i.e. the 'effectiveness' or 'clinical utility' of these ESTs in regular clinical settings (Barkham & Mellor-Clark, 2003; Bower, 2003; Kazdin, 2014; O'Neal, Jackson, & McDermott, 2014). I discuss each critique below.

RCTs typically use homogenous CMD groups and seldom include comorbid disorders (Shean, 2016). It is argued that ESTs are based on populations which are not representative of those who present to routine clinical settings. This brings into question the generalisability of ESTs to these settings (Westen, Novotny, & Thompson-Brenner, 2004), for example, university mental health services where there are high rates of comorbidity among university students (Alonso,

Vilagut,et al., 2018; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Cuijpers, et al., 2018; Bruffaerts et al., 2018). Various control and comparison groups are used to determine the ESTs (Kazdin, 2014). These include the no-treatment control group, the waitlist control group, the psychoeducation group, and the placebo group (Harrer et al., 2018; Kazdin, 2014). These groups are directly related to the impact of ESTs (Kazdin, 2014). Although essential to managing threats to internal validity, these control conditions may have unintended effects on the outcomes of RCTs (Mohr et al., 2009).

ESTs are required, at a minimum, to be more efficacious in treating a specific disorder than if the client had received no treatment. In RCTs this is established by comparing the outcome measures of the treatment group to those of the no-treatment control (or waitlist control) group. The randomisation procedure ensures that these groups do not differ on sociodemographic and baseline clinical characteristics. Randomisation also controls for the effects that maturation over time may have on influencing the group differences post-treatment. However, these control groups do not control for common or non-specific factors embedded in all therapies; which may be responsible for the change observed post-treatment (Kazdin, 2014). These factors may include the client's expectancy of or belief in the treatment, and a clear explanation of the client's presented difficulties, i.e. the working alliance (WA) or therapeutic alliance (TA) between the therapist and the client (Horvath, Del Re, Flückiger, & Symonds, 2011). Thus, no-treatment control or waitlist control groups indicate efficacy, although they cannot conclude whether the efficaciousness observed is a result of specific facets of the treatment, non-specific treatment factors, or a combination of both (Kazdin, 2014).

Attention placebo control groups (in which participants engage in some procedures) aim to address the role of expectancies and non-specific treatment factors (Kazdin, 2014). However,

in contrast to medical research, placebos used in psychotherapeutic research are not identical in procedures or appearance to the treatment provided. It is therefore possible that this might lead to differential expectancies of the treatment and attention-control group. Thus, post-treatment group differences might be a reflection of differential expectancies rather than the effect of the treatment provided (Baskin, Tierney, Minami, & Wampold, 2003). The need to control for differential expectancies and the related perceived credibility of the treatment is especially important to establish the mechanisms of change: why and how an EST led to the change observed. However, differential expectancies are seldom assessed or taken into consideration (Kazdin, 2014).

Standard, routine or TAU treatments, referred to as TAU, are often used to evaluate the efficacy of a new or novel treatment compared the available treatments used in the specific setting for the particular problem (Freedland et al., 2011; Kazdin, 2014). TAU has two advantages. Firstly, it is ethically preferred since the control group does receive treatment (compared to no-treatment or waitlist control conditions) and no attention placebo is provided. Secondly, it better controls for differential efficacy than the comparison groups mentioned above, although this needs empirical evidence (Kazdin, 2014). The use of TAU is limited; what is considered to be TAU differs across settings and is specific to the client based on the therapist's judgement (Kazdin, 2014). This problematises the replication and generalisations of these studies and their findings (Mohr et al., 2009). Thus, the difficulty lies in establishing the specific aspect of TAU that was less or more efficacious than the EST in a study, as the TAU is not standardised across settings (Freedland et al., 2011; Kazdin, 2014; Mohr et al., 2009; Wampold et al., 2011).

There are various outcome measures used in RCTs. Selective analysis and reporting of these measures tend to favour the conclusions drawn about the efficacy of the ESTs (De Los Reyes & Kazdin, 2008; Kazdin, 2014). Further, arbitrary metrics refer to the notion that scores on

psychometrically sound outcome measures do not necessarily reflect the functioning of an individual (Blanton & Jaccard, 2006; Kazdin, 2014). An arbitrary metric is therefore an unclear, often ambiguous referent to how a change to a measure reflects the level of functioning within the individual's life (Blanton & Jaccard, 2006; Kazdin, 2014). Qualitative measures, such as self-reported quality-of-life measures (Chambless & Ollendick, 2001), might act as a better non-arbitrary referent to how changes to arbitrary measures reflect in an individual's experiences and functioning (Hill, Chui, & Baumann, 2013).

Statistical significance, effect size and clinical significance are three broad indices that reflect the magnitude of the change observed on the outcome measures (Kazdin, 2014). Statistical significance demonstrates the probability of concluding that an effect exists when it does not; this is typically expressed as $p<0.05$ and is called the type I error rate) (Hickey, Grant, Dunning, & Siepe, 2018). There are various effect sizes (Lakens, 2013). The most commonly reported effect size is Cohen's d (Cohen, 1988), which expresses the size of the effect as the standardised mean difference (Bonett, 2015; Cohen, 1988; Cumming, 2013a). The standardiser is calculated in various ways, as explained in Chapter 4. There is an essential distinction between effect size and clinical significance. Effect size is a statistical concept which does not necessarily equate to clinically meaningful effects that are of practical relevance to the client; it is merely a statistical derivation (Cuijpers et al., 2014; Kazdin, 2014).

Clinically significant indices attempt to reflect to what extent the magnitude of change observed in the outcome measures translates to a practical significance for the client. There are three broad ways to determine clinical significance (Kazdin, 2014). The first is to evaluate whether a participant's post-treatment symptoms are similar to those of a normative sample with pre-specified cut-off scores. However, one should carefully consider the most appropriate normative

sample to use. The second is to determine the Reliable Change Index (RCI) (Jacobson, Roberts, Berns, & McGlinchey, 1999), which evaluates the magnitude of change to an outcome measure while controlling for the imprecision associated with that measure, in order to reliably detect a clinically significant change (Jacobson & Truax, 1991; Lambert & Ogles, 2009). Although the clinical significance indices mentioned provide a more practical evaluation of treatment than effect size, it does not reflect to what extent the difference observed had an impact on the functioning in the client's day-to-day living (Kazdin, 2014). Therefore, a clinical significance index should, thirdly, consider whether or not the client still meets the pre-treatment diagnosis (Kazdin, 2014), specifically whether the client has recovered according to the multi-dimensional approach to recovery (Kazdin, 2014; Whitley & Drake, 2010).

I attempted to show here that establishing ESTs is an invaluable endeavour and that RCTs do provide these results. However, the use of highly controlled conditions, and the reliance on effect sizes instead of clinically significant effects, are problematic and call into question how these findings translate to a practical impact on the client's functioning (Barkham & Mellor-Clark, 2003; Bower, 2003; Kazdin, 2014; Shean, 2016).

Evidence-based practice in psychology (EBPP)

In this section, I provide clarification of evidence-based practice in psychology (EBBP), the need for practice-based evidence (PBE), routine outcome measures, and the importance of considering various forms of evidence when planning student counselling services.

EBPP is defined as "the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences" (Goodheart et al., 2006, p.273). ESTs are an essential part of EBPP; however, there is a misconception that ESTs equate to EBPP (Goodheart et al., 2006; Kagee & Lund, 2012; Spring, 2007). The report of the American

Psychological Association's 2005 Presidential Task Force on Evidence-Based Practice argued that ESTs consider which treatment works best for a specific problem under controlled conditions, whereas EBBP entails a comprehensive decision-making process that focuses on the client and aims to integrate multiple streams of evidence (including relevant RCT results, i.e. efficacy results) to achieve the best outcome for the client (Goodheart et al., 2006). Thus, the use of RCTs to deliver efficacy results to determine ESTs is necessary. However, efficacy results do not provide sufficient results to ensure the best health outcomes for the patient (Bower, 2003). The evidence used in EBPP therefore includes but is not limited to evidence from RCTs (Goodheart et al., 2006).

EBPP therefore also incorporates practice-based evidence (PBE) in the form of effectiveness results generated through systematic outcome studies within routine clinical settings (Bower, 2003). Thus, EBPP is in line Barkham and Mellor-Clark (2003), who argue that EBP and PBE are not competing for paradigms, as was previously thought. This means that RCTs are necessary, although not sufficient, to ensure that the treatments provided in the healthcare setting are shown to improve client outcomes in highly controlled environments. EBP and PBE are therefore two cyclical and complementary research paradigms which jointly provide the best evidence in EBPP, namely to deliver the best outcomes for the client in these uncontrolled settings (Barkham & Mellor-Clark, 2003).

The need for practice-based evidence (PBE)

PBE refers to the collection of useful, quality data within a routine clinical practice setting (Margison et al., 2002). PBE consists of two key components (Barkham & Mellor-Clark, 2003). The first component is effectiveness research, which investigates whether or not efficacious treatments have a beneficial, measurable effect when implemented in uncontrolled settings with diverse populations (Barkham & Mellor-Clark, 2003). Therefore, PBE evaluates the external

validity of ESTs (Barkham & Mellor-Clark, 2003). The second component is practice research, which investigates the provision of and variation in treatments within a service setting, and examines how these findings can be disseminated and implemented (Barkham & Mellor-Clark, 2003). If implemented correctly, therapists will take ownership of this research, viewing it as a way to enhance reflection on their practice in a systematic and non-threatening way (e.g. Lucock et al., 2003).

The use of Routine Outcome Monitoring (ROM) in generating PBE

Routine Outcome Monitoring (ROM) is crucial in generating PBE, incorporating both components of PBE. Advantages of ROM include: (1) enabling the clinician to test the effectiveness of a treatment; and (2) increasing therapist responsiveness in order to assist clinicians in identifying clients at risk of symptom deterioration and treatment failure (Bantjes, Hunt, Tomlinson, & Smit, 2018; Lucock et al., 2003; Margison et al., 2002).

There are, however, challenges to adopting and implementing ROM measures (Bantjes et al., 2018; Lucock et al., 2003). Firstly, clinicians are hesitant to adopt the regular use of ROM measures within their clinical practice (Bantjes et al., 2018; Lucock et al., 2003). Clinicians may view it as burdensome and unrelated to the existing service delivery process. Ownership of and adherence to ROM may be promoted by involving all staff members in ROM from the outset, enabling positive feedback and better implementation (Lucock et al., 2003). Secondly, implementing ROM requires extra staff time (for administration and research), resulting in additional costs (Lucock et al., 2003). However, these costs are necessary and serve as an investment in the development of clinicians and the improvement of mental health service delivery (Lucock et al., 2003). Lastly, ROM will only be of clinical usefulness if it is shown to be reliable and valid for all cultural groups in the SA context (Campbell & Young, 2011). Thus, it is essential

to consider the availability of validated translated versions of the measures for the various indigenous languages (Bantjes et al., 2018).

The use of ROM at SA universities: CORE-OM

The CORE-OM (Clinical Outcomes in Routine Evaluation Outcome Measure) is part of the CORE system (Barkham et al., 1998), where the client and practitioner contribute equally to generating PBE (Barkham, Mellor-Clark, Connell, & Cahill, 2006). The CORE-OM is a self-reporting measure designed to measure psychological distress across four domains, namely subjective well-being, problems/symptoms, functioning, and risk to self and others (Barkham et al., 1998). It was shown to be a valid measure at an SA university (Campbell & Young, 2011). Furthermore, showcases good sensitivity (high- and low-intensity ranges of distress) to change, which is its primary purpose (Barkham et al., 2006; Evans et al., 2002). Therefore, the CORE-OM is recommended (1) as a screening tool; (2) to determine the degree of change in psychological distress experienced by the client following the termination of treatment (Evans et al., 2000); and (3) to evaluate the effectiveness of student counselling services (Campbell & Young, 2011; Young, 2009) – that is, evaluating whether the students who are accessing these counselling services have seen a meaningful improvement in the specific domains in which they experienced psychological distress (Barkham et al., 2006; Connell, Barkham, & Mellor-Clark, 2008). Meaningful improvement is determined using the reliable and clinically significant change model (Jacobson & Truax, 1991); however, clinicians should take into consideration the subjective nature of the CORE-OM; clients can over- or underestimate their symptom severity (Aveline, 2006).

In SA, the CORE-OM has demonstrated acceptable psychometric properties, suggesting that it is a valid measure of gross psychological distress for SA university students (M. M. Campbell & Young, 2011). Overall psychological distress had a Cronbach's α of 0.94. All the

other domains had α=0.75 or higher, except for the risk domain in the non-clinical sample (α=0.73) and the subjective well-being in the non-clinical sample (α=0.70). The clinical cut-off scores were higher for female students, black students and second-language English students across all domains and cut-off scores. These groups had higher non-clinical mean scores compared to the UK sample (Evans et al., 2002). It seems that in light of SA's socio-political history (Young, 2009), certain demographic factors such as ethnicity, sex and language may influence the clinical cut-off scores on the CORE-OM (Campbell & Young, 2011).

Importance of EBPP in planning student mental health services in SA

The findings above indicate that ROM (1) is suitable to university student counselling services; (2) should be validated within the SA context; and (3) can offer the benefits of PBE (Campbell & Young, 2011; Connell et al., 2008). Utilising ROM in SA universities may prove beneficial for four reasons. Firstly, it could assist in training psychologists at university counselling centres in assessing and referring students (Campbell & Young, 2011). Secondly, it could support university counselling centres to quantitatively monitor the degree of therapeutic change concerning specific therapists, particular therapeutic approaches used, and particular clients or population groups (Campbell & Young, 2011). Thirdly, it could decrease symptom deterioration (Lambert et al., 2003). Lastly, it could assist university counselling services in assessing intervention effectiveness (Connell et al., 2008) and in developing more effective interventions (Campbell & Young, 2011), enabling universities to address the high prevalence and burden of CMD, especially MDD, as highlighted in Chapter 1 (Alonso, Vilagut, et al., 2018; Auerbach et al., 2016; Bantjes, Lochner, et al., 2019; Bruffaerts et al., 2018).

Thus, ROM such as CORE-OM can provide clinicians with additional data to evaluate the ESTs in use (Connell et al., 2008), in line with the preferences and characteristics of the student,

to decide on which EST or combination of ESTs will lead to the best outcomes for students (Goodheart et al., 2006; Campbell & Young, 2011). It is this decision-making process that constitutes EBPP (Goodheart et al., 2006), which is especially important in SA for the following two reasons (Kagee & Lund, 2012). In the first instance, SA's mental healthcare system is under-resourced compared to those of certain other countries (Saxena et al., 2007). Therefore, it is essential to ensure the efficient use of the scarce resources available. Secondly, policymakers will only invest in mental healthcare if there is a sound base of evidence indicating that a treatment benefits its clients and is not harmful to them (Kagee & Lund, 2012). Investment in mental healthcare is crucial in light of the large treatment gap (Herman et al., 2009) and neglect of mental health within SA's mental health system; affecting national productivity and individuals' quality of life (Saxena et al., 2007). Below, I present evidence in support of e-interventions as a possible alternative or supplement to address the treatment gap among university students.

Evidence supporting e-interventions

Efficacy and effectiveness of iCBT in treating MDD

CBT is commonly used in e-interventions (when it is referred to as iCBT) to treat MDD (Andersson, 2009; Andersson & Cuijpers, 2009; Andersson & Hedman, 2013), although it is possible to deliver other ESTs through e-interventions (Zwerenz et al., 2017). Numerous meta-analyses have established the efficacy of guided and unguided iCBT in treating symptoms of MDD (Schröder et al., 2016). A meta-analysis of 20 RCTs investigating guided and unguided iCBT for MDD found a large mean within-group effect size of d=0.94 (95% CI [0.77, 1.11]) (Hedman, Ljotsson, & Lindefors, 2012). Andrews, Cuijpers, Craske, McEvoy and Titov (2010) found an overall effect size of g=0.78 (95% CI [0.59, 0.96]) for iCBT in treating MDD, whereas Richards and Richardson's 2012 meta-analysis found an overall pooled effect size of d=0.56 (95% CI [0.41,

0.71]). Guided e-interventions had effect sizes ranging from d=0.58 (95% CI [0.28, 0.88]) for administrative support to d=0.78 (95% CI [0.64, 0.92]) for therapist-supported e-interventions, while unguided e-interventions had an effect size of d=0.36 (95% CI [0.1, 0.61]) (Richards & Richardson, 2012). Similarly, Cuijpers, Donker, et al. (2011) found that unguided e-interventions had a small, but significant effect size (compared to control groups) of d=0.28 (95% CI [0.14, 0.42]; p=0.001). Andersson and Cuijpers (2009) also found that guided and unguided e-interventions for MDD are efficacious, although guided e-interventions are more efficacious (d=0.61; 95% CI [0.45, 0.77]) than unguided (d=0.25; 95% CI [0.14, 0.35]). Furthermore, Titov et al. (2013) found comparable treatment outcomes between clinician-assisted (CA) and technician-assisted (TA) iCBT for MDD. The 11-week post-treatment between-group effect size indicated no difference in the relative efficacy on the PHQ-9 where d=0.07 (95% CI [-0.36, 0.49]) (Titov et al., 2013). The within-group effect size on the PHQ-9 was d=1.60 (mean difference of 6.61; 95% CI [4.95, 8.27]) for the TA group and d=1.54 (mean difference of 5.48; 95% CI [3.75, 7.20]) for the CA group. Furthermore, the effects of the TA group seemed to be more favourable at the four-month post-treatment follow-up with between-group effect size d= 0.46 (95% CI [0.03 to 0.88]) with a mean difference measured by the PHQ-9, of 7.71 (95% CI [6.13, 9.28] (Titov et al., 2013). At the four-month post-treatment follow-up, 66% of the TA group and 43% of the CA group were classified as recovered (based on a 50% reduction of their pre-treatment scores on the PHQ-9). However, 59% of both groups indicated reliable clinical change, defined as a statistically reliable change and at least a 10-point reduction of pre-treatment scores on the BDI-II (Titov et al., 2013).

Guided iCBT appears to be as effective as face-to-face therapy in treating MDD (Andersson et al., 2014; Carlbring et al., 2018). A meta-analysis of 13 RCTs evaluating the relative

efficacy of guided iCBT to face-to-face CBT in treating various somatic and psychiatric disorders found a pooled g=-0.01 (95% CI [-0.13, 0.12]) at post-treatment across all 13 studies, indicating similar overall effects. Equivalent effects of g=0.05 (95% CI [-0.19, 0.30]) were also observed between iCBT and face-to-face CBT in treating depressive symptoms (Andersson et al., 2014). Carlbring et al.'s meta-analysis (2018) also indicated overall equivalent pooled effects between iCBT and face-to-face CBT in treating depressive symptoms (g=-0.02; 95% CI [-0.22, 0.19]) (Carlbring et al., 2018).

A meta-analysis of e-interventions for treating MDD among university students found an overall pooled effect size of g=0.18 (95% CI [0.08, 0.27]) (Harrer et al., 2018). This meta-analysis included studies with varying degrees of guidance and using different techniques (e.g. CBT, third-wave CBT techniques, skills training, etc.). Harrer et al. (2018) found various significant sub-group differences where the effects of e-interventions on students with MDD were significantly higher when: (1) the intervention was iCBT (g=0.28; 95% CI [0.15, 0.40]; p=0.027); (2) the intervention was moderate in length, i.e. four to eight weeks (g=0.31; 95% CI [0.13, 0.49]; p=0.027), which is in line with findings from Richards and Richardson (2012); (3) the intervention made use of online recruitment (g=0.30; 95% CI [0.25, 0.57]; p=0.003); (4) the students were not compensated (g=0.31; 95% CI [0.18, 0.45]; p=0.006); and when (5) the students were preselected based on standardised cut-off scores (g=0.29; 95% CI [0.16, 0.21]; p=0.026) (Harrer et al., 2018). However, their study did not detect significant differences in terms of the guidance provided (p=0.651), which is interesting in light of previous research on the efficacy of guided e-interventions (Andersson & Cuijpers, 2009; Richards & Richardson, 2012). The authors urged caution in interpreting these findings in light of the substantial heterogeneity in some of the analyses conducted; the high risk of publication bias in almost half the studies included; and the

possibility of various prescriptive factors affecting the treatment outcomes of e-interventions among university students that have yet to be established.

Williams and Andrews (2013) investigated the effectiveness of an iCBT for MDD in routine clinical practice among severely depressed individuals and individuals expressing suicidal ideation. Their sample consisted of 359 patients, with symptom severity falling into one of the following categories: (a) 26.5% (n=95) subthreshold range (PHQ9 scores < 9); (b) 26% (n=93) mild; (c) 23% (n=83) moderate; (d) 17% (n=61) severe; and (e) 7.5% (n=27) very severe. A large proportion of patients (54%; n=194) completed all six lessons of the program (the completers), while 32% (n=133) completed at least four lessons (the non-completers), and 15% (n=52) completed between one and three lessons (the drop-outs). Age was the only significant predictor of drop-out (p=<0.001), with younger patients being more likely to drop out (Williams & Andrews, 2013).

iCBT for MDD had medium to large effect sizes for reducing the symptoms of MDD. The completers group had a mean reduction of 5.96 points on the PHQ-9 (d=0.97; 95% CI [0.77, 1.16]). Completers who scored in the severe range and indicated suicidal ideation pre-treatment had a mean reduction of 8.40 points on the PHQ-9 (d=1.49; 95% CI [1.01, 1.96]) and a significant reduction on the PHQ-9 Suicide item (d=1.12; 95% CI [0.64, 1.59]). Lastly, 63% (n=91) of the completers who scored >9 on the PHQ-9 pre-treatment evidenced remission, while 49% (n=71) evidenced recovery (at least a 50% reduction in pre-treatment PHQ-9 scores). A large proportion of 54% (n =77) evidenced a reduction of at least 5 points on the PHQ-9 in addition to a lowering in the depression severity category. Importantly, as shown in an earlier study using this specific iCBT for MDD (Titov et al., 2013), the clinically reliable change was unrelated to the profession of the individual who provided guidance (x^2 (4) = 4.08, p>0.05). These results indicate that iCBT

for MDD can be effective in routine clinical settings for severely depressed individuals and individuals expressing suicidal ideation (Williams & Andrews, 2013).

In line with Harrer et al. (2018), the sufficient evidence in support of the efficacy and effectiveness of iCBT for MDD among adult populations, I would argue that it is essential to establish prescriptive treatment outcome factors among university students, as this might improve the efficacy and effectiveness of iCBT for MDD among the university student population. Similarly, The Royal College of Psychiatrists in the UK recommends that the availability of evidence-based e-interventions among university students should be increased (Royal College of Psychiatrists, 2011).

Critique of e-interventions

In this section I critique e-interventions in terms of (1) the role of the TA in e-interventions; (2) the possible adverse effect of e-interventions; (3) the potential limitations of utilising e-interventions in SA; (4) the cost and likely need for adaption; and (5) the high attrition rates.

Role of the TA in e-interventions

The evidence in support of the efficacy of unguided or minimally guided iCBT (Richards & Richardson, 2012; Williams & Andrews, 2013) brings into question the purpose of the therapeutic alliance (TA) in e-interventions. The TA is broadly defined as the collaboration between the therapist and client, which forms a bond that is thought to be crucial to the effectiveness of the traditional model of face-to-face therapy (Horvath et al., 2011; Horvath & Symonds, 1991; Krupnick et al., 1996; Martin, Garske, & Davis, 2000). The TA is also known as the working alliance (WA) (Andersson, Paxling, Wiwe, et al., 2012); a pan-theoretical concept as defined by Bordin (1979). WA is the empathetic bond formed between the client and the therapist and includes their agreement on the treatment tasks and goals (Bordin, 1979). The WA is a common factor

underlying different types of psychotherapies, and clients' rating of the WA is predictive of psychotherapy outcome (Horvath & Symonds, 1991) in individuals with MDD (Krupnick et al., 1996). The aforementioned has been confirmed in other meta-analytical reviews (e.g. Horvath et al., 2011; Martin et al., 2000).

Therefore, it is essential to establish: (1) whether the WA is present in guided e-interventions for MDD where there is minimal therapist contact; (2) the importance of the WA in the outcome of e-interventions; and (3) the development of the WA in e-interventions. Below, I present studies which aimed to address these points using the working alliance inventory (WAI) or variations thereof (Horvath & Greenberg, 1989) unless otherwise stated. Bordin's (1979) conceptualisation of the WA forms the foundation of the WAI (Horvath & Greenberg, 1989).

Firstly, high WA ratings, comparable to those found in face-to-face CBT for MDD (Preschl, Maercker, & Wagner, 2011), were found in iCBT for MDD (Andersson, Paxling, Roch-Norlund, et al., 2012; Preschl et al., 2011), although these were found to be unrelated to treatment outcomes in GAD (generalised anxiety disorder), SAD (social anxiety disorder) and MDD (Andersson, Paxling, Roch-Norlund, et al., 2012; Preschl et al., 2011). The WA in iCBT for MDD, GAD and SAD could be less important than in traditional face-to-face CBT (Andersson, Paxling, Roch-Norlund, et al., 2012; Preschl et al., 2011), although Meyer et al.'s RCT (2015) of an unguided e-intervention for MDD found a significant correlation of the HAQ-11 (eleven-item Helping Alliance Questionnaire) with pre- to post-treatment PHQ-9 change ($r=0.46$, $p<0.01$) and with pre- to post-treatment PHQ-9 percentage change ($r=0.42$, $p<0.01$). One should, however, be cautious in comparing these results with the studies mentioned above, as they used different measures to determine the WA (WAI and HAQ-11, respectively). Furthermore, higher ratings of the WA in iCBT focusing on other disorders such as obsessive-compulsive disorder (OCD)

(Andersson et al., 2015) and various anxiety disorders (Nordgren, Carlbring, Linna, & Andersson, 2013) predicted better treatment outcomes (Pihlaja et al., 2018).

Findings by Meyer et al. (2015) indicate a possible relationship between the client and the program (Cavanagh & Millings, 2013; Pihlaja et al., 2018). The text provided within the e-intervention may lead the client to perceive agreement on the core aspects of the WA (task, goal, and bond). The client may therefore view the therapist (whom they might regard as having written the self-help texts) as 'present' merely through reading the self-help texts, which could foster a sense of WA (Andersson, Paxling, Norlund, et al., 2012; Richardson, Richards, & Barkham, 2010). This is indicated by the high ratings of the WA even though there is minimal or even no therapist contact, as in the case with Meyer et al. (2015).

Richardson et al. (2010) utilised Cahill et al. (2008) a conceptual framework to determine whether or not it is possible to establish the WA in self-help books for MDD. Cahill et al. (2008) developed a framework that conceptualised the development of an effective WA as a progression through three common processes and associated factors. These factors and processes are: (1) 'establishing a relationship' (empathy, warmth, guidance, negotiation of goals, collaborative framework); (2) 'developing a relationship' (developing a secure base, feedback, responsiveness); and (3) 'maintaining a relationship' (rupture repair, flexibility and responsiveness) (Cahill et al., 2008; Richardson et al., 2010). Barazzone, Cavanagh and Richards (2012) made use of the work by Richardson et al. (2010) and Cahill et al. (2008) to qualitatively determine whether these common processes and factors are present in iCBTs for MDD. They found substantive evidence that iCBTs for MDD contained features to 'establish a relationship'; however, there were fewer features designed to "develop a relationship' and 'maintain a relationship' (Barazzone et al., 2012; Cahill et al., 2008).

The possible adverse effect of e-interventions: symptom deterioration

Ebert et al.'s 2016 meta-analysis indicated low rates of deterioration among participants using guided iCBT for MDD (3.36 %) compared to control conditions (7.6%). Participants in the iCBT were also less likely (OR=0.47; 95% CI [0.29, 0.75]) to experience symptom deterioration as a result of therapy. Rozental, Magnusson, Boettcher, Andersson, and Carlbring's 2016 meta-analysis of iCBT for various disorders found similar results with regards to iCBT (5.8%), whereas control groups were three times more likely to experience deterioration compared to the iCBT group (OR=3.10; 95% CI [2.21, 4.34]). These deterioration rates are comparable to those found in face-to-face psychotherapy in routine clinical settings (Whipple et al., 2003). Lower odds for deterioration in the iCBT group were associated with (a) being in a relationship (OR=0.58; 95% CI [0.35, 0.95]); (b) having at least a university degree (OR=0.54; 95% CI [0.33, 0.88]); and (c) older age (OR=0.78; 95% CI [0.62, 0.98]) (Rozental et al., 2016). Similarly, Ebert et al. (2016) found that individuals with lower levels of education are more likely to experience deterioration when utilising iCBT. Ebert et al. (2016) argued that participants with lower levels of education might have difficulty in applying psychotherapeutic self-help strategies, leading to a sense of hopelessness – although the majority evidenced treatment response and should therefore not be excluded from utilising e-interventions (Ebert et al., 2016). The current study targeted first-year university students; I would argue that education level does not pose such a great risk to this population compared to the general population. One should, however, be aware of the possible negative association between symptom deterioration and level of education.

Possible limitations of utilising e-interventions in SA

Cost and need for adaption

E-interventions are cost-effective (Hedman et al., 2012; Warmerdam, Smit, Van Straten, Riper, & Cuijpers, 2010). However, to date, no e-interventions have been developed or implemented within the SA context. Thus, e-interventions might need to be adapted or translated to the multi-cultural and multi-lingual context of SA. This may impact the cost-effectiveness of the intervention, possibly making it more expensive than utilising existing mental health services. However, once developed, e-interventions can be relatively inexpensive and easy to maintain (Kazdin & Blase, 2011). Although the translation of e-interventions to SA's multilingual context may be necessary, meta-analytical findings from Cuijpers, Karyotaki, Reijnders, Purgato and Barbui (2018) indicate that cultural adaptions may not be a necessity. Their meta-analysis showed that psychotherapies for MDD designed in Western countries were no less effective when used without adaption in non-Western countries. However, they do urge caution in the interpretation of these results, as the descriptions of the non-Western studies they included were brief. These studies may have been adapted even though this was not stated in their short descriptions (Cuijpers et al., 2018).

High attrition rates

Eysenbach (2005, p.1) refers to the high rates of attrition common to e-interventions as 'the law of attrition', and points to the inconsistencies in defining attrition observed in studies on e-interventions, arguing for the use of a more specific definition of attrition, such as that used by Fernandez et al. (2015). Attrition rates seem to be higher in iCBT than in traditional face-to-face CBT (Preschl et al., 2011), and higher in unguided e-interventions (66-74%) than in guided e-interventions (28–38%) (Richards & Richardson, 2012; Spek et al., 2007). A recent meta-analysis found that iCBT for MDD had an attrition rate of 34.2% (95% CI [22.5%, 48.3%]), while

individual face-to-face CBT for MDD had an attrition rate of 25.1% (95% CI [20.6%, 30.2%]) (Fernandez et al., 2015). However, Fernandez et al. (2015) did not report on whether this was for guided or unguided iCBT, and to what extent guidance was provided; they only referred to 'e-therapy'. Mohr, Cuijpers and Lehman (2011) argue that individuals' attrition may be the result of their perceived need for support, which in turn may be influenced by their level of intrinsic motivation. Thus, individuals with higher intrinsic motivation may need less support and be less likely to drop out of e-interventions that are perceived as providing minimal support (Mohr et al., 2011). Johansson, Michel, Andersson and Paxling (2015) proposed a more comprehensive working model of non-adherence based on the individual's experiences of non-adherence to e-interventions. They (Johansson et al., 2015) argue that non-adherence is a result of a mismatch between an individual's situation and their perception of the treatment.

Implementing e-interventions in SA universities

Advantages of implementing e-interventions

E-interventions are easily accessible and available irrespective of time and place (Barak, Hen, Boniel-Nissim, & Shapira, 2008), which could overcome the barrier posed by the stigma associated with CMD and help-seeking (Corrigan, 2004; Corrigan et al., 2014; Gega, Marks, & Mataix-Cols, 2004; Spek et al., 2007). However, weak or non-existent internet connections (Andersson, 2009) and concerns regarding the security of personal information (Yuen, Goetter, Herbert, & Forman, 2012) could moderate this advantage. E-interventions can also be accessed as frequently as needed. The frequency of exposure to CBT sessions is associated with increased effectiveness in treating MDD (Cuijpers, Huibers, Ebert, Koole, & Andersson, 2013). In addition, in line with international mental health trends, e-interventions provide the possibility for task-shifting (Kazdin, 2015; Kazdin & Blase, 2011). Findings by Titov et al. (2013) indicate that

individuals other than mental health professionals (such as MA Psychology students) could be trained to give support to those using e-interventions (for example, as eCoaches in the iCare intervention). E-interventions seem to be evidence-based, cost-effective and low-intensity interventions that could potentially address the treatment gap in mental health services (NICE, 2018; Warmerdam et al., 2010), especially among SA university students.

Potential barriers: attitudes of key stakeholders

The main barrier to implementing e-interventions in routine clinical settings is the attitudes of key stakeholders towards the acceptability of e-interventions (Baumeister et al., 2014; Gun, Titov, & Andrews, 2011; Musiat, Goldstone, & Tarrier, 2014; Topooco et al., 2017). These attitudes, as discussed in more detail below, directly influence the utilisation and implementation of e-interventions (Bennett & Glasgow, 2009). Musiat et al. (2014) argue that the acceptability and subsequent use of e-interventions are likely to be associated with the quality and quantity of information available about e-interventions (Musiat et al., 2014). For example, key stakeholders in European countries with well-integrated e-mental health services were more positive towards iCBT, as they had more knowledge thereof (Topooco et al., 2017). Furthermore, health professionals and laypeople indicated that they would be more likely to utilise e-interventions if more information was available regarding their effectiveness and availability (Gun et al., 2011).

Ebert, Berking, Cuijpers, et al. (2015) found that a short acceptance-facilitating intervention (AFI) in the form of a video, based on the assumptions of the unified theory of acceptance of technology (UTAUT), increased the acceptability of iCBT (Venkatesh, Morris, Davis, & Davis, 2003). This AFI contained information regarding e-interventions for MDD; the researchers found a significant increase in acceptance of iCBT after the AFI was shown [$t(126)=2.10$; $p=0.038$; $d=0.71$; 95% CI [0.09, 2.91]). There was also a significant increase in three

of the four indicators of acceptance proposed by the UTAUT (Venkatesh et al., 2003): performance expectancy ($t(126)=3.32$; $p=0.001$; $d=0.65$); effort expectancy ($t(126)=3.07$; $p=0.003$; $d=0.4$); and facilitating conditions ($t(126)=2.45$; $p=0.016$; $d=0.54$).

Similarly, Mitchell and Gordon (2007) observed significant changes in the attitudes of students towards the credibility of CCBT (median increasing from 13.5% to 20.5%; $z=-3.29$; $p<0.001$; $r=-0.52$); the expectancy of change (median expectancy for change increasing from 40.0% to 60.0%; $z=-3.54$; $p<.001$; $r=-0.56$); and the likelihood of utilising CCBT (median increasing from 40.0% to 80.0%; $z=-3.22$; $p=0.001$; $r=-0.51$). These results indicate the possible benefits of AFIs in increasing the uptake in e-interventions (Ebert, Berking, Cuijpers, et al. 2015) – and possibly in treatment outcome, since Kazdin (2014) argued that expectancy for change might moderate treatment effect. Although the majority of students indicated that they would be more likely to use iCBT, they would prefer to use this in addition to traditional face-to-face services (Mitchell & Gordon, 2007). It does seem that an integrative approach to implementing e-interventions is echoed among patients and clinicians (Topooco et al., 2017), suggesting its use in blended treatment (Mitchell & Gordon, 2007; Topooco et al., 2017; Wilhelmsen et al., 2013) or as a first-step in stepped care (Clark, 2011; Grist & Cavanagh, 2013; Williams & Andrews, 2013). These findings highlight the importance of understanding the preferences for, attitudes towards and experiences of individuals in terms of e-interventions, and the need for qualitative studies to investigate these aspects (Kaltenthaler, Parry, & Beverley, 2004).

Conclusion

In this chapter, I highlighted the need for EBBP to address the high prevalence and burden of CMDs, especially MDD, among SA university students. I showed how iCBT could serve as a complement or alternative to traditional face-to-face therapy for MDD. Thus, it could be a cost-

effective, low-intensity way to address the limitations of SA's mental health services, and more explicitly the treatment MDD among university students. I concluded this chapter by highlighting the advantages of and potential barriers to implementing e-interventions.

CHAPTER 3: iCare intervention

In this chapter, I discuss the theories underlying iCare, namely CBT and trans-diagnostic treatments. I then describe the format and content of iCare, including the role of the eCoach. I conclude the chapter by discussing the evidence in favour of and limitations of iCare.

Overview and principles of CBT

CBT evolved from Aaron Beck's cognitive therapy (CT), initially developed to treat MDD, which aims to address the dysfunctional thinking and beliefs that influence the client's mood and behaviour (Beck, 2011). CBT focuses on these dysfunctional beliefs while incorporating components of behavioural therapy – that is, focusing on changing problematic behaviour characterised by certain psychological disorders (Parker, Roy, & Eyers, 2003).

Beck (2011) identified ten basic tenets of CBT, which are as follows (see also Fenn & Byrne, 2013):

1. The client's cognitions are identified in terms of: (a) core beliefs which are learned early in life and seen as unconditional; (b) dysfunctional assumptions which are rigid, unrealistic and maladaptive conditional rules that people apply to their day-to-day lives; and (c) negative automatic thoughts which are involuntarily activated by certain situations. In people living with MDD, these thoughts evolve around themes of negativity (Fenn & Byrne, 2013).
2. A robust therapeutic alliance is expressed by genuine warmth, empathy, compassion and competence (Beck, 2011).
3. Active participation and collaboration are encouraged, during which the client eventually identifies their dysfunctional thinking through initial guidance by the therapist.

4. Goals are established in behavioural terms, evaluating and responding to the thoughts that interfere with these goals.
5. A strong focus is placed on the client's current problems and specific distressing situations.
6. Relapse prevention is fostered by focusing on psychoeducation.
7. The number of sessions is limited to between six and fourteen.
8. The sessions are highly structured to ease understanding and increase the likelihood of self-therapy after the termination of therapy.
9. Homework assignments are used to equip the client with strategies to identify, evaluate and respond to their dysfunctional thoughts and beliefs, which may include creating hypothetical scenarios where clients can directly test their thinking in specific situations.
10. Various behavioural and problem-solving techniques are used to change thinking, emotional state and behaviour.

An overview of trans-diagnostic treatments

Trans-diagnostic treatments (Clark, 2009) utilise a specific treatment modality, and focus on the core processes and domains of dysfunction (coping, managing stress and maladaptive cognitions) across multiple disorders rather than confining a specific treatment, such as CBT, to a particular disorder, such as MDD (Kazdin, 2015). One such trans-diagnostic treatment is the unified protocol (UP) for emotional disorders, initially described by Barlow, Allen and Choate (2004). The UP is based on CBT and aims to address the commonalities between MDD and symptoms of anxiety (generalised psychological vulnerabilities related to the underlying symptom structure), which take shape in highly negative effect (Clark, 2009).

The UP consists of three principles: (1) to change emotion-based misappraisals of critical life events; (2) to avoid negative emotional triggers; and (3) to change emotionally driven

behaviours (Clark, 2009). There is evidence supporting the efficacy of the UP in treating comorbid symptoms of GAD and MDD, showing significant improvements in clinical severity, daily functioning, levels of positive affect, and an improvement in the general symptoms of both MDD and anxiety (Farchione et al., 2012).

An overview of the iCare intervention

iCare is an individually tailored, trans-diagnostic iCBT accessible on most internet-enabled devices, and has been developed to address the symptoms of and risk factors associated with MDD and GAD, and to strengthen certain protective factors. It is based on previously developed evidence-based iCBT modules for the prevention of MDD (Buntrock et al., 2016), the treatment of MDD (Buntrock et al., 2015, Buntrock et al., 2016; Ebert, Nobis, et al., 2017; Ebert, Cuijpers, Muñoz, & Baumeister, 2017; Nobis et al., 2015), and the targeting of sleeping problems (Ebert, Berking, Thiart, et al. 2015; Ebert, Zarski, et al. 2015; Thiart et al., 2016).

iCare is delivered through MindDistrict (www.minddistrict.com), a configurable and secure online platform offered by an e-health business service provider (Vlaescu, Alasjö, Miloff, Carlbring, & Andersson, 2016). On their first login on MindDistrict, the participant establishes an anonymous username and password. An anonymous eCoach is assigned to the participant. The eCoach provides manualised feedback (through MindDistrict's internal messaging function) on the participant's completed sessions. All communication between the eCoach and the participant takes place through MindDistrict's internal messaging function to ensure anonymity. The eCoach is notified via an email from MindDistrict when the participant posts a message or completes a session. Similarly, a notification email is sent to the participant's preferred email address (defined at user setup) whenever the eCoach posts a message for them on MindDistrict. Additionally, participants receive reminders from the eCoach to complete the weekly sessions and homework

assignments. These assignments are aimed at encouraging participants to practice and integrate what they have learned through the sessions into their daily lives. The ultimate goal is to foster self-help (Weisel et al., 2018; Weisel et al., 2019).

Format of the iCare intervention

iCare has seven primary sessions consisting of student testimonials, audio-video components (e.g. educational video clips), and interactive elements such as exercises and homework assignments. The eighth session is a booster session. Each session takes approximately 45 to 60 minutes to complete and follows a basic format: the content of the specific session is explained, followed by a review of the homework assignments completed in the previous session. The participants can tailor certain content (known as optional modules) to fit their needs (Bolinski et al., 2018).

During this study, participants could choose to complete one to two of the eight optional modules per session; these were available to them from Session 2 to 7. Participants were advised to complete at least one session per week in order to gain access to the subsequent sessions. It was recommended not to do more than two sessions per week, although participants could review each session as frequently as they found useful. Four weeks after completing the seventh session, participants gained access to the booster session (Weisel et al., 2018; Weisel et al., 2019).

Participants also had access to iCare's mobile application (app). This app gave them access to automatic push notifications a number of times a day, containing motivational texts and minor tasks (Bolinski et al., 2018), as well as various diaries where they could track their engagement in positive activities; negative thoughts; sleep hygiene; challenging situations faced; and alcohol consumption (Bolinski et al., 2018).

Content: Sessions and optional modules

Session 1: Behavioural activation (reducing incongruence)

Participants were familiarised with the core components of the sessions, and introduced to goal setting and behavioural activation. They were encouraged to set individual, realistic and concrete goals, and were made aware of the important relationship between values, personal needs and their own well-being. They were also encouraged to plan activities that addressed their unfulfilled needs and core values. An online diary enabled participants to note the difficulties they faced during these activities, and to track their progress towards their goals (Weisel et al., 2018; Weisel et al., 2019).

Session 2: Behavioural activation (overcoming difficulties and scheduling pleasant activities)

Participants were introduced to strategies aimed at overcoming the challenges they experience in implementing the planned activities identified in Session 1. This included strategies for managing avoidance behaviours. This session highlighted the importance of mood-enhancing/mood-stabilising activities, and encouraged participants to plan and engage in their self-selected pleasant activities (Weisel et al., 2018; Weisel et al., 2019).

Session 3: Psychoeducation

Participants received information on MDD and the symptoms of GAD, specifically information on (1) aetiology; (2) criteria for diagnosis; (3) factors responsible for the maintenance of MDD and symptoms of GAD, including the cycles of upkeep; (4) and the risk factors associated with these disorders. They received a prompt to identify their current or previous symptoms. Following this, participants could review detailed information on either MDD, GAD or both. At the end of this session, participants were encouraged to use the information provided to identify the development and course of their symptomatology (Weisel et al., 2018; Weisel et al., 2019).

Session 4: Cognitive restructuring

Session 4 consisted of two parts. First, it explained the relationship between cognition and emotions and introduced a strategy to evaluate this relationship, called a thought record. This required participants to deconstruct situations into three components: (a) the specific situation, (b) their thoughts during that situation, and (3) the consequences of their thoughts during that situation. Participants were invited to apply this to their own experiences, thoughts and emotions. Secondly, participants were introduced to the concept of negative thoughts and encouraged to (1) identify their negative thoughts, (2) critique the basis of these thoughts in reality, and (3) focus on and practice helpful, positive thinking (Weisel et al., 2018; Weisel et al., 2019).

Sessions 5 and 6: Problem-solving or exposure

Participants had the option to choose either MDD-specific or GAD-specific modules. The MDD-specific module focused on teaching and enhancing participants' problem-solving skills. Participants were further introduced to the distinction between solvable and unsolvable problems, and encouraged to apply this distinction to problems they were experiencing. Following this, participants were introduced to a six-step problem-solving plan and invited to apply this plan and reflect on its implementation in the subsequent session (Weisel et al., 2018; Weisel et al., 2019).

The GAD-specific module introduced participants to avoidance and safety behaviours and discussed the benefits of confronting one's fears through exposure. Participants could complete an exercise where they had to identify a fear-inducing situation and evaluate their resulting symptoms of anxiety. Participants were presented with strategies to manage and overcome these symptoms, after which they were prompted to imagine a more intense fear-inducing situation (if they felt that the strategies that were provided had enabled them to manage the previous situation). They were provided with a protocol which aimed to prepare them to deal with their planned fear-inducing

situation. In the subsequent session, participants had to reflect on their implementation of this protocol, identify their safety behaviours, and set up a plan to practice exposure to more fear-inducing situations (Weisel et al., 2018; Weisel et al., 2019).

Session 7: Planning for the future

This session focused on relapse prevention. After brief summaries of each previous session, participants were encouraged to identify which aspects of iCare had assisted them the most. Session 7 encouraged participants to reflect on their progress, and motivated them to plan which strategies they would implement daily in the four weeks until the booster session (Weisel et al., 2018; Weisel et al., 2019).

Session 8: Booster session

Session 8 encouraged participants to reflect on their learning process throughout the use of iCare, including to what extent to they had achieved their personal goals set in Session 1. Participants were prompted to reflect on their current mental health, and received additional support information if needed. The session concluded by encouraging participants to construct a plan to implement the strategies they have learned (Weisel et al., 2018; Weisel et al., 2019).

Optional modules and trans-diagnostic elements

The optional modules consisted of strategies targeted at (a) coping with excessive worrying and reducing rumination, (b) accepting undesirable emotional states, (c) relaxation through progressive muscle relaxation, (d) addressing affect regulation through alcohol consumption, (e) recognising and strengthening feelings of self-worth, (f) perfectionism, (g) appreciation and gratitude, and (h) improving and enhancing sleep hygiene and quality (Weisel et al., 2018; Weisel et al., 2019). This psychoeducation on the predisposing and maintaining factors of symptoms of MDD and GAD,

which targeted common risk factors, highlighted the trans-diagnostic elements of iCare. Participants could also tailor Sessions 5 and 6 to deal with either depressive mood or symptoms of anxiety. The optional modules related to difficulties common to GAD and MDD, and enabled participants to tailor each session to fit their needs at that specific time (Weisel et al., 2018; Weisel et al., 2019).

Role of the eCoach

There were two eCoaches in this study: an MA psychology student and a post-doctoral fellow trained and supervised by a Counselling Psychologist registered with the HPCSA. The training consisted of three parts: (a) theory (e.g. intervention materials), (b) assignments (how to review and tailor comments to completed exercises), and (c) practice. Group supervision was provided each week for reviewing active cases. The eCoaches provided guidance and support in the form of session-specific manualised, pre-formulated standardised text blocks adapted to match the participants' input and progress on the sessions. The eCoaches' feedback was designed to increase retention and therefore primarily of an encouraging nature (e.g. "Great job completing Session 1. Good luck with Session 2."). Participants were also provided with the contact details of campus and other support services in case of a clinical emergency. These contact details were added to the session feedback provided on the MindDistrict platform. eCoaches were advised to spend between 20 and 30 minutes on each individual feedback, thus spending approximately 2.5 hours per student throughout the iCare intervention. eCoaches also sent out email reminders when participants failed to complete a session within seven days, and after that on Day 14 and Day 21 (Weisel et al., 2018; Weisel et al., 2019).

Evidence for and limitations of iCare

Prevention and treatment of MDD

The iCBT modules used in the iCare intervention had been efficacious in reducing sub-threshold symptoms of MDD in a German adult sample, with a large significant difference observed between the intervention (d=1.06; 95% CI [0.86, 1.27]) and the control group (d=0.69; 95% CI [0.49, 0.89]) (Buntrock et al., 2015). Furthermore, these modules were more efficacious than TAU in reducing elevated symptoms of MDD in adults with Type 1 and Type 2 diabetes; a significant between-group effect size of d=0.89 (95% CI [0.64, 1.15]; p=0.001) was found (Nobis et al., 2015). The vast majority (95%; n=121) of participants found these modules satisfactory and would recommend them to others (Nobis et al., 2015). The between-group effects were maintained at the six-month follow-up (d=0.83; 95% CI [0.57, 1.08]). Those in the e-intervention group were more likely to show response (relative risk or RR=2.60; 95% CI [2.01, 3.36]; p=0.0001) and remission (RR=3.36; 95% CI [2.98, 5.44]; p=0.0001) than those in the TAU group (Ebert, Nobis, et al., 2017).

Limitations of iCare

RCTs to evaluate the efficacy and (cost-) effectiveness of iCare is underway (Beecham et al., 2019; Bolinski et al., 2018; Weisel et al., 2018; Weisel et al., 2019). However, to date, no published RCT data on the efficacy of (cost-) effectiveness of iCare in its current form is available (Beecham et al., 2019; Bolinski et al., 2018; Weisel et al., 2018; Weisel et al., 2019). Furthermore, there is no published work on the experiences of individuals utilising iCare. Despite these limitations, preliminary work done by the developers shows promising results of the efficacy and effectiveness of the modules used in iCare to prevent symptoms of depression and treat MDD (Buntrock et al., 2015, Buntrock et al., 2016; Ebert, Nobis, et al., 2017; Nobis et al., 2015).

Conclusion

In this chapter, I presented the theory underlying iCare and discussed its format and content in detail. I highlighted its capability to be tailored (to a certain degree) to fit the needs of each student. I concluded this chapter by indicating that, to date, efficacy and effectiveness data on iCare in its current form is very scarce.

CHAPTER 4: Methodology

In this chapter, I describe the research design and methods used to address the aims of this study, namely:

1. To assess the critical feasibility aspects of iCare, i.e. recruitment, randomisation, and implementation (utilisation, retention, the assessment of the outcome measures and the follow-up rates).
2. To investigate the students' experiences of using iCare, and to document their suggestions for improving iCare to make it more culturally appropriate for use in the SA context.

Ethical approval and institutional permission

This study formed part of an ongoing research project on student mental health (Protocol N13/10/149) and received ethical clearance from the Human Research Ethics Committee (HREC) at Stellenbosch University (HREC Reference M17/10/036; project reference #1788) (see Appendix A and B) I obtained institutional permission to conduct this study at Stellenbosch University (service desk ID: IRPSD-827) (see Appendix C).

Research design

The study was a randomised pilot study (Eldridge, Lancaster, et al., 2016; Leon et al., 2012) implementing a single-group repeated measures design (also called a paired-samples design) (Field, 2013) to assess the feasibility of iCare. It employed quantitative and qualitative methodologies (Bless, Higson-Smith & Sithole, 2013), which I describe in more detail below.

Recruitment of participants

All first-year Stellenbosch University students received an invitation email to complete a voluntary online survey on their current mental health (see Appendix D). Students were presented with an Online Consent Form (OCF) (see Appendix E) at the outset of the survey, which had to be completed before they could start with the survey. The OCF outlined the primary aims of the study, the inclusion and exclusion criteria, as well as participants' rights (e.g. to skip any question, and to withdraw from the study). This survey included the following items (see Appendix F):

(a) Demographic characteristics

(b) Patient Health Questionnaire – 9 items (PHQ-9)

(c) Generalised Anxiety Disorder – 7 items (GAD-7)

(d) EuroQol 5 Dimensions 5 Levels Questionnaire (EQ-5D-5L)

The survey explicitly informed students that based on their survey responses, they may receive an automated follow-up email about different intervention options, and that participation in these interventions would be optional. Thus, responses to this survey were used to assess students' eligibility for inclusion in the study based on the following criteria:

1. Inclusion criteria:

(a) aged 18-25 years

(b) enrolled as a student at Stellenbosch University

(c) English fluency

(d) moderate or moderately severe symptoms of depression:

i. PHQ-9 score 10-14 or

ii. HQ-9 score 15-19 (a PHQ-9 score of ≥10 indicates a probable diagnosis of MDD according to Levis, Benedetti, & Thombs, 2019)

(e) completed OCF

2. Exclusion criteria:

(a) severe symptoms of depression:

i. PHQ-9 score ≥20

(b) suicidality, endorsing option 3 (nearly every day) on item 9 of the PHQ-9 (Thoughts that you would be better off dead or of hurting yourself in some way) (Kroenke, Spitzer, & Williams, 2001)

(c) no internet availability

Students with a PHQ-9 score of ≤ 9 were not included in this study, as their symptoms fell within the normal range (Levis et al., 2019). Eligible students are from here on referred to as participants.

Participants were randomised (using a random number generator according to a ratio of 2:1) to iCare (two-thirds, n=91) and TAU (one-third, n=47). The randomisation ratio aimed to compensate for the expected high drop-out (attrition) rate (Eysenbach, 2005; Fernandez et al., 2015). The current study did not aim to determine the efficacy of iCare compared to TAU, but the inclusion of the TAU group did enable a more realistic evaluation of the feasibility of the recruitment and randomisation procedure (Leon et al., 2012). All participants randomised to iCare received a de-identified, anonymous alphanumeric code (called a study ID) to determine who: (a) provided consent, (b) initiated the intervention, (c) dropped out of iCare, and (d) completed iCare. The TAU group participants received information regarding community-based services, student counselling services, and private practitioners who provide psychological services to university students in the Stellenbosch area (see Appendix G).

Participants randomised to the iCare group received an invitational email (see Appendix H) to partake in iCare. A website link to MindDistrict, embedded in the invitational email, took

participants to iCare's login screen to establish an anonymous account (with an anonymous username, self-configured password and their preferred email to which notifications were sent). Immediately after participants created their anonymous online account, they were presented with the OCF for participation in the intervention (see Appendix I). The OCF outlined: (a) the aim of the research, (b) the risks and benefits of the study, (c) their assurance of confidentiality, and (c) their rights as a participant, including the right to refuse to answer any question, and discontinue participation at any time. Only participants who agreed to the terms outlined in the OCF were able to proceed with iCare and received a PDF copy of this form for their records (through MindDistrict). No obtained information was used without having received the approved OFC.

Ethical considerations: potential risks

(a) Clinical risks. Protection was put in place for students who were at elevated risk of suicide, regardless of whether they were included in the study or not. These measures considered and respected individuals' autonomy to make an informed choice about receiving psychological services, provided that they had sufficient and understandable information and space to make such decisions (Stirrat & Gill, 2018). Students were assessed for elevated risk of suicide at the initial screening, some students subsequently being excluded from the study, as mentioned under the exclusion criteria). iCare participants were also assessed for elevated risk of suicide at one month and three months post-intervention. At the respective post-intervention follow-up assessments, participants were considered to be at elevated risk of suicide if they reported: (1) severe depression (PHQ-9 score ≥20) and/or (2) suicide risk, endorsing option 2 (more than half the days) or option 3 (nearly every day) on item 9 of the PHQ-9 (Thoughts that you would be better off dead or of hurting yourself in some way) (Kroenke & Spitzer, 2001). Participants (at the screening, one-month and three-month post-intervention follow-up assessments) who reported a PHQ-9 score ≥20

received an email (see Appendix J) within 24 hours of completing the screening and/or follow-up assessment, as well as after 48 hours, and again after seven days. This email provided a list of emergency resources tailored to the Stellenbosch University area. Individuals who endorsed option 2 or 3 on item 9 of the PHQ-9 received an automated email (see Appendix K) (a) immediately, (b) 24 hours after, and (c) 48 hours after they endorsed this option.

(b) Discomfort. Both the OCFs (Appendix E and Appendix I) informed participants that they had the right to: (a) refuse to answer any question, and (b) discontinue iCare if they experienced any discomfort. In addition, iCare participants were presented with emergency contact numbers at the end of each session's feedback in case they experienced distress or discomfort.

(c) Privacy. Participants' privacy was ensured through their study ID and the secure, anonymous communication facilitated by the MindDistrict platform. Furthermore, a two-step process was in place if participants provided identifying information through their correspondence with the eCoach. Firstly, the post-doctoral fellow responsible for data management deleted any communication which contained the participant's identifying information. Secondly, participants were reminded that all communication between them and the eCoach would remain anonymous.

Description of participants

Table 1 presents the aggregated sociodemographics and baseline clinical characteristics of the participants (n=138) enrolled in this study. The description of participants at an aggregated level ensures their anonymity and the confidentiality of the information provided during the interviews.

Table 1.
Sociodemographic and baseline clinical characteristics of participants enrolled in the study.

		Total sample	TAU group	iCare group	Finished iCare	Completed post-intervention individual interviews
Number of participants		138	47	91	6	9
Gender (male), %		19.57	27.66	15.38	33.33	33.3
Age (mean, SD, range) [95% CI]		19.07, 1.13, 17-26 [18.9, 19.3]	19.23, 1.43 18-26 [18.8, 19.6]	18.98, 0.93 17-24 [18.8, 19.2]	19.00, 0.89 18-20 [18.1, 19.9][c]	18.89, 1.17, 17-20 [17.99,19.79][c]
Ethnicity, %	Black[a]	44.20	61.70	42.90	33.33	16.70
	White	55.80	53.20	57.10	66.67	83.30
Home language, %	English	52.90	46.80	56.00	66.67	50.00
	Afrikaans	31.20	34.00	29.70	22.22	50.00
	isiXhosa	5.10	8.50	3.30	0.00	0.00
	Other official SA languages	10.90	11.00	0.00	11.11	0.00
Campus, %	Main campus	91.30	95.70	89.00	88.89	83.30
	Tygerberg (Bellville)	8.70	4.30	11.00	11.11	16.70
Type of Accommo-dation, %,	Not living with parent(s)[b]	87.00	87.20	86.80	66.67	50.00
	Living with parent(s)	13.00	12.80	13.20	33.33	50.00
PHQ-9 score (mean, SD, range), [95% CI]	Baseline	14.21, 2.80 10-19, [13.7,14.7]	14.57, 2.73 10-19, [13.8, 15.4]	14.02, 2.84 10-19, [13.4, 14.6]	12.78, 1.99, 10-15, [11.25,14.31][c]	12.67, 2.25 10-15, [10.9,14.5]
GAD-7 score (mean, SD, range), [95% CI]	Baseline	10.46, 4.06, 0-21, [9.8, 11.1]	10.89, 4.44, 3-21 [9.6, 12.2]	10.24, 3.86, 0-21, [9.5, 11.0]	9.33, 3.46, 6-17, [6.67,11.99][c]	9.50, 4.04, 6-17, [6.3, 12.7]

[a] A broad definition of Black to encompass students who identified as Black-African, Indian, and Coloured (an official term used for population classification and census data in SA).

[b] Not living with parents included staying in the following types of accommodation: university residence, private halls of residence/communal blocks, other university accommodation, renting/owned.

[c] The t-statistic used to construct 95% CI as n<30.

Data collection

Quantitative data collection: screening and follow-up assessments

Participants randomised to iCare received one-month and three-month post-intervention follow-up assessments to monitor symptom change. Data obtained from these assessments were used to address the first aim of this study. Participants' utilisation of iCare was tracked and recorded on a Microsoft Excel spreadsheet, using the study ID assigned to them on MindDistrict.

One-month and three-month post-intervention assessments

Only iCare participants received an invitational email (sent four weeks after completion of the booster session) to complete the one-month post-intervention assessment. Three months after the completion of the booster session, iCare participants received an invitational email to complete the three-month post-intervention assessment. These follow-up assessments included:

(a) PHQ-9

(b) GAD-7

(c) EQ-5D-5L

(d) Client satisfaction questionnaire: 8 items (CSQ-8) (only at the one-month post-intervention assessment)

Quantitative data collection measures

These self-report instruments are presented in Appendix C.

(a) *Patient Health Questionnaire – 9 items (PHQ-9).* The PHQ-9 (Kroenke et al., 2001) is a nine-item self-report outcome measure used to screen for depressive symptoms and possible MDD. Item responses are on a Likert scale (coded as 0-3) with total scores ranging from 0 to 27. Symptom severity is classified according to a range of scores: minimal (0-4),

mild (5-9), moderate (10-14), moderately severe (15-19) and severe (≥20) (Kroenke et al., 2001; Spitzer, Kroenke, & Wiliams, 1999). A PHQ-9 score of ≥10 is the standard cut-off score established for a probable diagnosis of MDD (Kroenke et al., 2001; Levis et al., 2019). Although the PHQ-9 has, to date, not been validated among the SA university students, it has shown good reliability and validity elsewhere in SA (Bhana, Rathod, Selohilwe, Kathree, & Petersen, 2015) and among Nigerian university students (Adewuya, Ola, & Afolabi, 2006).

(b) *Generalised Anxiety Disorder scale – 7 items (GAD-7).* The GAD-7 (Spitzer, Kroenke, Williams & Lowe, 2006) is a seven-item self-report outcome measure that has demonstrated good reliability and validity. It is useful in identifying probable GAD and monitoring change across time (Jordan, Shedden-Mora, & Löwe, 2017). It is scored on a Likert scale (coded as 0-3), and total scores range from 0 – 21. Symptom severity is based on GAD-7 score ranges; minimal (0-4), mild (5-9), moderate (10-14) and severe (≥15). A GAD-7 score of ≥10 has been identified as the cut-off score for probable GAD diagnosis, with a specificity of 0.82 and a sensitivity of 0.89 (Spitzer et al., 2006). The GAD-7 scale has been shown to have high internal consistency (α=0.92) (Spitzer et al., 2006), although it yet to be validated among SA university students.

(c) *EuroQol – 5 Dimensions 5 levels (EQ-5D-5L).* Quality of life was measured with the EQ-5D-5L (EuroQol Group, 1990); a widely used self-report questionnaire which measures health-related well-being for clinical and economic appraisals. The EQ-5D-5L consists of five items or dimensions: mobility, self-care, ordinary activities, discomfort, and mood state (related to symptoms of anxiety or depression). Each dimension consists of five levels, ranging from no problems to few and finally to a lot of problems (EuroQol Group, 1990).

EQ-5D-5L's construct validity is adequate; it can detect meaningful changes in patients with anxiety disorders, and it is generally consistent in measuring mood state (symptoms of depression/anxiety) (König et al., 2010).

(d) *Client satisfaction with treatment questionnaire – 8 items (CSQ-8).* This self-report questionnaire consists of eight items (based on a Likert scale and coded as 1-4) with total scores ranging from 8 to 32. Higher scores indicate higher satisfaction with the intervention. The CSQ-8 has been shown to have a high internal consistency (α=0.93) (Attkisson & Zwick, 1982; Larsen, Attkisson, Hargreaves, & Nguyen, 1979) and has been used to evaluate satisfaction with psychotherapy outcomes.

Qualitative data collection: semi-structured individual interviews

To address the second aim of this study, participants randomised to iCare were invited via email (see Appendix L) to take part in a one-on-one semi-structured post-intervention interview. I conducted the interviews at a convenient time for the interviewees in the privacy of an office in one of the main buildings on campus. I met the interviewees outside this building and walked with them to the office. I used this opportunity to build rapport, establish a warm and conversational tone and show a non-judgemental attitude (DiCicco-Bloom & Crabtree, 2006). I adopted this approach to put the interviewees at ease, making it easier for them to share their experiences of using iCare. Upon arrival in the office, I repeated the purpose and confidentiality of the interview. I informed them that the interview would be audio-recorded and transcribed. Once participants gave verbal consent to have the interview audio-recorded, I presented them with an information leaflet, an attached consent form and time to read through this document (Appendix I). Once participants had given written consent, I asked them if they would prefer to be interviewed in English or Afrikaans and then conducted the interview accordingly.

Semi-structured interviews allow for a conversational flow while ensuring that all the topics and sub-topics are covered; resulting in an in-depth exploration and clarification of participants' experiences and ideas (Willig, 2013). I adopted the stance of a 'naïve interviewer' (Willig 2013, p.110); thus, I did not make explicit my role as one of the eCoaches or my knowledge of the iCare platform and content. This ensured that participants gave comprehensive and detailed accounts of their experiences of iCare (Willig, 2013). This approach may also have limited the influence that I, as a researcher, may have had on the data collection. To further enhance the credibility of the data obtained, I employed spot member checking; asking clarifying questions during the interview to ensure correspondence between the data collected and participants' perceived reality (Guba, 1981; Mays & Pope, 2000). The semi-structured interview (see Appendix M) included open-ended questions aimed at neutrality (DiCicco-Bloom & Crabtree, 2006). It included questions on participants' experience of utilising iCare, and on how iCare compared to other mental health services that they may have used. Participants were also prompted to share their suggestions on how to adapt iCare for ongoing use among SA university students. The interviews typically lasted between 30 and 60 minutes and a fading of energy in the interpersonal interaction usually indicated the end of the interview. When I sensed that participants had reached this stage, I took care to conclude the interview. Participants received a R200 gift voucher as compensation for their time.

A priori sample size estimation in pilot studies

A priori sample size estimation is important in designing null hypothesis significance testing (NHST) studies, such as RCTs (Hickey et al., 2018). The power (1-β) of the proposed study, as mentioned in Chapter 2, is the probability of a study detecting a population effect when the effect does exist and is directly proportional to the sample size (Field, 2013; Hickey et al., 2018; O'Keefe,

2007). Power is also related to the type I error rate (α-level) and the size of the population effect (Leon et al., 2012; O'Keefe, 2007). Thus, the smaller the possible population effect size, the more power and subsequently, the larger the sample sizes that are required (everything else being equal) (O'Keefe, 2007).

Inferences about the population are based on the sample (Field, 2013), through constructing confidence intervals (CIs) with a 95% confidence level (CL) (i.e. α-level set at 0.05) around sample estimates or parameters, specifically around the variability (standard error and the standard deviation) of the sample data (Bonett, 2015; Cumming, 2013a; Cumming & Finch, 2001). The width of the CI (also called the precision) reflects how precisely, in this case, the sample effect size captures the potential population effect sizes (Cumming & Finch, 2001; Leon et al., 2012).

Pilot studies are typically associated with small sample sizes (Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006; Leon et al., 2012) where large variability is observed due to the relation between the standard error (SE), standard deviation (SD) and sample size (n) (Altman & Bland, 2005). The large variability will lead to wide CIs, resulting in imprecise estimates of the population effect size; which leads to either an overpowered or an underpowered study when used in sample size estimations for a future RCT (Kraemer et al., 2006; Leon et al., 2012; Vickers, 2003). Therefore, some authors have argued against using pilot studies for NHST to provide preliminary efficacy results of an intervention (Kraemer et al., 2006; Leon et al., 2012). Authors such as Leon et al. (2012) and Kraemer et al. (2006) argue that pilot studies should thus rather focus on evaluating critical aspects of feasibility (screening, recruitment, retention and assessment procedures, such as follow-up rates). These results will inform the design and implementation of subsequent larger RCTs. In light of this, Leon et al. (2012) argue that a priori sample size estimation for pilot studies should be based on pragmatics such as budgetary constraints, rather

than on ensuring a sufficiently powered study to detect a possible population effect size (Leon et al., 2012).

Similarly, Teare et al. (2014) found that studies with a sample size of at least 70 total participants lead to estimates of the SD (for continuous outcomes) with acceptable levels of precision and minimal bias, while a total of at least 60 participants ensures adequate levels of precision and minimal bias in estimating event rates such as utilisation and follow-up (Teare et al., 2014). The estimates obtained from these studies can, therefore, be used in sample size calculations for a larger RCT. As such, this study aimed to recruit a total of at least 70 participants. As shown in Table 1, this study was able to enrol 138 participants, randomising n=91 to iCare and n=47 to TAU.

Quantitative data analysis

Key feasibility aspects

In this section, I discuss the statistical analyses conducted to address the first aim of this study. I also present and discuss the formulas used in the quantitative data analyses in Appendix N. Statistical analyses were performed in SPSS version 25 (2017) unless stated otherwise. I used descriptive statistical analyses to assess: (a) the sociodemographic and clinical characteristics of eligible participants enrolled in the study; (b) participants' self-reported quality of life throughout the study; (c) the iCare completers' satisfaction with iCare; and (d) critical feasibility aspects (see Table 2).

Table 2.
Quantified key feasibility aspects of the iCare study assessed[a].

Key feasibility aspect assessed	Quantified key feasibility aspect
Recruitment rate	$\frac{\text{number of students who completed the screening survey}}{\text{number of students invited to complete the screening survey}} \times 100$
Risk assessment(s)[b]	$\frac{\text{number of participants who met criteria for suicide risk}}{\text{number of participants who completed the respective assessments}} \times 100$
Study enrolment rate	$\frac{\text{number of respondents who met the inclusion criteria}}{\text{number of students who completed the screening survey}} \times 100$
Participation rate: iCare	$\frac{\text{number of participants at each stage of iCare}}{\text{number of participants randomised to iCare}} \times 100$
Utilisation rate: iCare	$\frac{\text{number of participants who completed the respective stage of iCare once started}}{\text{number of participants who began the individual stage of iCare}} \times 100$
(a) Pre-intervention drop-out	$\frac{\text{number of participants who did not start with Session 1 after accepting the invitation to enrol in iCare}}{\text{number of participants who were randomised to iCare and accepted the invitation to enrol in iCare}} \times 100$
(b) During-intervention drop-out	$\frac{\text{number of participants who did not complete iCare after having started Session 1}}{\text{number of participants starting Session 1}} \times 100$
Follow-up rate	$\frac{\text{number of participants randomised to iCare who did not complete the follow-up assessments}}{\text{number of participants randomised to iCare}} \times 100$
Direct cost (per participant per session)	feedback time per participant per session *X* hourly rate paid to eCoaches; where hourly rate[c] $= \frac{R\ 75}{60\ minutes}$

[a] Adapted from Leon, A. C., Davis, L. L., & Kraemer, H. C. (2012). Role and Interpretation of Pilot Studies in Clinical Research. *Journal of Psychiatric Res*earch *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008.

[b] Students were considered to be at risk of suicide if they reported (a) severe depression (PHQ-9 score ≥20) and/or (b) suicide risk (endorsing option 2 (more than half the days) or 3 (nearly every day) on item 9 of the PHQ-9 (Thoughts that you would be better off dead or of hurting yourself in some way) (Kroenke & Spitzer, 1999).

[c] The hourly rate refers to the possible costs of using Masters students (who are typically paid R75/hour for research) as eCoaches.

In addition, I evaluated the feasibility of recruitment, randomisation and participation. Firstly, the feasibility of the recruitment procedure was further assessed using a one-proportion z-test (see N.1 in Appendix N) (Gauvreau, 2006; Zou, Fielding, Silverman, & Tempany, 2003) to determine if the participants enrolled in this study differed significantly ($p<0.05$) (Gauvreau, 2006,

Field, 2013) from the entire university population in terms of the proportion of participants represented in the demographic variables of gender, ethnicity and home language.

Secondly, I assessed the randomisation procedure by determining whether or not the iCare group differed significantly from the TAU group at baseline. I conducted chi-square analyses on the sociodemographic characteristics and baseline quality of life (EQ-5D-5L); comparing the column proportions in the contingency table using a z-test and the associated adjusted p-values. The chi-square test has two critical assumptions. It assumes independence in that each participant should only contribute to one cell in the contingency table (Field, 2013); this assumption was met. The test also assumes that the expected cell counts should be greater than one, and no more than 20% of the cell counts should be less than five (Field, 2013). In the cases where the latter assumption was violated, I reported Fisher's exact test-statistic (FET) and its associated p-value, as suggested by Field (2013).

Furthermore, I conducted independent t-tests to determine if a significant difference existed in the mean baseline PHQ-9 and GAD-7 scores between the iCare and TAU groups. Independent t-tests assume normality and homogeneity of variance. Normality was assessed using converted z-scores (Kim, 2013, p.53; Field, 2013, p.184) (see N.2.1 and N.2.2 in Appendix N). According to Kim (2013), the absolute skewness and excess kurtosis converted z-scores for medium-sized samples ($50 \leq n \leq 300$) should be less than the absolute value of $z=3.29$ for the distribution to be considered normal. Table 3 shows that the data used for the independent t-test was normally distributed and the assumption of normality met (Field, 2013). The assumption of homogeneity of variance was assessed using Levene's test. The non-significant finding of this test on both outcome measures indicates that this assumption was met (Field, 2013).

Table 3.
The assumption of normality assessed using converted z-scores: independent t-test.

Outcome measure (number of participants)	Mean (SD)	Skewness value (SE[a])	*Skewness converted z-score*[b]	Kurtosis value (SE[a])	*Kurtosis converted z-score*[b]
PHQ-9 screening survey (n=138)	14.21 (2.80)	0.049 (0.206)	0.237	-1.226 (0.410)	-2.99
GAD-7 screening survey (n=138)	10.46 (4.06)	0.094 (0.208)	0.451	-0.283 (0.413)	-0.685

[a] Standard error (SE).

[b] If the absolute value of z is less than 3.29, normality can be assumed.

Next, I attempted to determine the sociodemographic and clinical predictors of participation in the different stages of iCare. Due to the small number of events per variable (EPV) (Peduzzi, Concato, Feinstein, & Halford, 1993), the multivariate binary logistic regression model suffered from quasi-complete separation, which led to estimation problems (Field, 2013). Therefore, I conducted univariate binary logistic regression analyses. EPV refers to the acceptable number of events (subjects) in the lowest level of the binary outcome to ensure that the results of the binary logistic regression are accurate (Peduzzi et al., 1993). It is calculated as the number of participants in the level of the binary outcome, with the smallest number of participants divided by the number of independent variables (in this case, one). EPV should be ≥10 to ensure accurate results without estimation problems (Peduzzi et al., 1993). Enrolment (EPV=29), commencement (EPV=7) and completion of iCare (EPV=6) (each coded as yes/no) represented participation in iCare and were used as the dependent variables. The respective sociodemographic and clinical variables were used individually as the independent variables in the univariate binary logistic regression (Field, 2013). Thus, the results of the univariate binary logistic regression on the commencement and completion of iCare, respectively, should not be seen as conclusive, whereas

enrolment in iCare did have an acceptable EPV (Peduzzi et al., 1993). Multicollinearity is only evaluated when two or more continuous independent variables are included in the model; therefore, it was not assessed in the univariate binary logistic regression (Field, 2013). Additionally, I constructed 95% CIs around the participation rates (see N.3 in Appendix N) (Hazra, 2017, p.4127).

Assessment of the outcome measures

This study did reach its minimum recruitment target of at least 70 participants (Teare et al., 2014) (total n=138; iCare n=91 and TAU n=47). Analyses of the primary outcome measures should, therefore, lead to estimates of the SD that will provide acceptable levels of precision and minimal bias (Teare et al., 2014). However, missing data is common in clinical trials, especially in e-mental health research (Blankers, Koeter, & Schippers, 2010; Haukoos & Newgard, 2007). Data missing at follow-up assessments (drop-out attrition) is especially problematic, affecting the conclusions that can be drawn regarding the treatment (Blankers et al., 2010; Eysenbach, 2005; Rubin, 1996). This study had a large proportion of data missing at the one-month (65.9%; n=60) and three-month (71.4%; n=65) post-intervention follow-up assessments. It was, therefore, necessary that missing data be handled appropriately (Blankers et al., 2010; Schafer & Graham, 2002).

Inappropriately handling missing data can lead to a reduction in power and to biased estimates, resulting in invalid conclusions (Collins, Schafer, & Kam, 2001; Haukoos & Newgard, 2007). Therefore, I applied three commonly used approaches to handling missing data in clinical trials. This also acted as a sensitivity analysis to indicate how the missing data may have influenced the results (Sainani, 2010), while giving an overarching view of the impact of iCare. I present here the advantages and limitations of each approach. However, to evaluate the appropriateness of each of these approaches to handling missing data, it is necessary to first discuss two important concepts

in modern missing data theory: patterns of missingness, and mechanisms of missingness (Blankers et al., 2010; Rubin, 1996).

Missing data: patterns and mechanisms

In modern missing data theory, *R* ('missingness') is used as an indicator variable to show what data is present (coded as 1) or missing (coded as 0) for each case on the respective variables in a data set (Graham, 2009; Schafer & Graham, 2002, p.150). A matrix is created using the *R* variables (rows representing the participants, and the columns represent the variables or items) to describe the missing data pattern (Graham, 2009; Rubin & Little, 2019; Schafer & Graham, 2002). *R* has a joint probability distribution, which refers to the probability of a relationship existing between two or more random variables. The missing data pattern aims to capture the statistical relationship between the "missingness" (Graham, 2009; Rubin & Little, 2019; Schafer & Graham, 2002, p.150) and the observed data (Rubin, 1976). The probability distribution of *R* is called the "probabilities of missingness" (Schafer & Graham, 2002, p.151) or the missing data mechanisms (Rubin & Little, 2019; Rubin, 1976; Schafer & Graham, 2002). The various missing data mechanisms, therefore, express the probability of this particular statistical (not causal) relationship between the "missingness" and the observed data (Graham, 2009; Rubin & Little, 2019; Schafer & Graham, 2002, p.150).

Three missing data mechanisms exist: (a) missing at random (MAR); (b) missing completely at random (MCAR); and (b) missing not at random (MNAR) (Graham, 2009; Rubin, 1976; Schafer & Graham, 2002). In MAR, the probability distribution of the "missingness" is dependent on the observed data and not on the variable that contains the missing values itself (Graham, 2009; Rubin, 1976; Schafer & Graham, 2002, p.150; Sinharay, Stern, & Russell, 2001). The "missingness" may, therefore, be more frequent for specific subgroups than others; however,

the information needed to define these subgroups is observed in the data set for all the participants (van Ginkel, Linting, Rippe, & van der Voort, 2019; Schafer & Graham, 2002, p.150). Within MAR, the observed data can be used to control for the missing data, and the remaining "missingness" is entirely random, i.e. not based on the unobserved data (Schafer & Graham, 2002, p.150) Therefore, Graham, (2009, p.553) argues that MAR could also be called 'conditionally missing at random'. In repeated-measures study designs, the MAR assumption will hold when the data is missing due to drop-out attrition (lost to follow-up). Diggle and Kenward (1994, p.50) refer to these as 'random drop-out' (RD), and the missing data depend on any or all observed responses to the outcome measures (baseline PHQ-9 and GAD-7 scores, in this study) before the participants dropped out.

A specific case of MAR is MCAR, where the typical use of 'random' is applicable; the missing data forms a truly random subset of the data (Blankers et al., 2010; Graham, 2009; Rubin & Little, 2019; Schafer & Graham, 2002) and the probability of "missingness" is not dependent on either the observed or the missing (unobserved) data (Graham, 2009; Rubin & Little, 2019; Schafer & Graham, 2002, p.150), hence 'completely random drop-out' (CRD) (Diggle & Kenward, 1994, p.50). Data is MNAR when the "missingness" is dependent on the unobserved data; the data which is missing due to drop-out attrition (Schafer & Graham, 2002, p.150; Diggle & Kenward, 1994). MNAR is also referred to as "non-ignorable missingness" (Graham, 2009, p. 553; Rubin & Little, 2019; Schafer & Graham, 2002), or 'informative drop-out' (ID) (Diggle & Kenward, 1994, p. 50).

As per its definition, it is only possible to empirically test for and verify the MCAR assumption (Baraldi & Enders, 2010; van Ginkel et al., 2019). Thus, when the tests for MCAR (mentioned in the following section) are significant, the assumption of MCAR is rejected, and the

data is either MAR or MNAR (van Ginkel et al., 2019). The unobserved values (the actual missing values) are needed to verify the MAR or MNAR assumption, and therefore, these assumptions cannot be verified (Baraldi & Enders, 2010; Schafer & Graham, 2002). However, it is per definition also possible to provide evidence in support of the plausibility of the MAR assumption, namely by showing that the missing data depends on any or all observed responses to the outcome measures before the participants dropped out (Diggle & Kenward, 1994; Schafer & Graham, 2002). In the following section, I present the statistical tests used to test the MCAR assumption and provide evidence in support of its plausibility.

Independent t-tests (for continuous variables), Little's MCAR test (the omnibus MCAR test for continuous variables) (Little, 1988) and chi-square tests (for categorical variables) can be used to test the MCAR assumption (van Ginkel et al., 2019), although Nicholson, Deboeck, & Howard (2017) argue that independent t-tests are more useful than Little's MCAR test. I therefore used the independent t-test procedure under the missing value analysis (MVA) function in SPSS. Baseline means of participants on the outcome measures (GAD-7 and PHQ-9) were grouped according to the specific indicator variable (automatically created in the MVA by SPSS, where observed data on the outcome measures was coded as 1 and missing data was coded as 0) and subsequently compared to see if the mean baseline scores of participants differ according to whether or not they have missing data at the respective follow-up assessments.

The only significant difference observed was between the baseline PHQ-9 scores and the one-month post-intervention PHQ-9 scores ($p=0.044$). Thus, participants with missing values at the one-month follow-up had higher PHQ-9 mean scores at baseline (14.45 versus 13.19) than those who had completed the one-month post-intervention follow-up. This provides evidence in support of the MAR assumption for the missing PHQ-9 data at the one-month post-intervention

follow-up (Diggle & Kenward, 1994). The MCAR assumption held for the PHQ-9 missing data at the three-month post-intervention follow-up and for the missing data on the GAD-7 at both post-intervention follow-ups, indicated by the non-significant independent t-tests.

Analysis of the primary outcome measures

In the section to follow, I present three commonly used approaches to analysing the primary outcome measures in clinical trials. These are (1) complete case analyses (CCA); (2) intention-to-treat analyses (ITTA); and (3) per-protocol analyses (PPA) (Blankers et al., 2010; Graham, 2009; Haukoos & Newgard, 2007; Rubin & Little, 2019; Salim, Mackinnon, Christensen, & Griffiths, 2008). Following this, I discuss how the amount of missing data and the missing data mechanisms may have influenced the results, commenting on the appropriateness of the respective approaches and specific analyses used under these approaches.

Complete Case Analysis (CCA)

CCA is widely used by statistical software (Graham, 2009; Haukoos & Newgard, 2007; Rubin & Little, 2019). In CCA, only individuals with data at both baseline and all follow-up assessments included in the analyses are analysed, irrespective of whether they adhered to the intervention or not (Ranstam et al., 2012). Thus, CCA 'treats missing data as missing' by utilising 'list-wise deletion' (Graham, 2009). This should only be performed under the MCAR assumption (Salim et al., 2008; Schafer & Graham, 2002). Under this approach, I conducted repeated measures analysis of variance (RM-ANOVA) (Rana, Singhal, & Singh, 2013, Field, 2013) and paired-samples t-tests (Cumming, 2013b; Julious, Campbell, & Altman, 1999, Field, 2013), which I describe below.

(a) RM-ANOVA. This study employed a repeated measures design (also referred to as a within-participant design), where the same participants (iCare group) provided outcome data at

three different time points. I conducted an RM-ANOVA to assess the main effect of change over time to the mean scores of the outcome measures (GAD-7 and PHQ-9) with repeated measures on the time factor (Rana et al, 2013; Field, 2013). RM-ANOVA has two essential assumptions. Firstly, that of normality, which was assessed using converted z-scores (for samples n<50, where a converted z-score <1.96 indicates normality) as recommended by Kim (2013), and is presented in Table 4. The data did not violate the assumption of normality.

Table 4.
The assumption of normality assessed using converted z-scores: CCA RM-ANOVA.

Outcome measure (number of participants)	Mean (SD)	Skewness value (SE[a])	*Skewness converted z-score*[b]	Kurtosis value (SE[a])	*Kurtosis converted z-score*[b]
PHQ-9 at screening (n=19)	12.68 (2.61)	0.830 (0.524)	1.58	-0.536 (1.014)	-0.53
PHQ-9 at one-month post-intervention follow-up (n=19)	9.68 (3.25)	0.001 (0.524)	0.002	-0.738 (1.014)	-0.73
PHQ-9 at three-month post-intervention follow-up (n=19)	10.74 (5.31)	0.147 (0.524)	0.28	-1.236 (1.014)	-1.22
GAD-7 at screening (n=18)	9.17 (3.88)	0.997 (0.536)	1.86	0.041 (1.038)	0.39
GAD-7 at one-month post-intervention follow-up (n=18)	8.78 (4.60)	0.492 (0.536)	0.92	-0.769 (1.038)	-0.74
GAD-7 at three-month post-intervention follow-up (n=18)	8.44 (5.33)	0.302 (0.536)	0.56	(-0.858)	-0.83

[a] Standard error (SE).

[b] If the absolute value of z is less than 1.96, normality can be assumed for samples of n<50 (Kim, 2013).

Secondly, the assumption of sphericity (or circularity, denoted by Ɛ), which asserts that the variances of the differences between the assessment points should be equal (Rana, et al, 2013; Field, 2013). This assumption was assessed in SPSS using Mauchly's test, where a non-significant result confirms the assumption of sphericity, as was the case with this analysis (Field, 2013). The results of Mauchly's test are shown in Table 5. However, in small samples, Mauchly's test lacks sufficient power to detect significant deviations of sphericity (Rana et al., 2013). Various corrections can be applied; however, the most appropriate correction, according to Field (2013), is the Huynh-Feldt correction, as the estimates of sphericity were $Ɛ > 0.75$ (shown in Table 5) (Rana et al., 2013; Field, 2013, p. 548). All RM-ANOVA results reported are based on this correction.

Table 5.
Mauchly's test for sphericity: CCA RM-ANOVA.

					Epsilon		
	Mauchly's W	Df[a]	Approximate chi-square distribution	p-value	Greenhouse-Geisser	Huynh-Feldt	Lower bound
PHQ-9	.758	2	4.716	0.095	.805	.872	.500
GAD-7	.863	2	2.362	0.307	.879	.973	.500

[a] Df = degrees of freedom

I further conducted post hoc comparisons using Sidak's correction (when I detected an overall significant difference) to determine between which specific assessments the significant difference occurred (Rana et al., 2013; Field, 2013). I applied Sidak's correction, as suggested by Field (2013), since Bonferroni's correction is associated with a loss of power, which is especially problematic in light of the small sample size (as seen in Table 4).

In line with the American Psychological Association's Publication Manual (6th edition) (APA, 2010, p. 33), I report the effect sizes for both the main effects and the post hoc comparisons.

Partial eta-squared (η_p^2) is the effect size commonly reported for ANOVAs and RM-ANOVAs. However, η_p^2 can only be compared against effect sizes from studies using the same experimental design, whereas generalised eta-squared (ηG^2) facilitates the comparison of effect sizes between studies with different experimental designs (Bakeman, 2005; Lakens, 2013; Olejnik & Algina, 2003). Both of these effect sizes are, however, biased estimates. Therefore, I also calculated and reported the bias-corrected omega-squared (ω^2) effect size, which is the most appropriate measure of overall effect size for ANOVAs and RM-ANOVAs (Bakeman, 2005; Lakens, 2013; Olejnik & Algina, 2003; Field, 2013). Negative ω^2 can be obtained; however, despite convention to round this to zero, I reported the obtained negative ω^2, as suggested by Okada (2017). The use of multiple effect sizes enables a better understanding of the observed effects (Preacher & Kelley, 2011); therefore, I report all three aforementioned effect sizes for the main RM-ANOVA effects.

Firstly, I calculate generalised eta-squared (ηG^2) using the formula presented in Bakeman (2005) for a single-factor repeated measures design (see N.4 in Appendix N). In light of the importance of CIs (Cumming, 2013b; Cumming & Finch, 2001) and of Lakens' (2013) recommendations, I constructed 90% CIs around generalised eta-squared (ηG^2). 90% CIs always exclude the value of zero when the F-value is statistically significant, whereas 95% CIs do not (Lakens, 2013). Lakens (2013) recommends constructing 90% CIs around partial eta-squared (η_p^2) using Smithson's SPSS script (2001). However, this SPSS script calculates the 90% Cis for eta-squared (η^2), not for partial eta-squared (η_p^2) (Smithson, 2001), as pointed out by Lakens (2013). Yet for RM-ANOVA with a single-factor, eta-squared (η^2) and generalised eta-squared (ηG^2) are equal (Bakeman, 2005). Therefore, I calculated the 90% CIs for generalised eta-squared (ηG^2) using Smithson's script. Secondly, bias-corrected omega-squared (ω^2) was calculated using the formula provided by Field (2013) (see N.5 to N.5.1.3 in Appendix N). I constructed 90% CIs

around the bias-corrected omega-squared ($\boldsymbol{\omega^2}$) using Fidler and Thompson's SPSS script (2001), which was specifically written for use with the SPSS script by Smithson (2001) to construct 90% CIs around the bias-corrected omega-squared ($\boldsymbol{\omega^2}$)(Fidler & Thompson, 2001). These formulae (N.4 and N.5 to N.5.1.3 in Appendix N) utilised the information provided by the SPSS output unless otherwise stated. Partial eta-squared (η_p^2) was also generated using SPSS.

(b) Paired-samples t-test. I conducted a paired-samples t-test for two reasons. Firstly, it is more insightful to evaluate the mean difference in the scores on the respective outcome measures from baseline to (a) one month, and (b) three months post-intervention, respectively, than to evaluate the overall change (Field, 2013). Secondly, only analysing two assessment points at a time ensured that more participants could be included in the analysis (see Table 6). This resulted in a test that is more sensitive to change, delivering more precise estimates of key parameters compared to RM-ANOVA (Cumming, 2013b; Cumming & Finch, 2001; O'Keefe, 2007). The assumption of normality for a paired-samples t-test is based on the differences between the scores at the respective assessment points (Field, 2013). Therefore, I tested the assumption of normality using the same method as with the RM-ANOVA (Kim, 2013) (see Table 6). However, I applied this method to the differences between the scores, which indicated normality. To ensure a robust 95% CI around the mean difference, I applied the bias-corrected and accelerated (BCa) bootstrap method (Field, 2013).

Table 6.
The assumption of normality assessed using converted z-scores: CCA paired-samples t-test.

Outcome measure (number of participants)	Mean (SD)	Skewness value (SE[a])	*Skewnessconverted z-score*[b]	Kurtosis value (SE[a])	*Kurtosisconverted z-score*[b]
PHQ-9 at one-month post-intervention follow-up (n=31)	9.55 (4.86)	0.104 (0.421)	0.247	0.566 (0.821)	0.689
PHQ-9 at three-month post-intervention follow-up (n=26)	11.27 (5.25)	0.031 (0.524)	0.057	0.843 (1.014)	0.831
GAD-7 at one-month post-intervention follow-up (n=30)	8.23 (4.77)	0.418 (0.427)	0.978	0.238 (0.833)	0.285
GAD-7 at three-month post-intervention follow-up (n=25)	9.08 (5.93)	0.659 (0.524)	1.257	0.535 (1.014)	0.527

[a] Standard error (SE).

[b] If the absolute value of z is less than 1.96, normality can be assumed for samples of n<50 (Kim, 2013).

The most commonly reported effect size for t-tests in general is Cohen's d (Cohen, 1988), which expresses the size of the effect as the standardised mean difference (Bonett, 2015; Cumming, 2013b; Cumming & Finch, 2001; Fritz, Morris, & Richler, 2012; Lakens, 2013). There are variations in calculating the standardiser in the formula for Cohen's d which affect the comparability of Cohen's d across study designs and the extent to which inferences can be made about the population parameters (Cumming, 2013b; Cumming & Finch, 2001; Fritz et al., 2012; Lakens, 2013). The most meaningful standardiser (in terms of the specific sample and research design) is not always the most appropriate to use to draw inferences, construct CIs and compare effect size estimates across study designs (Cumming, 2013a; Fritz et al., 2012; Lakens, 2013). Therefore, I employed Cohen's d using two different approaches to calculating the standardiser

(Cohen, 1988). I also constructed the 95% CIs around these two variations of Cohen's d (Cumming, 2013b, 2013a; Cumming & Finch, 2001; Fritz et al., 2012; Lakens, 2013).

The most meaningful standardiser to use in a repeated-measures (paired-samples) design, as in this case, is the standard deviation (SD) of the baseline scores of the respective outcome measures. Thus, before participants were exposed to iCare (Cumming, 2013b, 2013a; Cumming & Finch, 2001; Fritz et al., 2012; Lakens, 2013), the resultant effect size is referred to as Glass' d (Lakens, 2013, Glass et al., 1981), which I calculated along with its associated 95% CIs (see formulae N.6 to N.6.1.1.3 in Appendix N) (Bonett, 2015).

Next, I calculated the average of the pre-post score SDs (SD_{av}) (Cumming, 2013a, 2013b; Cumming & Finch, 2001). This standardiser is preferred when the SDs between the two points differ, but the group sizes are similar or equal. SD_{av} is calculated by averaging the square of the SDs and taking the square root of this value (Cohen, 1988; Keppel & Wickens, 2004). This facilitates the comparison of effect sizes between studies with different designs and is the appropriate standardiser to use when estimating population parameters (Cumming, 2013a, 2013b). In line with Cumming (2013b) and Lakens (2013), I refer to Cohen's d estimated using SD_{av} as Cohen's d_{av} which I calculated with its associated 95% CIs using the formulae in Bonett (2015) (see formulae N.7 to N.7.1.1.3 in Appendix N).

Both these variations of Cohen's d tend to overestimate the population effect size estimate, especially in small samples (Cumming, 2013b; Lakens, 2013). Therefore, it is recommended to correct for this bias using Hedges' correction (Hedges, 1981); the resulting unbiased effect size estimate is Hedges' g or d_{unb} (Cumming, 2013b). I applied Hedges' correction (see formula N.8 in Appendix N) to both the above-calculated variations of Cohen's d and in the use of different

standardisers. I refer to the effect size estimates calculated above as (a) Glass' d_{unb}, and (b) Cohen's d_{avunb}

(c) Appropriateness of the CCA. Firstly, the MAR assumption was shown to be plausible for the PHQ-9 outcome measure at the one-month post-treatment follow-up. However, the CCA only leads to unbiased results under the MCAR assumption (Salim et al., 2008; Schafer & Graham, 2002). Thus, the CCA in the current study would lead to biased results, as only participants with significantly lower PHQ-9 baseline scores were included at this follow-up. This causes an overestimation of the intervention effect (compare Tables 13 and 14 in Chapter 5). Secondly, the CCA leads to a significant loss of statistical power, due to the small number of participants included in the analysis in light of the substantial proportions of missing data (Graham, 2009; Haukoos & Newgard, 2007; van Ginkel et al., 2019). Thirdly, the small number of participants included in the CCA (a maximum of n=31) was less than the suggested n=70 and would lead to bias and imprecise estimates (Teare et al., 2014), in turn leading to an underpowered study (Kraemer et al., 2006; Leon et al., 2012). In light of this, the CCA was not an appropriate analysis to estimate accurate and precise estimates to use for sample size calculations in preparation for a future RCT, as argued by other authors (e.g. Blankers et al., 2010; Kraemer et al., 2006; Leon et al., 2012)

Intention-to-treat analyses using multiple imputations (ITTA-MI)

The use of intention-to-treat analyses (ITTA) is recommended by the CONSORT guidelines (Gupta, 2011; Moher, Schulz, & Altman, 2001). The ITTA is a pragmatic approach which evaluates the effectiveness of an intervention rather than its efficacy (Salim et al., 2008; Schwartz & Lellouch, 1967). As mentioned in Chapter 2, effectiveness reflects the real-world applicability and acceptability of an intervention (Kazdin, 2014). Thus, a highly efficacious intervention

(determined by 'as treated' or per-protocol analysis, discussed separately) may be found not to be effective (Salim et al., 2008; Schwartz & Lellouch, 1967). In ITTA, all randomised participants are included in the analyses, whether or not they have complete outcome data (Little & Yau, 1996; Sainani, 2010). Thus, all participants that were randomised to iCare (n=91) were included in the analyses, irrespective of whether or not they completed the post-intervention follow-up assessments.

Such a scenario, however, requires the correct handling of the data missing due to drop-out attrition (Croy & Novins, 2005; Gupta, 2011; Little & Yau, 1996; Ranstam et al., 2012). The last observation carried forward (LOCF) is most commonly used to handle missing data in ITTA. In LOCF, participants' most recent available data is used to substitute the missing data (Blankers et al., 2010; Little & Yau, 1996; Molenberghs et al., 2004; Ranstam et al., 2012). However, the LOCF method has been criticised for not considering the natural variability in CMDs, thereby introducing bias (Blankers et al., 2010; Molenberghs et al., 2004; Ranstam et al., 2012). Therefore, it is suggested to use multiple imputations (MI). This is considered to be one of the two state-of-the-art methods for properly handling missing data (Schafer & Graham, 2002; van Ginkel et al., 2019) and has been shown to appropriately handle data sets with large proportions (up to 90%) of missing data (Madley-Dowd, Hughes, Tilling, & Heron, 2019). In addition, MI leads to statistically valid results and estimates (Rubin, 1996).

(a) MI and its underlying assumptions

MI has three phases: imputation, analysis and pooling (Baraldi & Enders, 2010; Enders, 2006; van Ginkel et al., 2019), all of which have been automated in statistical software such as SPSS. During imputation, MI generates a specified number of complete data sets, each of which contains different imputed values (Baraldi & Enders, 2010; Enders, 2006). The imputed values are random

samples drawn from a posterior predictive conditional distribution (i.e. from the observed data) (Rubin, 1996; Salim et al., 2008; Schafer, 1997), making the values plausible. They are based on the Data Augmentation (DA) two-step iterative algorithm, which is repeated *m* times, leading to *m* imputed data sets (Baraldi & Enders, 2010; Enders, 2006). The variability between the *m* imputed data sets reflects the uncertainty of the missing values (van Buuren, 2018). Each of the *m* data sets is analysed separately using standard statistical analyses, resulting in multiple unique sets of parameter estimates and standard errors (Baraldi & Enders, 2010; Enders, 2006; Rubin & Little, 2019). These are then pooled into a single set of results using Rubin's (1987) rules (Baraldi & Enders, 2010; Enders, 2006; Rubin & Little, 2019). The combined results ensure unbiased estimates (means and covariances) with correct CIs, while also incorporating the uncertainty of the missing data in the significance tests and standard errors (van Buuren, 2018; van Ginkel et al., 2019). MI assumes a multivariate normal distribution and that data are MAR, although even under MNAR, MI produces less biased estimates than CCA (Schafer, 1997). It also performs well under non-normal distributions (Kleinke, 2017).

(b) The application and evaluation of MI in this study

The Fully Conditional Specification method or FCS, an iterative Markov chain Monte Carlo (MCMC) method (van Buuren, 2018), is a frequently used approach to MI. There are two approaches within the FCS: the regression approach and the predictive mean matching (PMM) approach (Morris, White, & Royston, 2014; van Buuren, 2018; van Ginkel et al., 2019). PMM is a variant of the regression method and randomly imputes a value from a donor (*k)* pool of observed values with similar predictive means (Morris et al., 2014). PMM performs optimally when: (a) the donor pool is $k>10$ (however, in SPSS the default $k=1$ cannot be changed) (Morris et al., 2014); and when (b) no more than 30% of the data has to be imputed (Kleinke, 2017). In light of this, I

used the regression method, specifying the Markov Chain to run n=1000 iterations to ensure that the Markov Chain converges given the substantial proportion of missing data. In specifying the number of imputations (the *m* data sets), one should consider the fraction of missing information (FMI, indicated by γ) (Graham, Olchowski, & Gilreath, 2007; Rubin & Little, 2019; Rubin, 1996). FMI is similar to the amount or proportion of missing data, although it tends to be lower in cases where the variable with missing data is correlated with other variables in the imputation model (Graham et al., 2007). The FMI is used to determine the number of *m* data sets needed to obtain a certain level of relative efficiency, which refers to how precise the MI estimates are compared to estimates from an infinite number of imputed data sets (Graham et al., 2007; Newgard & Haukoos, 2007; Rubin, 1987). Relative efficiency (*RE)* is expressed as follows (Rubin, 1987, p.114):

$$RE = \left(1 + \frac{\gamma}{m}\right)^{-1}$$

The GAD-7 measure at the three-month post-intervention follow-up assessment had the highest proportion of missing data (72.53%; n=65); thus, a (conservative) estimated γ=0.725. With *m*=100, then *RE*=99.28% for the variable with the highest amount of missing data. The number of specified imputed data sets (*m*=100) is in line with suggestions by Bodner (2008) and Graham et al. (2007). The imputation model aims to preserve key aspects of the joint distribution (such as the means, correlates and variances) in the imputed values (Schafer & Graham, 2002). Therefore, the imputation model should contain at least the variables intended for use in the analyses (Schafer, 1997).

Auxiliary variables are variables not used in the analyses, but which are highly correlated with those variables that are used in the analyses (Graham, 2009). Auxiliary variables assist in preserving critical aspects of the joint distribution in the imputed values while providing more support for the MAR assumption, reducing estimation bias due to the possibility of data MNAR

(Graham, 2009). Thus, auxiliary variables are accounted for in the imputed values despite not being included in the subsequent analyses (Graham, 2009; Rubin, 1987, 1996). For this reason, in specifying the imputation model, I made use of a strategy including auxiliary variables (Collins et al., 2001). I evaluated all the sociodemographic and baseline clinical variables (including the scale items) for inclusion in the imputation model. This was done using the chi-square test and independent t-test described earlier (Field, 2013). Variables were included as auxiliary variables if they had a correlation of 0.3 or higher and were significantly associated with the missing data (see Table 7). Higher scores on the baseline scale items were significantly ($p<0.5$) associated with the missing data, specifically the missingness on the total scores of the respective outcome measures at the three-month post-intervention follow-up. Lastly, I constrained the imputed values (a) on the PHQ-9 to a minimum value of 0 and a maximum value of 27; and (b) on the GAD-7 to a minimum value of 0 and a maximum value of 21, to reflect the possible range of the respective scales. I set the number of case and parameter draws to n=1000, ensuring that the imputed values fell within the aforementioned ranges).

(c) The statistical analysis conducted and the appropriateness of the ITTA-MI

I conducted a paired-samples t-test, as explained earlier, and calculated both Glass' d_{unb} and Cohen's d_{avunb} and the associated 95% Cis using formulae N.6.1 to N6.1.1.3 and N.7.1 to N.7.1.1.3 in Appendix N. SPSS version 25 only produces the pooled standard error (SE) and not the standard deviations (SDs) of the respective outcome measures at the follow-up assessments, which were needed to estimate the effect sizes. However, the SDs could be calculated from the sample size and the pooled SE using the formula by Altman and Bland (2005) (see formula N.9 in Appendix N). The resultant SDs were used in formulae N.6.1 to N.6.1.1.3 and N.7.1 to N.7.1.1.3 in Appendix N).

Table 7.
Variables included in the imputation model.

Imputation model for ITTA using MI		
Variables used for analysis	Auxiliary variables	
	Baseline scale item (three-month post-treat-assessment total score missingness associated with)	p-value
Baseline PHQ-9 total scores	PHQ-9 item 1[a] (GAD-7; PHQ-9)	0.033
Baseline GAD-7 total scores	GAD-7 item 3[b] (GAD-7; PHQ-9)	0.025
PHQ-9 one-month post-intervention follow-up total scores	GAD-7 item 6[c] (PHQ-9)	0.016
GAD-7 one-month post-intervention follow-up total scores		
PHQ-9 three-month post-intervention follow-up total scores		
GAD-7 three-month post-intervention follow-up total scores		

[a] PHQ-9 item 1: "*Little interest or pleasure in doing things*."
[b] GAD-7 item 3: "*Worrying too much about different things*."
[c] GAD-7 item 6: "*Becoming easily annoyed or irritable*."

The ITTA-MI ensured that n=91 participants could be included in the analysis, hence a more powerful test than the CCA (n=31) (Collins et al., 2001; Graham, 2009; Haukoos & Newgard, 2007; Newgard & Haukoos, 2007; van Ginkel et al., 2019). In addition, this resulted in a sufficient number of participants (n>70) to ensure precise and minimally biased estimates, which could be used to conduct sample size estimations to scale a future RCT (Teare et al., 2014). I identified variables that provided support for the plausibility of the MAR assumption, subsequently including these variables in the imputation model. This resulted in increased efficiency of the imputation model and subsequent analysis to produce precise estimates (Graham et al., 2007; Newgard & Haukoos, 2007; Rubin, 1987). Table 8 presents the proportion of missing data for each respective outcome measure, the FMI (γ), the auxiliary variables, and the relative efficiency (RE) of the respective outcome measures (Graham et al., 2007; Newgard & Haukoos, 2007; Rubin, 1987).

Table 8.
The performance of the MI model in producing precise estimates in light of the proportion of missing data and the FMI (γ).

Outcome measures at each respective follow-up assessment	Proportion of missing data (n)	FMI (γ)[a]	Relative efficiency (RE)
PHQ-9 one-month post-intervention	65.93 (n=60)	0.615	0.994
PHQ-9 three-months post-intervention	71.43 (n=65)	0.658	0.993
GAD-7 one-month post-intervention	67.03 (n=61)	0.595	0.994
GAD-7 three-months post-intervention	72.53 (n=66)	0.683	0.993

[a] Calculated by SPSS version 25, taking the auxiliary variables into consideration.

I used the results and estimates obtained through the ITTA-MI in sample size estimations to scale iCare to a larger RCT.

Per Protocol analysis (PPA): indication of the efficacy of iCare

The PPA reflects the efficacy of an intervention as it only uses complete data from participants who adhered to the intervention (Salim et al., 2008). Only six participants completed iCare. Thus, a valid statistical analysis to draw conclusions regarding iCare's efficacy could not be conducted; too few participants were present. However, it was still useful to get an indication of iCare's possible efficacy. Therefore, I compared the respective PHQ-9 outcome assessments of the iCare completers with the criteria established by McMillan, Gilbody, and Richards (2010) for successful treatment outcome. This outcome is defined as Reliable and Clinically Significant Change (RCSC) and is based on the Reliable Change Index (RCI) developed by Jacobson et al., (1999) and Jacobson and Truax (1991). RCSC on the PHQ-9 occurred when individuals moved from a pre-intervention PHQ-9 score of ≥10 to a post-intervention score of ≤9 with a change of ≥5 points. Deterioration occurred when the pre-intervention score increased by ≥5 points (McMillan et al., 2010). Participants included in this study had a PHQ-9 score range of 10-19 points. To meet the

criteria set by McMillan et al. (2010), participants would need to have a mean PHQ-9 score change of either 5 or 10 points.

Sample size estimation for scaling iCare to an RCT

Safeguard power analysis

RCTs are often underpowered due to the overestimation of the effect sizes on which the sample size estimations are based (Perugini, Gallucci, & Costantini, 2014; Vickers, 2003). The safeguard power analysis aims to provide a certain level (80%) of protection against this. It uses the lower bound of the 60% two-tailed CI of the sample effect size to determine the sample size needed for a future RCT (Perugini et al., 2014). The resultant sample size estimates will ensure a sufficiently powered study (thus the power of 0.8) at least 80% of the time (Perugini et al., 2014).

I constructed 60% CIs around Cohen's d_{avunb}, calculated for the PHQ-9 at the respective follow-up assessments in the ITTA-MI. I did this by substituting the two-sided critical z-value for the 95% CIs ($z_{\alpha/2} = 1.96$) with the two-sided critical z-value for the 60% CIs ($z_{\alpha/2} = 0.841$) (Hickey et al., 2018) in formulae N.6.1.1.3 and N.7.1.1.3 respectively (see Appendix N). I then used the lower bound of the 60% CI as the effect size in the sample size estimations of a paired design, as used in this study (Julious et al., 1999; see formula N.10 in Appendix N); and an independent-group design (Campbell, Julious, & Altman, 1995; see formulae N.11 and N.11.1 in Appendix N). The safeguard power analysis is a very conservative approach, especially when based on a sample with n≤400 and Cohen's d≤0.8 (as in this study). In these cases, the power observed by using the estimated sample size (power set at 0.8 and alpha at 0.05) is above 0.9 and often close to 1.0 (Perugini et al., 2014).

Minimal clinically significant effect sample size estimation

Some authors such as Leon, Davis and Kraemer (2012) and Kazdin (2014) advocate the use of the minimal clinically significant effect. Furthermore, it has been shown that the ITTA-MI produces precise estimates with minimal bias (Rubin & Little, 2019; Rubin, 1987; Schafer & Graham, 2002; Teare et al., 2014; van Ginkel et al., 2019) Using the suggestions by Leon et al. (2012) and the criteria established by McMillan et al. (2010) for RCSC on the PHQ-9, I calculated the minimal clinically significant effect at the respective post-intervention follow-up assessments (see N.12 in Appendix N).

Teare et al. (2014) found that sample size estimations (with α set at 0.05 and power at 0.9) based on estimates obtained from a pilot study with $n \geq 70$ will ensure a sufficiently powered study (i.e. with a true power of at least 0.8) to detect a Cohen's d_{avunb} of 0.5 90% of the time. Therefore, I conducted a minimal clinically significant sample size estimation for an independent group design (see formulae N.13 and N.13.1 in Appendix N) using the SDs from the ITTA-MI (see formula N.9 in Appendix N) and the clinically meaningful effects calculated using formula N.12 (see Appendix N).

Qualitative data analysis

To conclude this chapter, I discuss how qualitative data was analysed in this study. In light of the novelty of e-interventions in SA and the exploratory nature of pilot studies (Leon et al., 2012), I conducted a thematic analysis (TA) on the transcribed interviews using a data-driven (inductive) approach, based on the six phases of TA outlined by Braun & Clark, (2006, p.36), which I discuss below.

1. Familiarising yourself with the data. I transcribed the majority of the interviews myself, which enabled me to re-familiarise myself with the data. For the same reason, as well as to ensure the accuracy of the transcriptions, I listened to the audio-recordings while reading through the interviews that I did not transcribe personally. I grouped the transcribed interviews into iCare completers, and participants who started iCare but did not complete all eight sessions. I re-read the interviews of the participants in each group to get a better sense of the experiences that may be specific to their group. I made use of memos during this process to note my initial reflections on the data and keep track of possible themes in each group (Willig, 2013). To ensure that the TA was data-driven, I refrained from engaging in the literature regarding individuals' experiences of e-intervention until after I had analysed the transcribed interviews and defined the themes.

2. Generating initial codes. I coded the transcribed interviews of the respective groups separately in Atlas.ti[1]. I used open, line-by-line coding to ensure that I gave equal attention to each data item in a thorough, comprehensive and inclusive coding process (Braun & Clark, 2006). I compared the codes of each individual transcribed interview with other participants in the respective group. This enabled me to immerse myself in the data and get a better sense of the possible themes within these individual groups.

3. Searching for themes. I analysed the generated codes to see how these codes could be combined to form a coherent pattern, within individual transcribed interviews as well as

[1] Version 7.5.18, Copyright © 2013-2019 ATLAS.ti Scientific Software Development GmbH.

within the respective groups. This resulted in the preliminary overarching themes for the respective groups.

4. *Reviewing themes.* I re-evaluated the ordering of the generated codes from the previous phase to see if it formed a logical pattern for each individual transcribed interview. Following this, I proceeded to evaluate these themes across participants to ensure that the themes generated in the previous phase reflected the data set as a whole. To aid in this, I made use of the memos and notes that I took in the first phase of TA. This enabled me to construct a thematic map for each of the respective groups, which highlighted the relationships between the identified themes and the data of each group as a whole.

5. Defining and naming themes. In generating the thematic maps, I saw a significant overlap between the two respective groups. Therefore I refined the themes to represent both groups as a whole, where appropriate, while retaining themes that were specific to each respective group. I did this to ensure that the identified themes captured the essence of the data set as a whole, without compromising the uniqueness of the respective groups. Following this, I defined and named the resultant themes and sub-themes.

6. Producing the report. I identified compelling extracts that were representative of the core themes and sub-themes. I included data from all nine interviews to ensure that no bias was shown towards or against any participant in terms of their experiences of and suggestions to improve iCare. I present these extracts in Chapter 6.

Conclusion

In this chapter, I presented and discussed the methodologies used in this study. I quantified the key feasibility aspects, highlighted the limitations of pilot studies, and evaluated commonly used approaches to assessing outcome measures in e-mental health in light of the 'law of attrition' (Eysenbach, 2005, p.1). In addition, I presented the TA technique that was used to approach the qualitative data analysis inductively.

CHAPTER 5: Quantitative results and discussion

In this chapter, I present the recruitment and enrolment rates and an evaluation of the randomisation procedure. Following this, I present the utilisation and adherence rates to the iCare intervention, including a preliminary analysis of predictors of enrolment, commencement and completion of iCare. The results of three commonly used approaches to analysing outcome data in clinical trials are presented, after which I discuss sample size estimations based on safeguard power analysis and the minimal clinically significant effect. I explain the direct costs of this pilot study and the potential direct costs of the larger RCT. I conclude with a discussion of the implications of these results and present suggestions to improve the feasibility of a scaled iCare RCT.

Recruitment and enrolment

A total of 5094 first-year university students received an invitational email to complete the online mental health survey; which was opened by 20.46% (n=1042) of the students. However, only 10.80% (n=551) completed the survey. Of the students who completed the survey, 3.53% (n=180) did not provide a valid email address, thus only 7.28% (n=371) of the students invited to complete the survey could be considered for enrolment in the study. Of these, 20.23% (n=75) were identified to be at elevated risk of suicide and were sent emails giving them details of campus counselling and crisis services and urging them to seek professional assistance. Therefore, only 138 students met the inclusion criteria. Two-thirds of these participants were randomised to iCare (n=91) and one-third to TAU (n=47). Participants randomised to iCare received an email giving them feedback on their screening results and inviting them to the iCare intervention; 31.87% (n=29) of whom indicated their intention to take up iCare. The recruitment and enrolment process is summarised in Figure 1 (based on Eldridge, Chan, et al., 2016).

Sample characteristics

The demographic characteristics of the participants enrolled in the study (n=138, enrolment rate 37.20%) are shown in Table 9, alongside the demographic characteristics of the university student population ("Statistical Profile", 2019). The one-proportion z-tests (Table 9) indicate that male students were significantly under-represented in this study (19.57% versus 45.29%; p=0.001), while female students were over-represented (77.54% versus 54.70%; p=0.001). Participants whose home languages were not English, Afrikaans or isiXhosa were also over-represented (10.9% versus 6.4%; p=0.03). Table 10 shows the sociodemographic information and baseline scores on the clinical variables of all participants (n=138) at each stage of the study. The sample subject was on average 19.07 years old (SD 1.13; range 17-26) and the majority self-identified as female (77.54%; n=107), White (55.80%; n=77) and English-speaking (52.90%; n=73). At baseline, participants had an average PHQ-9 score of 14.02 (SD 2.84; range 10-19), and an average GAD-7 score of 10.46 (SD 4.06; range=0-21). Participants' self-reported quality of life (see Figure 2) indicated that the majority of participants (44.20%; n=61) reported some difficulty engaging in their usual daily activities, such as working or studying; and feeling moderately anxious and/or depressed (40.58%; n=56).

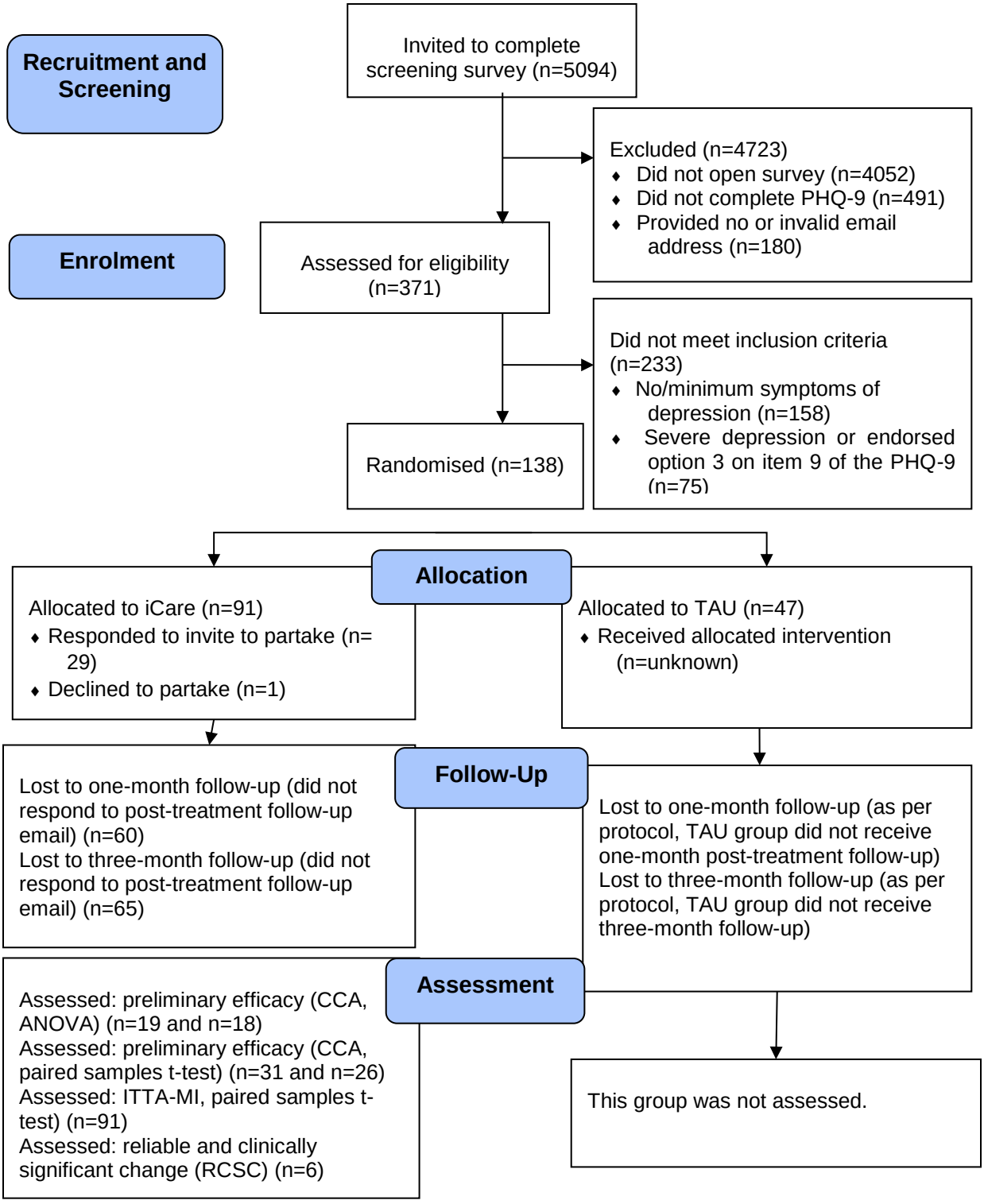

Figure 1. Participant flow chart following the Consolidated Standards of Reporting Trials (CONSORT) extension for Pilot and Feasibility Trails Diagram. ANOVA = analysis of variance; CC = complete case analysis; ITT= intention-to-treat. Adapted from Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., … Tugwell, P. (2016a). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. BMJ (Online), 355. https://doi.org/10.1136/bmj.i523

Table 9.
Demographic characteristics of participants enrolled compared to the general student population.

		General student population (N=31765) % (n)	Eligible participants enrolled (n=138) % (n)	z-statistic, p-value
Gender, %(n)[a]	Male	45.29 (14299)	**19.57 (27)**	**6.06, p = 0.001***
	Female	54.70 (17273)	**77.54 (107)**	**5.38, p = 0.001***
Ethnicity, %(n)	Black[b]	41.64 (13228)	44.20 (61)	-0.61, p = 0.542
	White	58.07 (18447)	55.80 (77)	0.54, p = 0.589
Home language, %(n)	English	47.77 (15176)	52.90 (73)	-1.21, p = 0.228
	Afrikaans	37.77 (12000)	31.16 (43)	1.59, p = 0.109
	isiXhosa	3.89 (1236)	5.07 (7)	0.72, p = 0.473
	Other official SA languages	6.42 (2039)	10.87 (15)	**-2.14, p = 0.032***
	Other	4.12 (1310)	n/a	n/a

*Note that p<0.05 is statistically significant.

[a] The data available for the entire university population for gender (n=31 572) excluded gender non-binary.

[b] A broad definition of Black to encompass students who identified as Black-African, Indian, and Coloured (an official term used for population classification and census data in SA).

Table 10.
Sociodemographic and baseline clinical characteristics of participants in each stage of the pilot study (n=138).

		Total sample	TAU group	iCare group	Responded to invitation	Started iCare	Finished iCare
Number of participants		138	47	91	29	22	6
Participation rate, %, [95% CI]					31.87 [22.3, 41.5]	24.18 [15.4,33.0]	6.59 [1.6, 11.8]
Gender (male), %		19.57	27.66	15.38	17.24	18.18	33.33
Age (mean, SD, range) [95% CI]		19.07, 1.13, 17-26 [18.9, 19.3]	19.23, 1.43 18-26 [18.8, 19.6]	18.98, 0.93 17-24 [18.8, 19.2]	19.00, 0.93 17-21 [18.7, 19.4]	18.82, 0.85 17-20 [18.4, 19.2][c]	19.00, 0.89 18-20 [18.1, 19.9][c]
Ethnicity, %	Black[a]	44.20	61.70	42.90	44.80	50.00	16.70
	White	55.80	53.20	57.10	55.20	50.00	83.30
Home language, %	English	52.90	46.80	56.00	65.50	72.70	50.00
	Afrikaans	31.20	34.00	29.70	24.10	18.20	50.00
	isiXhosa	5.10	8.50	3.30	3.40	4.50	0.00
	Other official SA languages	10.90	11.00	0.00	6.80	4.50	0.00
Campus, %	Main campus	91.30	95.70	89.00	86.20	86.40	83.30
	Tygerberg (Bellville)	8.70	4.30	11.00	13.80	13.60	16.70
Type of Accommo-dation, %,	Not living with parent(s)[b]	87.00	87.20	86.80	79.30	77.30	50.00
	Living with parent(s)	13.00	12.80	13.20	20.70	22.70	50.00
PHQ-9 score (mean, SD, range), [95% CI]	Baseline	14.21, 2.80 10-19, [13.7,14.7]	14.57, 2.73 10-19, [13.8, 15.4]	14.02, 2.84 10-19, [13.4, 14.6]	13.69, 0.93 10-19, [12.8, 14.6]	13.59, 2.40 10-18, [12.6,14.6]	12.67, 2.25 10-15, [10.9,14.5]
GAD-7 score (mean, SD, range), [95% CI]	Baseline	10.46, 4.06, 0-21, [9.8, 11.1]	10.89, 4.44, 3-21 [9.6, 12.2]	10.24, 3.86, 0-21, [9.5, 11.0]	9.45, 2.51, 3-17, [8.1, 10.8]	9.50, 3.57, 4-17, [8.0,11.0]	9.50, 4.04, 6-17, [6.3, 12.7]

[a] A broad definition of Black to encompass students who identified as Black-African, Indian, and Coloured (an official term used for population classification and census data in SA).

[b] Not living with parents included staying in the following types of accommodation: university residence, private halls of residence/communal blocks, other university accommodation, renting/owned.

[c] Used t-score to construct 95% CI as n<30.

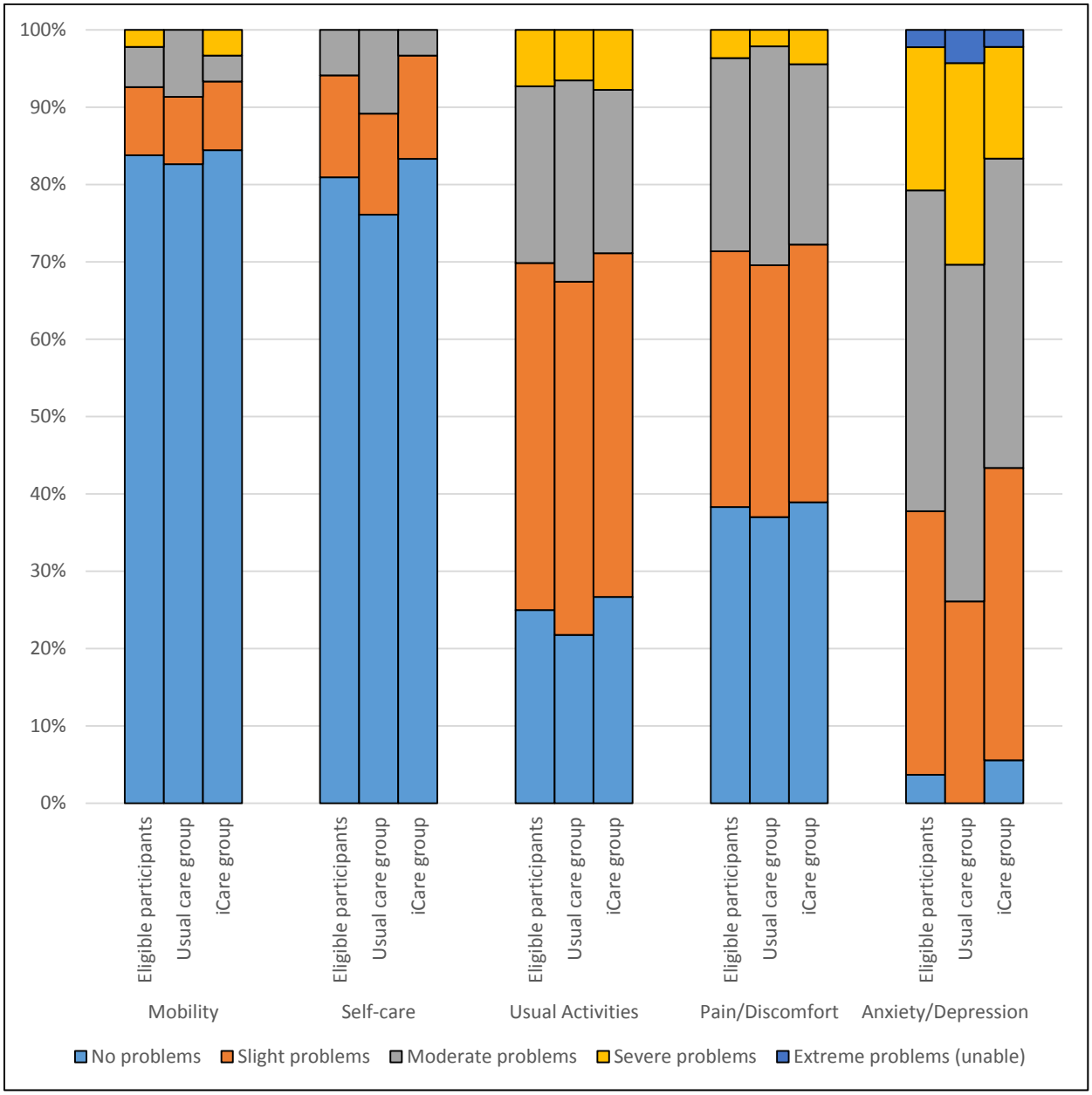

Figure 2. The distribution of baseline EQ-5D-5L profiles for participants enrolled in the study (n=138) expressed in percentages.

Assessment of randomisation procedures

I compared the sociodemographic and clinical characteristics of the TAU group with those of the iCare group using independent t-tests, chi-square analyses and Fisher's exact test (FET). No significant differences were observed at baseline between participants randomised to iCare and those randomised to TAU on age ($t_{66.62}$=-1.267; p=0.21), PHQ-9 total scores ($t_{136.62}$=-1.10; p=0.27), GAD-7 total scores (t_{134}=-0.88; p=0.38), gender (p=0.545; FET), ethnicity (X^2_3=5.19; p=0.162), home language (p=0.635; FET), on-/off-campus living (p=0.221; FET) or type of accommodation (p=0.766; FET). Similarly, no statistically significant differences were found between these groups on any of the five EQ-5D-5L dimensions (see Figure 2) of mobility (p=0.404; FET), self-care (X^2_2=3.14; p=0.239), usual activity (X^2_3=0.70; p=0.865), pain/discomfort (p=0.904; FET) or anxiety/depression (p=0.131; FET).

iCare utilisation rates

The majority of participants randomised to iCare (68.1%; n=63) did not respond to the invitation to utilise iCare, and one participant declined to participate. Participants who accepted the invitation to utilise iCare (n=29) were on average 19 years old (SD 0.93; range 17-21), the majority of whom identified as female (68.97%; n=20), White (55.17%; n=16) and English-speaking (65.52%; n=19). On average, these participants had baseline PHQ-9 and GAD-7 scores of 13.69 (SD=2.50; range 10-19) and 9.45 (SD=3.67; range 3-17), respectively (see Table 10). A total of 22 participants logged on to iCare and commenced with Session 1. Shortly after commencing Session 1, two participants withdrew from iCare, citing "other commitments, time-constraints and religious reasons" as reasons for withdrawing. Only six participants completed all eight sessions. The majority (75.86%; n=22) of participants enrolled in iCare dropped out before Session 3. The highest drop-out rate (45.45%; n=10) was observed in Session 1 (see Figure 3).

Bivariate logistic regression analysis was used to explore the associations between sociodemographic and baseline clinical variables, and enrolment, commencement and completion of iCare (see Table 11). The only significant finding was that individuals in the intervention group with GAD-7 scores ≤10 were 2.5 times (OR= 2.52; 95% CI [1.02, 6.25]; p=0.045) more likely to have accepted the invitation to enrol in iCare compared to those with GAD-7 scores of ≥10.

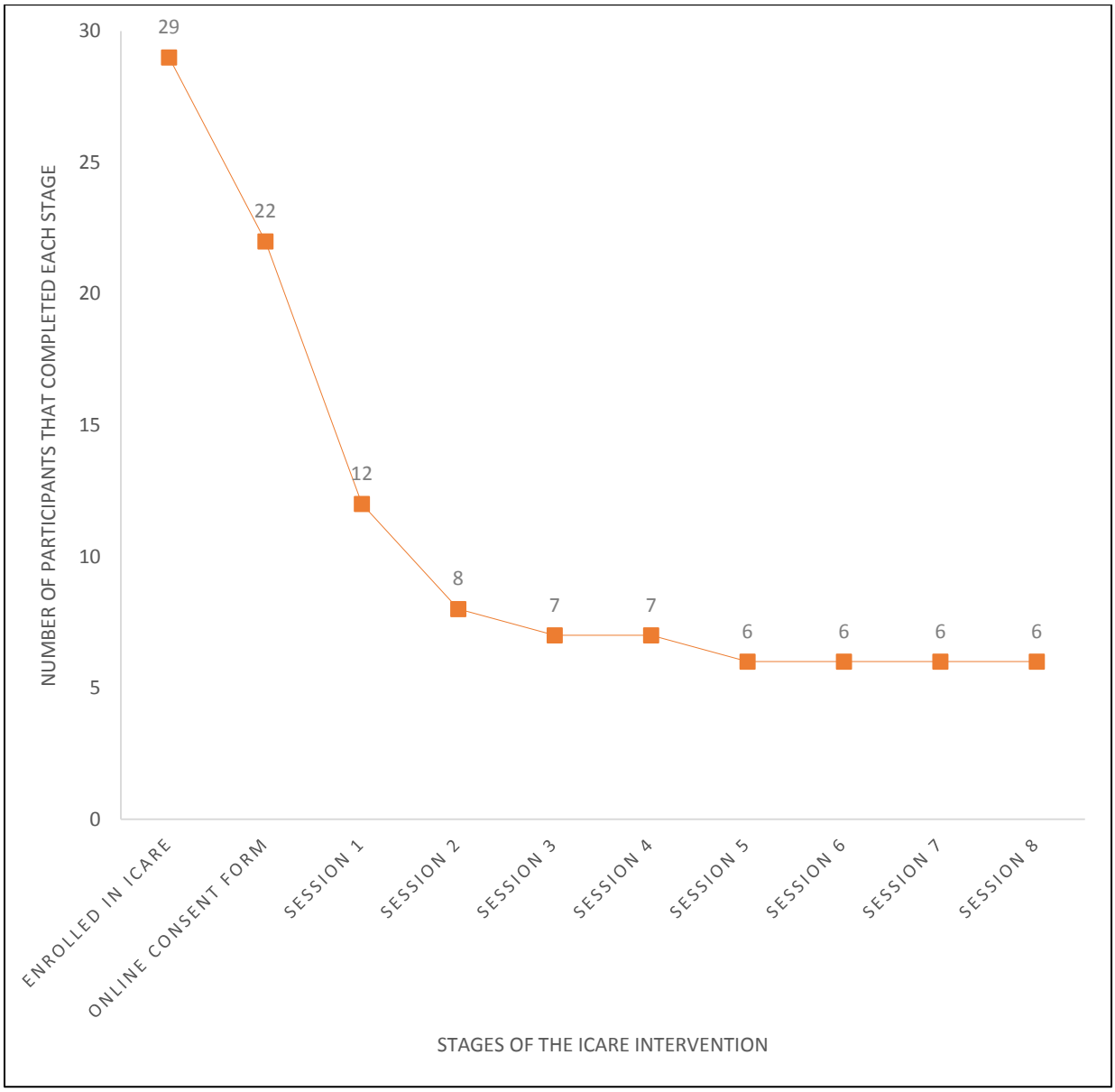

Figure 3. Utilisation of iCare expressed as the number of participants that completed each stage.

Table 11.
Sociodemographic and clinical predictors of enrolment, commencement and completion of iCare.

Predictors*	Enrolled into iCare (n=29)	Commencement of iCare (completed the online consent form) (n=22)	Completed iCare (n=6)
	OR [95% CI], p-value	OR [95% CI], p-value	OR [95% CI], p-value
Age	1.04 [0.65, 1.66], p=0.880	0.35 [0.11, 1.11], p=0.075	1.45 [0.45, 4.62], p=0.534
Medical Aid (Control: No)	1.12 [0.38, 3.29], p=0.842	1.80 [0.25, 12.85], p=0.588	1.15 [0.10,13.88], p=0.910
Gender (Control: Female gender)	2.65 [0.92,7.63], p=0.737	3.43 [0.35, 33.80], p=0.346	0.83 [0.12,6.01], p=0.857
PHQ-9 score (Control: High PHQ-9 scores, i.e. between 15-19)	1.35 [0.55, 3.32], p= 0.517	0.58 [0.09, 3.66], p=0.560	1.56 [0.22, 11.09], p=0.659
GAD-7 Scores (Control: High GAD-7 scores, i.e. ≥10)	2.52 [1.02, 6.25], **p=0.045***	0.90 [0.16, 5.01], p=0.904	2.00 [0.28, 14.20], p=0.488
Sexual orientation (Control: Heterosexual)	1.98 [0.75, 5.29], p=0.171	1.43 [0.22, 9.14], p=0.706	0.28 [0.02,2.73], p=0.260
Population group (Control: White)	1.13 [0.46, 0.74], p=0.795	2.50 [0.22, 9.14], p=0.329	0.12 [0.01,1.29], p=0.080
Accommodation (Control: Not living with parents)	2.44 [0.71, 8.34], p=0.157	1.77 [0.17, 18.32], p=0.634	7.00 [0.79, 61.98], p=0.080

* Predictors were coded as follows: age (continuous); medical aid (yes/no); gender (female gender/other gender); PHQ-9 score (high scores: 15-19 points/low scores: 10-14 points); GAD-7 scores (high scores ≥ 10 points/low scores points ≤ 10); sexual orientation (heterosexual/atypical = lesbian, gay, bisexual, asexual or questioning); population group (white/black: broad definition to encompass students who identified as Black-African, Indian, and Coloured); accommodation (living with parents/not living with parents: staying in university residences/private halls of residence/communal blocks/other university accommodation, renting or owning a flat or house.

Results of the follow-up assessments

Follow-up rates and results of the primary outcome measures

A one-month post-treatment follow-up assessment was sent to all participants in the iCare group (n=91). However, 65.93% (n=60) of participants did not complete this assessment (lost to follow-up). All six participants who completed iCare completed this assessment. On average, participants at this follow-up had a PHQ-9 score of 10.24 (SD=5.25; range 2-22; 95% CI [7.83, 11.26]) and a GAD-7 score of 8.23 (SD=4.77; range 1-17; 95% CI [6.52, 9.94]). At this follow-up, 12.90% (n=4) of participants were identified to be at an elevated risk of suicide and received follow-up emails immediately, as well as 24 hours, 48 hours, and seven days post-screening.

Similarly, a three-month post-treatment follow-up assessment was sent to all participants in the iCare group (n=91). A total of 65 (71.43%) participants were lost to follow-up. Only 26 participants completed the three-month follow-up survey. All six participants who completed iCare completed the three-month post-intervention follow-up survey. On average, participants at this follow-up had a PHQ-9 score of 11.27 (SD=5.25; range 2-22; 95% CI [9.15, 13.39]) and a GAD-7 score of 9.08 (SD=5.93; range 1-21; 95% CI [6.68, 11.48]). At this follow-up, 19.23% (n=5) of participants were identified to be at elevated risk of suicide and received follow-up emails, as mentioned in Chapter 4.

Quality of life assessment

The self-reported quality of life of the iCare group (n=91) at baseline, one month and three months post-intervention is presented in Figure 4. At one month post-intervention the majority of the iCare group did not experience any difficulty in their mobility (87.09%; n=27) or self-care (87.09%; n=27); and experienced no pain/discomfort (35.48%; n=11). However, the majority experienced slight difficulties engaging in their usual activities (48.39%; n=15) and reported feeling moderately

anxious and or depressed (38.71%; n=12). At the three-month post-intervention follow-up assessment, the majority of the iCare group did not experience any difficulty in their mobility (88.46%; n=23) or self-care (65.38%; n=17); experienced no pain/discomfort (42.31%; n=11) or difficulties engaging in their usual activities (46.15%; n=12), although the majority (38.46%; n=10) reported feeling slightly anxious and or depressed.

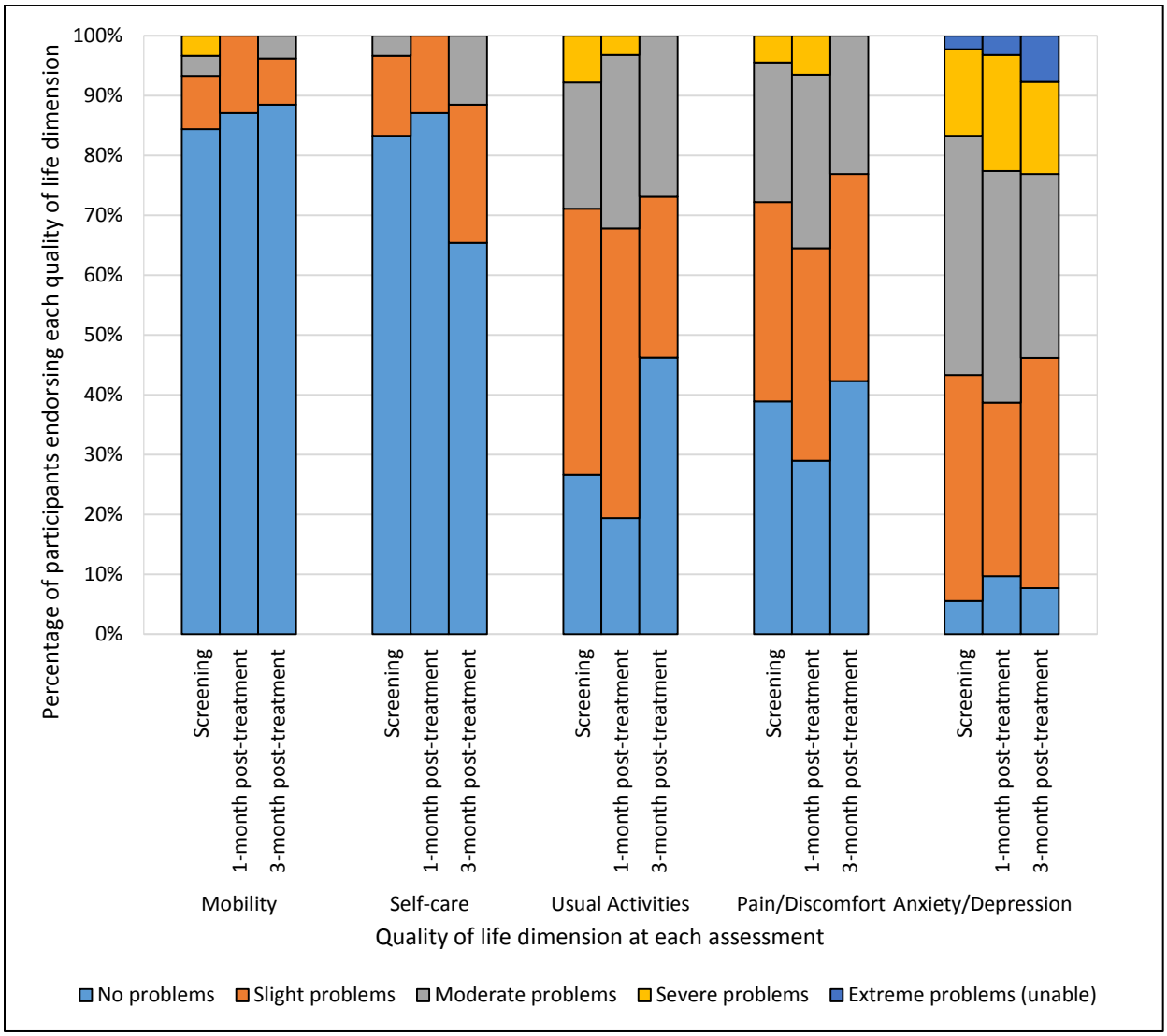

Figure 4. The distribution of EQ-5D-5L profiles at baseline assessment, one-month and three-month post-intervention for participants randomised to iCare; expressed as the percentage of participants endorsing a specific quality of life in each of the five dimensions of the EQ-5D-5L across the various assessments.

Assessment of satisfaction with iCare

All iCare completers (n=6) provided feedback using the client satisfaction questionnaire (CSQ-8) (Attkisson & Zwick, 1982; Larsen et al., 1979) as part of the one-month post-intervention follow-up assessment. Participants' satisfaction with iCare ranged from a minimum score of 18 (56.25%; 18/32) to a maximum of 31 (96.88%; 31/32), with a mean satisfaction score of 25 (78.13%; 25/32) (SD=4.77). This indicates that participants were moderately to highly satisfied with iCare. Figure 5 shows to what extent iCare completers had a favourable view of specific aspects of iCare. Half (50%; n=3) of iCare completers would recommend iCare to their friends and felt that iCare assisted them in dealing with their problems more effectively. Although the majority (66.67%; n=4) felt that iCare did not address all their needs, they indicated that they were mostly satisfied with iCare.

Analysis of primary outcome measures

In this section, I present the results of the three commonly used approaches to analysing the primary outcome measures in clinical trials: (1) complete case analysis (CCA); (2) intention-to-treat analysis (ITTA); and (3) per-protocol analysis (PPA).

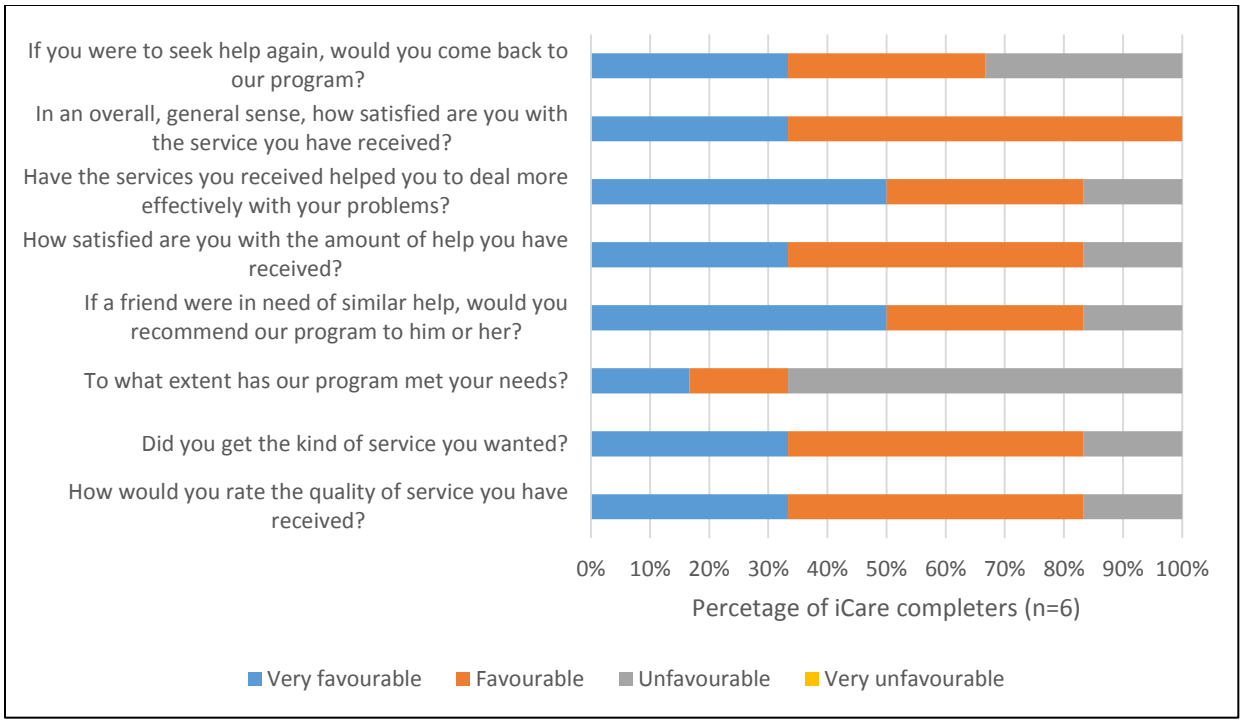

Figure 5. iCare completers' satisfaction with iCare as measured by the CSQ-8 (Attkisson & Zwick, 1982; Larsen et al., 1979). Satisfaction with iCare is expressed as the percentage of iCare completers who endorsed varying degrees of favourability towards certain aspects of iCare (as elicited by the CSQ-8).

Complete Case Analysis (CCA)

The results of the repeated measures ANOVA with a Huynh-Feldt correction (Ɛ=0.87) indicate that overall, the mean PHQ-9 scores differed significantly across the various time points, F(1.744, 31.397)=4.394; p=0.025; η_p^2=0.20 and ηG²=0.15; 90% CI [0.02, 0.36]. However, the bias-corrected omega squared (ω^2) was smaller than ηG² and non-significant, with w^2=0.08; 90% CI (-0.04, 0.36)]. Post-hoc tests using Sidak's correction revealed a statistically significant mean PHQ-9 score reduction of three points (95% CI [1.03, 4.97]; p= 0.002), with a large effect (*r*=0.69) from pre-intervention to one month post-intervention. A statistically non-significant mean reduction of 1.95 points on the PHQ-9 was revealed (95% CI [-1.21, 5.11]; p= 0.324) with a moderate effect (*r*=0.23) between pre-intervention scores and three-month post-intervention follow-up assessments. Although there was a mean increase of 1.05 points (95% CI [-1.78, 3.89]; p=0.714)

on the PHQ-9 between the one-month and three-month post-intervention follow-up assessments, this was not statistically significant, as shown in Figure 6.

The results of the repeated measures ANOVA with a Huynh-Feldt correction (Ɛ=0.97) indicate that overall, the mean GAD-7 scores did not differ significantly across the various time points, $F(1.95,33.08)=0.189$; $p=0.823$; $\eta_p^2=0.01$ and $\eta G^2=0.007$; 90% CI [0.00, 0.07]. Furthermore, ω^2 was smaller than ηG^2 and non-significant ($\omega^2=-0.03$; 90% CI [-0.06, 0.02]; $p=0.823$). Figure 7 presents these results.

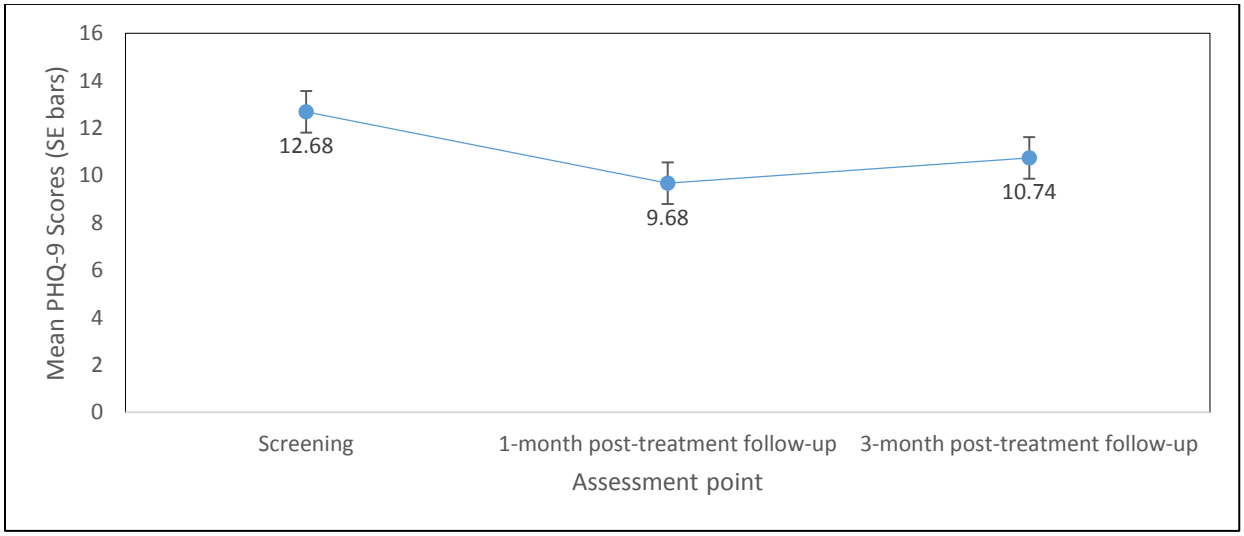

Figure 6. The change in PHQ-9 scores across time in the iCare group (n=19). These results are based on the CCA. The error bars represent the 95% CI for the standard error (SE) of the mean PHQ-9 score.

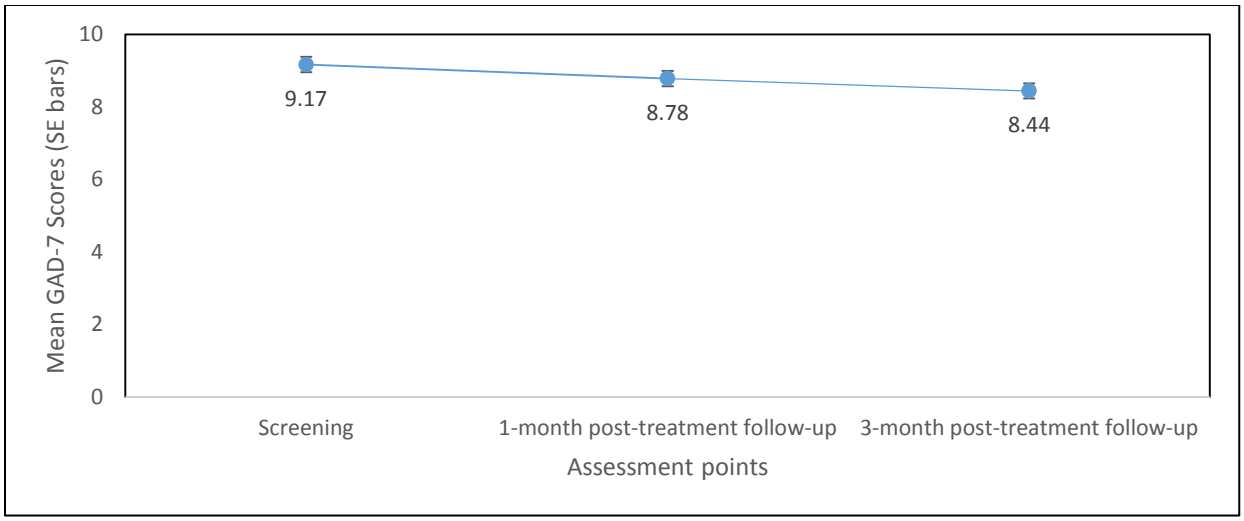

Figure 7. The change in GAD-7 scores across time in the iCare group (n=18). These results are based on the CCA. The error bars represent the 95% CI for the standard error (SE) of the mean GAD-7 score.

Tables 12 and 13 show the results of the CCA paired t-test. On average, participants' (n=31) PHQ-9 scores were lower (M= 9.55; SE=0.87) one month post-treatment compared to their PHQ-9 scores at screening (M=13.19; SE=0.49). This difference (3.65; BCa 95% CI [1.91, 5.39]) was the only statistically significant ($t(30)=4.28$; p=0.0001) mean change in scores found in the CCA and had a large effect (Cohen's d_{unb}=0.9; 95% CI [0.43, 1.40]). Neither the mean score differences of participants (n=26) on the PHQ-9 at three months post-intervention ($t(25)=1.77$; p=0.089) nor the GAD-7 at either one month ($t(29)=1.53$; p=0.137) or three months ($t(25)=-0.07$; p=0.948) post-intervention were statistically significant.

Table 12.
CCA paired-samples t-test results.

	Mean (SD)	t-statistic	p-value
PHQ-9 screening survey (n=31)	13.19 (2.73)		
PHQ-9 at one month post-intervention (n=31)	9.55 (4.86)	4.28	**0.0001***
PHQ-9 screening survey (n=26)	13.23 (2.73)		
PHQ-9 at three months post-intervention (n=26)	11.27 (5.25)	1.77	0.089
GAD-7 screening survey (n=30)	9.58 (3.58)		
GAD-7 at one month post-intervention (n=30	8.23 (4.77)	1.53	0.137
GAD-7 screening survey (n=26)	9.00 (3.93)		
GAD-7 at three months post-intervention (n=26)	9.08 (5.93)	-0.07	0.948

*Note that p<0.05 is statistically significant.

Table 13.
CCA results of the paired-samples t-test: mean differences and effect sizes.

	Mean difference [BCa 95% CI of the mean difference]	Within-subjects Cohen's d_{avunb} [95% CI]	Within-subjects Glass' d_{unb} [95% CI]	p-value
PHQ-9 at one month post-treatment (n=31)	3.645 [1.91, 5.39]	0.90 [0.43,1.40]	1.30 [0.59, 2.00]	**0.0001***
PHQ-9 at three months post-treatment (n=26)	1.962 [-0.33, 4.25]	0.46 [-0.07, 1.00]	0.70 [-0.14, 1.55]	0.089
GAD-7 at one month post-treatment (n=30)	1.333 [-0.45, 3.12]	0.31 [-0.10, 0.73]	0.36 [-0.15, 0.87]	0.137
GAD-7 at three months post-treatment (n=26)	- 0.076 [-2.49, 2.34]	-0.02 [-0.47, 0.44]	-0.02 [-0.62, 0.58]	0.948

*Note that p<0.05 is statistically significant

Intention-to-treat analyses using multiple imputation (ITTA-MI)

Similar to the CCA, the ITTA-MI paired samples t-test found participants' (n=91) PHQ-9 scores to be lower at one-month post-treatment (M=10.39; SE=0.89) than at screening (M=14.02; SE= 0.30). This difference was statistically significant ($t(253)=4.12$; p=0.0001) with a moderate effect (Cohen's d_{avunb}=0.57; 95% CI [0.30, 0.85]. The mean score differences on the GAD-7 were not statistically significant at either one month ($t(270)=1.58$; p=0.116) or three months ($t(207)=0.39$; p=0.696) post-intervention. In contrast to the CCA, the mean change in scores on the PHQ-9 at three months post-intervention (2.247; BCa 95% CI [0.13, 4.37]) was statistically significant ($t(222)=2.09$; p=0.038) with a small effect (Cohen's d_{avunb}=0.30; 95% CI [0.02, 0.58]).

Table 14.
ITTA-MI of outcome measures (n=91).

	Mean (SD)	t-statistic	Mean difference [BCa 95% CI]	[b]Cohen's d_{avunb} [95% CI]	[b]Glass' d_{unb} [95% CI]	p-value
PHQ-9 screening survey	14.02 (2.83)					
PHQ-9 at one month post-intervention	10.39 (8.47)	4.12	3.63 [1.89, 5.37]	0.57 [0.30, 0.85]	1.27 [0.65, 1.87]	**0.001***
PHQ-9 screening survey	14.02 (2.83)					
PHQ-9 at three months post-intervention	11.78 (10.10)	2.09	2.25 [0.13, 4.37]	0.30 [0.02, 0.58]	0.77 [0.02, 1.51]	**0.038***
GAD-7 screening survey	10.26 (3.88)					
GAD-7 at one month post-intervention	8.82 (8.35)	1.58	1.44 [-0.36, 3.23]	0.22 [-0.04, 0.48]	0.37 [-0.08, 0.81]	0.116
GAD-7 screening survey	10.26 (3.88)					
GAD-7 at three months post-intervention	9.82 (10.59)	0.39	0.44 [-1.79, 2.67]	0.06 [-0.21,0.32]	0.11 [-0.4, 0.6]	0.696

*Note that p<0.05 is statistically significant.

[b] Within-subjects effect sizes.

Per Protocol analysis (PPA)

Half (50%; n=3) of iCare completers achieved an RCSC at the three-month post-intervention assessment, although 16.7% (n=1) experienced symptom deterioration at this point (see Table 15).

Table 15.
A reliable and clinically significant change of iCare completers (RCSC).

Participant	Baseline PHQ-9 Score	PHQ-9 score at one month post-treatment	RCSC at one month post-intervention	PHQ-9 score at three months post-treatment	RCSC at three months post-intervention
A	14	12	No	19	Deterioration
B	11	11	No	4	Yes*
C	10	4	Yes*	6	No
D	11	7	No	2	Yes*
E	15	6	Yes*	5	Yes*
F	15	12	No	12	No

* Achieved an RCSC at specific follow-up. Thus, moved from a pre-treatment PHQ-9 score of ≥10 to a post-treatment score of ≤9 with a change of ≥5 points, while deterioration occurred when the pre-treatment score increased by ≥5 points (McMillan et al., 2010).

Sample size estimation for scaling iCare to an RCT

Below, I present the results of the two approaches to sample size estimation used in the current study: (1) a conservative estimation, namely safeguard power analysis (Perugini et al., 2014); and (2) the minimal clinically significant effect, based on the suggestions by Leon et al. (2012) and the criteria presented by McMillan et al. (2010).

Safeguard power analysis of sample size calculation

For a paired-samples design (see Table 16), a total of 245 participants would be needed to have sufficient power (0.8, with alpha set at 0.05 according to a two-tails hypothesis) to detect a Cohen's d_{avunb} of 0.18 at the three-month post-intervention follow-up. However, in a future RCT, one would

employ an independent-group design. Thus, an independent-group design that is sufficiently powered (0.8, with alpha set at 0.05 according to a two-tails hypothesis) to detect a Cohen's d_{avunb} of 0.18 at the three-month post-intervention follow-up would require n=1094 participants, of which n=729 would be randomised to iCare (see Table 17).

Table 16.
ITTA safeguard power analysis for a paired design based on Cohen's d_{unb}

	Cohen's d_{avunb} [60% CI]	Lower bound of 60% CI used for safeguard power analysis (paired design)	Total n needed in intervention group
PHQ-9 at one month post-treatment	0.57 [0.45, 0.69]	0.45	54
PHQ-9 at three months post-treatment	0.30 [0.18, 0.42]	0.18	245

Table 17.
ITTA safeguard power analysis for an independent design based on Cohen's d_{avunb}

	Lower bound of 60% CI used for safeguard power analysis (PHQ-9)	Total n needed per group (1:1 ratio)	Total n needed (2:1 ratio)	Total n needed in iCare	Total n needed in TAU
One month post-treatment	0.45	105	236	157	79
Three months post-treatment	0.18	972	1094	729	365

Table 18 shows the expected number of individuals that would need to be invited to complete the mental health screening survey to: (a) ensure that n=729 participants are randomised to iCare, and (b) ensure n=729 participants complete the three-month post-intervention follow-up assessment to achieve sufficient power. This table was constructed using the proportion of participants as they progressed throughout this study (as presented in Figure 1) and based on the assumption that no

additional recruitment and retention strategies would be employed if this study were to be replicated or scaled.

Table 18.
Conservative estimation of the projected number of students to invite using safeguard power analysis sample size estimation.

Proportion of participants as they progressed through the study (n=5094)				Minimum n (n=40600) needed to be invited to ensure n=728 randomised to iCare	Minimum n (n=142 000) required to be invited to ensure n=728 at three-month post-intervention follow-up
Flow of participants and essential stages in a pilot study		n at a specific stage	% retained after each step	Projected n retained	Projected n retained
Recruitment and screening	Invited to complete the mental health screening survey	5094	20.5 (n=1042/5094)	**40600**	**142000**
	Opened and/or completed survey	1042	52.9 (n=551/1042)	8302	29047
	Completed PHQ and provided valid email	551	25.1 (n=138/551)	3779	13216
	Met inclusion criteria	138	65.9 (91/138)	1103	3859
Enrolment	Randomised to iCare	91	32.0 (n=29/91)	**728**	2547
Intervention	Responded to invite to take up iCare	29	75.9 (n=22/29)	233	815
	Commenced Session 1	22	27.3 (n=6/22)	177	618
	Completed iCare	6		48	169
Follow-up	1-month (iCare)	31	34.1 (n=31/91)	248	868
	3-month (iCare)	26	28.6 (n=26/91)	208	**728**

Clinically meaningful effect sample size calculation

As calculated in Chapter 4, the clinically meaningful effect at the one-month post-intervention follow-up assessment was Cohen's d_{avunb}=0.79 (for a five-point change) and Cohen's d_{avunb}=1.58 (for a ten-point change, representing a move from a PHQ-9 of 19 to ≤9). At the three-month post-intervention follow-up assessment, Cohen's d_{avunb} was 0.67 (for a five-point change) and 1.38 (for a ten-point change).

The results presented in Table 14 indicate that the paired design using ITTA-MI was sufficiently powered to detect the aforementioned clinically meaningful effects (as the statistically significant effects detected were smaller than the determined clinically meaningful effects). Thus, no clinically meaningful effects were detected at either one month or three months post-intervention. The PHQ-9 mean difference scores at one month (14.02−10.39=3.63) and three months (14.02−11.78=2.24) post-intervention reflect this; the mean change on the PHQ-9 ≤5 and therefore does not reflect an RCSC as defined by McMillan et al. (2010).

The independent-samples design would require a total of n=78 participants (n=52 randomised to iCare and n=26 to TAU) at the one-month post-intervention follow-up assessment to detect Cohen's d_{avunb}=0.79. At the three-month post-intervention assessment, a total of n=108 participants (n=72 randomised to iCare and n=36 to TAU) would be needed to detect Cohen's d_{avunb}=0.67. Table 19 estimates the number of participants that would need to be invited to ensure a sufficiently powered study at the three-month post-intervention follow-up assessment in an independent design, to detect Cohen's d_{avunb}=0.67. Table 19 is based on the same assumptions used in Table 18 and relates to the employment of additional recruitment and retention strategies.

Analysis of the direct costs of iCare

The eCoaches spent between 30 and 40 minutes per session providing feedback to each participant, i.e. between 4 and 5.33 hours in total per participant throughout eight sessions. This would amount to a cost of approximately R400 (R300 to R399.75) per participant over the course of eight sessions. Each of iCare's sessions therefore costs approximately R50 per participant (40 minutes of feedback per session at R75/hour, the direct cost as defined in Chapter 4), excluding the costs of the MindDistrict platform which hosts iCare.

Table 18 (based on the safeguard power analysis sample size estimation) predicts that a total of 142 000 individuals would need to be invited to complete the mental health screening survey to ensure a sufficiently powered study at three months post-intervention. This would lead to 618 participants starting Session 1. However, based on the data presented in Figure 3, approximately 281 participants (45.5%) would drop out after Session 1. The eCoaches would therefore not need to provide feedback on Session 1 to these participants, only to a total of 337 participants. Furthermore, Table 18 projects an approximate total of 169 iCare completers. Thus, if iCare were to be scaled to a larger RCT, based on these assumptions and calculations, the cost of eCoaches to provide feedback would range between R67 200 (R400 × 168) and R134 800 (R400 × 337). However, if all the participants projected to accept the invite to take up iCare (n=815) were to complete all eight sessions, the aforementioned amount would increase to R326 000 (R400 × 815). Finally, the cost of providing eCoaching to the number of students needed in the intervention group to achieve a sufficiently powered study (Table 18), would amount to a direct cost of R291 200 (R400 × 728).

Table 19 is based on the minimal clinically significant effect sample size estimation and predicts that a total of 14 000 individuals (44.1% of the university's total student population, n=31

765) (“Statistical Profile”, 2019) would need to be invited to complete the mental health screening survey to ensure a sufficiently powered study at three months post-intervention. This would lead to 61 participants starting with Session 1. However, based on the data presented in Figure 3, a total of 28 participants (45.5%) would drop out of Session 1 and therefore the eCoaches would not be required to provide feedback to these students; only to 33 participants. Furthermore, Table 19 projects an approximate total of 17 iCare completers. If iCare were to be scaled to a larger RCT, based on these assumptions and calculations, the cost of eCoaches to provide feedback would range between R6 800 (R400 × 17) and R13 200 (R400 × 33). However, if all participants projected to accept the invite to take up iCare (n=80) were to complete all eight sessions, the aforementioned amount would increase to R32 000 (R400 × 80). The cost of providing eCoaching to the total number of students needed in the intervention group (n=72) would amount to R28 800 (R400 × 72).

Table 19.
Projected number of students to invite to detect the minimal clinically significant effect (on the PHQ-9) of Cohen's d_{avunb}=0.67 at three months post-intervention.

			Proportion of participants as they progressed through the study (n=5094)	Minimum n (n=14 000) required to be invited to ensure n=72 at three-month post-intervention follow-up
The flow of participants and essential stages in a pilot study		n at a specific stage	% retained after each step	Projected n retained
Recruitment and screening	Invited to complete the mental health screening survey	5094	20.5 (n=1042/5094)	14000
	Opened and/or completed survey	1042	52.9 (n=551/1042)	2863
	Completed PHQ and provided valid email	551	25.1 (n=138/551)	1514
	Met inclusion criteria	138	65.9 (91/138)	380
Enrolment	Randomised to iCare	91	32.0 (n=29/91)	250
Intervention	Responded to invite to take up iCare	29	75.9 (n=22/29)	80
	Actively engaged Session 1	22	27.3 (n=6/22)	61
	Completed iCare	6		17
Follow-up	One-month (iCare)	31	34.1 (n=31/91)	85
	Three-month (iCare)	26	28.6 (n=26/91)	72

Discussion

Pilot studies represent a subset of feasibility studies incorporating specific elements of an RCT to evaluate the feasibility of the study design and procedures before the study is scaled to a larger RCT (Eldridge, Lancaster, et al 2016). In this section, I discuss the key feasibility aspects that warrant attention if this study is to be scaled to an RCT. These aspects are: (1) recruitment; (2)

utilisation; (3) retention; and (4) follow-up assessment procedures. I then present suggestions on how to address these aspects. Following this, I discuss the results of the ITTA-MI in relation to previous studies on iCBTs for MDD, after which I discuss the implications of the ITTA-MI and PPA results with regard to scaling iCare to a larger RCT. I conclude this chapter with a discussion of the two sample size estimations used, and propose a strategy which may improve the chances of a successful implementation of a larger RCT.

(1) Recruitment. A small proportion of students responded to the invitation to complete the mental health screening survey (participation rate = 7.28%), resulting in a small number of respondents that could potentially be screened for eligibility and enrolled in the study. Despite these low participation rates, this study was successful in recruiting and effectively randomising the proposed number of students (a minimum of n=70 in total). However, as shown in this chapter, this study had low uptake rates and high drop-out rates. Thus, increasing the participation rate, as mentioned above, would require a larger number of participants that could be assessed for eligibility; potentially leading to a larger number of participants enrolled. This could navigate the low uptake and drop-out rates. Additional recruitment sources might therefore be needed to scale this intervention. Furthermore, compared to the general university population, individuals who self-identified as males were significantly under-represented in the students who met the inclusion criteria. This may be a result of the fact that depressive disorders are less common among men suggesting that one would expect women to be over-represented in intervention trials of this nature (Bantjes, Lochner, et al., 2019). Kauer, Mangan and Sanci's systemic review of e-mental health services (2014) also found that males were under-represented in e-mental health service use. Similarly, in Harrer et al.'s meta-analytical study (2018) on e-interventions among university students, a significant proportion of participants (74%) identified as female, a trend which is also

typically reflected in traditional face-to-face psychological service utilisation (Addis & Mahalik, 2003).

(2) Utilisation. The vast majority (68.13%; n=60) of participants randomised to iCare did not respond to the invitation to partake in iCare, or declined to do so (1.1%; n=1). This is referred to by Eysenbach (2005) as non-usage attrition, and it highlights the importance of engaging and encouraging participants to promote their readiness to utilise iCare. This should be done before they are invited to take up iCare, as non-usage attrition has been theorised to influence drop-out attrition (lost to follow-up assessments), significantly affecting the inferences that can be drawn about an intervention's efficacy (Eysenbach, 2005). It seems that students may be reluctant to use e-mental health services or to be involved in intervention research about mental health. Knowledge of and attitudes towards e-mental health interventions may bias individuals' participation in these kinds of trials (Casey, Wright, & Clough, 2014; Musiat et al., 2014). Casey et al. (2014) found that despite perceiving fewer barriers to e-interventions, individuals indicated a preference for face-to-face therapy (Casey et al., 2014). Musiat et al. (2014) found that the preference for face-to-face therapy is a result of it being viewed as more helpful and credible than e-interventions (Musiat et al., 2014). Thus, perceived helpfulness and credibility are important to the acceptability of mental health services in general; and are likely to be influenced by the amount and quality of information available (Musiat et al., 2014).

(3) Retention. The proportion of participants who chose to enrol in iCare (31.86%; n=29) correspond to the proportion of young people (16-24 years of age) with high levels of symptoms of anxiety and depression that typically seek help from traditional mental health services (Gulliver, Griffiths, & Christensen, 2010). Pre-treatment drop-out is defined by Fernandez et al. (2015) as the number of participants who (after having been screened and accepting the intervention) do not

start with the first session. iCare's pre-treatment drop-out rate (24.2%; n=7) fell within the range reported by Melville, Casey and Kavanagh (2010) of 4 to 52%; although it is slightly higher than their reported weighted mean pre-treatment drop-out rate of 21%. iCare's during-treatment drop-out rate, defined by Fernandez et al. (2015) as individuals who failed to complete the treatment after having started the first session, was substantially higher (72.73%) than the rate reported for other e-therapies (34.2%) (Fernandez et al., 2015), although it did fall within in the range reported by Melville et al. (2010) of 0 to 78%. The during-treatment drop-out could be the result of an improvement in participants' symptoms as a result of starting the intervention, a phenomenon that has been observed in face-to-face therapy (Simon, Imel, Ludman, & Steinfeld, 2012).

Rates of drop-out attrition in the iCare group were higher at both one-month (65.93%; n=60) and three-month (71.42%; n=65) follow-up compared to rates reported by Christensen, Griffiths and Farrer (2009) of between 1% and 57% for e-interventions aimed at symptoms of GAD and MDD. These rates were substantially higher than that reported for individual face-to-face CBT (16.6%) (Cooper & Conklin, 2015). The high rates of drop-out attrition may be influenced by the high non-usage attrition mentioned earlier (Eysenbach, 2005).

In the section to follow, I discuss three suggestions to address these key feasibility aspects, namely:

a) The use of additional and/or other recruitment sources.
b) The use of acceptance-facilitating interventions (AFIs).
c) The use of trans-diagnostic Motivational Enhancement Therapy for Treatment Adherence (MET-TA).

(a) The use of additional and/or other recruitment sources. Low participation rates in the completion of the screening survey may have been the result of the recruitment method used:

an invitational email. Krusche et al. (2014) found web-based advertising (advertisements on a local community-based website and on a website providing background information on the intervention) and radio advertising to be the most (cost-)effective methods to generate initial contact with potential participants, returning respectively 22.3% (n=300) and 30.67% (n=412) of participants that could be evaluated for eligibility. These recruitment sources may be helpful in future trials of iCare in SA, given that in other settings they have resulted in substantially higher participation rates than that obtained in this study (7.28%).

(b) The use of acceptance-facilitating interventions (AFIs). As mentioned in Chapter 2, AFIs have been shown to increase the uptake of e-interventions, as they target the barriers to the acceptance of e-interventions (Batterham et al., 2019; Ebert, Berking, Cuijpers, et al., 2015; Mitchell & Gordon, 2007). AFIs, such as the acceptance-facilitating video used by Ebert, Berking, Cuijpers, et al (2015) or the demonstration by Mitchell and Gordon (2007), could help address the barriers to the acceptability of e-interventions, improving the uptake of and adherence to iCare among SA university students. However, AFIs do not impact attitudes towards general psychological help-seeking (Ebert, Berking, Cuijpers, et al. 2015). Addressing these attitudes in general is crucial, as attitudinal barriers are the most significant barriers to initiating treatment, especially among individuals with mild to moderate symptoms of CMDs (Andrade et al., 2014). A low perceived need for treatment, stigma, and the need for self-reliance when dealing with distress all pose substantial attitudinal barriers to help-seeking among emerging adults (Gulliver et al., 2010).

(c) The use of trans-diagnostic Motivational Enhancement Therapy for Treatment Adherence (MET-TA). MET-TA could proactively address pre-treatment drop-out, as it is administered pre-therapy to enhance treatment retention, through the use of motivational

interviewing strategies (Mistler, Sheidow, & Davis, 2016). MET-TA is an effective method of reducing treatment attrition in emerging adults with mental health problems and can be used to improve adherence to other kinds of mental health interventions (Mistler et al., 2016). Implementing MET-TA in conjunction with or separate from AFIs after randomising participants to iCare could possibly increase enrolment and improve retention in subsequent trials. AFIs and MET-TA could assist in reducing during-treatment drop-outs. In addition, it is also suggested that MET-TA should be implemented after an individual has gone two weeks without attending a session (Mistler et al., 2016). MET-TA could, therefore, be a useful strategy to implement, ideally after Session 1 (which had the highest during-treatment drop-out in this study). Lastly, it is especially important to do MET-TA before inviting students to take up iCare, as non-usage attrition has been theorised to influence drop-out attrition (Eysenbach, 2005). Therefore, it is possible that drop-out attrition could be reduced by utilising MET-TA and AFIs pre-treatment and, if necessary, MET-TA during treatment.

In the section to follow, I discuss the results of the ITTA-MI in relation to previous studies on iCBT for MDD. The within-group effect sizes, based on the ITTA-MI, observed at one month (d_{avunb} =0.57; 95% CI [0.30, 0.85], mean difference on PHQ-9 of 3.63; 95% CI [1.89, 5.37]) and three months post-intervention (d_{avunb}=0.30; 95% CI [0.02, 0.58], mean difference on PHQ-9 of 2.25; 95% CI [0.13, 4.37]) were lower than those reported by Titov et al., (2013), (who evaluated the effectiveness of a TA iCBT intervention for MDD). Titov et al., (2013) found post-treatment (d=1.60; mean difference on PHQ-9 of 6.61; 95% CI [4.95, 8.27]) and at four-month post-treatment (d=1.89; mean difference on PHQ-9 of 7.71; 95% CI [6.13, 9.28]). Furthermore, the within-group effect size observed in this study at one month post-intervention (d_{avunb}=0.57) was lower than the within-group effect size (d=0.97; 95% CI [0.77, 1.16]) in Williams and Andrews

(2013), who evaluated the effectiveness of an iCBT for MDD in a primary care setting. The mean difference on the PHQ-9 of 5.96 reported by Williams and Andrews (2013) was higher than that observed in this study at one month (3.63) and three months post-intervention (2.25). The observed within-group effect size of this study at one month post-intervention (d_{unb}=0.57; 95% CI [0.21, 0.93]) was higher than that found in Harrer et al.'s meta-analysis (2018) of e-interventions for mental health among university students, especially iCBT for MDD (g=0.28; 95% CI [0.15, 0.40], although the effect size observed at three months post-intervention (d_{avunb}=0.30; 95% CI [0.02, 0.58]) was similar to the effect size reported in Harrer et al. (2018).

These findings highlight the importance of considering effect sizes in relation to their clinical significance, as mentioned in Chapter 2 (Kazdin, 2014). Using the definition of RCSC on the PHQ-9 proposed by McMillan et al. (2010), it seems that the results of the ITTA-MI do not reflect an RCSC within this group as a whole. This was confirmed by the sample-size estimates based on the minimal clinically significant effect, which showed that although this study was sufficiently powered to detect such an effect, it failed to do so. In light of the small number of participants in the intervention group who were exposed to and started iCare, and the passage of time between assessments, it is possible that the ITTA results may reflect the variable course of MDD and the typical fluctuations in depressive symptoms (Malhi & Mann, 2018; Penninx et al., 2008; Penninx et al., 2011; Verduijn et al., 2017), rather than the effect of iCare.

This said, the PPA results of the iCare completers look promising, as a large proportion (50%; n=3) achieved an RCSC (McMillan et al., 2010) at three months post-intervention. This is supported by their moderate to high satisfaction ratings on the CSQ-8, with a mean satisfaction score of 25/32 (78.13%). However, the results presented in this chapter should not and cannot be used to draw conclusions about the efficacy of iCare, even though it highlights the effectiveness

of iCare as ITTA and evaluates the effectiveness of the intervention, i.e. its real-world applicability (Kazdin, 2014; Salim et al., 2008). To determine the efficacy of iCare, a larger and properly implemented RCT is needed, ideally addressing the key feasibility aspects mentioned earlier.

Having discussed the differences in sample size estimations, I conclude by proposing a strategy to scale iCare to a larger RCT. The sample size estimation based on the safeguard power analysis estimated a substantially larger sample size needed for the larger RCT compared to the minimal clinically significant effect sample size estimation. However, safeguard power analysis estimations are overly conservative (Perugini et al., 2014). This is especially true for sample sizes $\leq$400 and d $\leq$0.8; in these situations (as was the case with this study), the power observed by using the estimated sample size was always above 0.9 and often close to 1.0 (Perugini et al., 2014). These overly conservative estimates have important economic considerations. For example, with the safeguard power analysis estimate, the total cost of providing eCoaching to all the students needed in the intervention group would be almost 10 times greater than that based on the clinically significant effect (R291 200 versus R28 800).

I would argue for the use of minimal clinically significant sample size estimations for the following three reasons. Firstly, Teare et al. (2014) have shown that when using estimates from pilot studies with a total of $\geq$70 participants to calculate the estimated sample size needed to ensure a study powered at 0.9 and alpha set at 0.05, it achieves at least a power of 0.8 (80%), which is the conventional goal (Hickey et al., 2018). Thus, using estimates from this pilot study will with 90% confidence (Perugini et al., 2014) not lead to an underpowered study (Teare et al., 2014). Secondly, it has been argued that it is practically and ethically more useful to design studies around the minimum number of participants to detect the minimal clinically meaningful effect (Kazdin, 2014;

Leon et al., 2012). Lastly, the effective and efficient use of the available human and financial resources is critical in SA, which is an LMIC.

The results and findings presented in this chapter suggest at least three possible strategies in scaling this study to ensure that it is sufficiently powered. Firstly, additional recruitment strategies (Krusche et al., 2014) could be employed. This will not necessarily ensure better uptake or retention rates; however, increasing the recruitment rates while the other rates remain the same could lead to larger number of students that could be screened for eligibility and meet the inclusion criteria. Secondly, the results presented in Table 19 suggest that targeting existing recruitment sources (e-mail invitations) to approximately 50% (n=14 000) of the entire university population could ensure a sufficiently powered study at the three-month post-intervention follow-up assessment. However, this does not guarantee that these students would have completed the intervention. Therefore, a third possible strategy would be to employ MET-TA and AFIs to improve uptake and retention rates, while utilising existing recruitment strategies.

The cost-effectiveness of these proposed strategies should be considered. Employing additional strategies to improve recruitment, uptake and retention rates will require additional financial and human resources, increasing both the direct and indirect costs associated with iCare. Of the three proposed strategies to replicate or scale this study, the third strategy would seem to require the most additional human and financial resources. However, I would argue that this strategy is preferred. It is the most likely to promote the uptake and completion of iCare, thereby giving a better indication of iCare's efficacy compared to the other strategies.

Conclusion

This chapter presented the findings on the first aim of this study, namely to assess the feasibility of iCare. The key feasibility aspects assessed were: (a) recruitment, (b) randomisation, and (c) implementation (utilisation, retention, the assessment of the outcome measures, and follow-up rates). The recruitment and randomisation strategy employed was shown to be feasible, as the proposed minimum of 70 participants were recruited and adequately randomised. However, the sample size estimation based on the minimal clinically significant effect suggests that a larger number of participants than initially proposed would be needed. Additional recruitment strategies were suggested. Low utilisation, retention and follow-up rates were identified as areas that could hamper the feasibility of conducting a larger iCare RCT. I recommended employing strategies proven to enhance not only the uptake of e-interventions but also their retention rates, namely MET-TA and AFIs.

CHAPTER 6: Qualitative findings and discussion

In this chapter, I present and discuss the participants' experience of iCare. The TA yielded seven superordinate themes and several sub-themes (summarised in Table 20). I discuss these in light of the current literature on e-mental health and previous qualitative research on university students' experiences of e-interventions.

Table 20.
Summary of themes emerging from participants' experience of using iCare.

Superordinate theme	Sub-themes
1) The motivation for utilising iCare	1.1) Awareness and acceptance of the need for psychological help
	1.2) Coping with university pressures
	1.3) Assisting in mental health research
	1.4) Interest in surveys
	1.5) Perceived barriers to traditional face-to-face therapy.
	1.5.1) Perceived inaccessibility and unavailability of campus counselling services
	1.5.2) Perceived stigma in seeking and receiving (psychological) help
2) Perceived user-friendliness of iCare	2.1) Absence of direct human interaction reduces the perceived stigma of utilising traditional mental health services
	2.2) Allows anonymity and enables emotional expression
	2.3) Perceived availability and accessibility of ICare
	2.4.) Perceived privacy provided
	2.5) Usefulness of feedback provided by eCoach
3) Perceived positive impact of utilising iCare	3.1) Provided effective coping strategies
	3.2) Enabled participants to reflect
	3.3) Promoted further help-seeking and breaking the stigma
	3.4) Promoted acceptance of distress

Superordinate theme	Sub-themes
4) Perceived limitations of iCare	4.1) Lack of direct human contact *4.1.1) Problematic and possibly harmful* *4.1.2) Hinders formation of a personal connection* 4.2) Expectations of reflectiveness and responsiveness of face-to-face therapy not met 4.3) The un-relatability of the student testimonials
5) Reasons for attrition	5.1) Technical difficulties 5.2) Time constraints and time demands of the intervention 5.3) Received necessary help: awareness of the importance of self-reflection
6) Suggestions for improving the format and content of iCare	6.1) Include indigenous languages and content 6.2) Need for more engaging content and interactive format 6.3) Adjust session frequency and length
7) Suggestions for implementing iCare	7.1) Make iCare available to all students 7.2) Offer iCare as a first step in receiving help 7.3) Implement iCare in combination with face-to-face therapy 7.4) Include online support groups as part of the intervention 7.5) Implement as a targeted e-intervention 7.6) Implement as a tool to prevent relapse

Findings

1. The motivation for utilising iCare

1.1. Awareness and acceptance of the need for psychological help

The majority of the participants perceived the screening survey feedback as an accurate reflection of their reoccurring distress at the time. Mari found this specific episode exceptionally distressing; she needed help:

> *"… this year was an exceptionally severe one, like when I did the survey, it had been going on for quite a while… an exceptionally severe one…Like maybe I really do need help."*

She felt a sense of relief, as the screening survey feedback legitimised her feelings and confirmed her perception that she needed help and that it would be provided:

> *"... when I got the feedback, I did not... it was kind of... thank goodness I am not overreacting. Like maybe I really do need help. Um, so it was, reassuring to know that okay, this is a thing and help is on the way..."*

Similarly, Anisha used the survey to reflect on the state of her mental health and to confirm if she needed help:

> *"I was like, OK lemme see where this is going, what this feedback I'll get. 'Cause they did mention that there'll be feedback. So I wanted to see."*

For many participants, the extent to which they had accepted their distress influenced their decision to complete the screening survey, their perception of the difficulty to do so, and whether or not to enrol in iCare. Katy, for example, had difficulty in completing the survey, as she was still coming to terms with her recent comorbid diagnosis. She went on to say that if she had received the screening survey feedback while in denial, she would not have taken part in the iCare intervention, as this would have meant that she had to accept her diagnosis:

> *"... they had diagnosed me with anxiety, depression, OCD, and ADD.... And like, even doing the survey, I was like, it really did like show, really what I was going through... I felt like, it did feel like uncomfortable like, admitting to certain things...I think if I had to do it now, I'd be more easy about it... I've fully gone through that process... I think if it had been like a little bit earlier when I was still struggling when I first found out, I would have been like no, not something else to remind me of this?"*

Ayanda described the critical role of acceptance in her decision to take part in the intervention, saying:

> *"... If I stayed in that whole denial stage, I wasn't gonna do the program... So first you need to accept that there is something that needs to be sorted out. Then, you'll, then you'll, it will be easier to do the program."*

1.2. Coping with university pressures

Many of the participants said they experienced difficulty adjusting to university and coping with the increased workload. Stephanie described how challenging the transition from high school to university was; she had experienced it as a "big jump", saying: *"... first-year was pretty rough. Ja, it's a big gap"*. Christopher explained how his problems with anxiety had been exacerbated by the transition to university and the significant increase in academic pressure. He said:

> *"I have, I just have got anxiety. I have always had to deal with it; it just becomes a lot more elevated in university ... but actually, as soon as the workload picks up and that, it actually becomes a problem..."*

Christopher expressed his need for coping skills to deal with the academic demands of his course, saying: *"...especially in the science and engineering field where the workload is insane and just having some sort of coping mechanism would be massive."*

Participants also identified other social challenges, such as the binge-drinking culture, which had complicated the transition to university, as Stephanie stated: "*And drinking culture is a massive problem here."* Many of the participants noted that these challenges and adjustments caused them distress, which they had hoped the iCare intervention would alleviate. Some of the participants sought help to deal with the distress they experienced from failing their first semester and having to deregister. Their distress motivated them to complete the screening survey and enrol in iCare, as Kevin stated:

> *"… 'Cause I'd failed some of my modules for first year. So that was the reason why I actually signed up for this. I saw the email then, I think at that time I was in, dire need of like some kind of help…"*

1.3 Assisting in mental health research

Some students stated altruistic motives for taking part in iCare. Stephanie mentioned the importance of mental health research in enabling people to receive psychological help. This motivated her to complete the screening survey and enrol in iCare: *"Ja. 'Cause it's important to me that people get help. 'Cause a lot of people don't."* Similarly, Katy felt that by partaking in this research, she could potentially assist other students dealing with the distress of academic failure to receive the necessary help:

> *" … like with any survey, I've always been like willing to help, if it helps other people… like I said, if I, if you doing the research now could help other people what I've been through, so that they wouldn't have to… Like, face the consequences. Like, for me, my exams and stuff. And, making me deregister. Then, then it's always helpful for other people I think…"*

1.4. Interest in surveys

Some participants mentioned that their interest in completing surveys motivated them to take part. For Rachel, it was her interest in psychology-related surveys that motivated her. She said: *"… and also I am very interested in psychology and so I, like the fact that I did the survey…So I find that interesting.*" While Ayanda stated that her interest in data collecting methods motivated her to complete the screening survey:

> *"So, I tend to do a lot of surveys just to see how people ph-, phrase their questions…And how they collect their data specifically. So like ja, that's one of the reasons why I tend to do surveys."*

1.5. Perceived barriers to traditional face-to-face therapy

1.5.1. Perceived inaccessibility and unavailability of campus counselling services

The majority of participants perceived campus mental health services as inaccessible. Christopher stated that there is a lack of information on where to access these services: *"… if I needed help, I don't know where actually to go to."* He went on to describe the common perception that it was both complicated and time-consuming to access student counselling services, saying:

> *"…it's not this, go through ten forms and then you have to go to this and this building and then meet this and this person and then you get on to this list somewhere. It actually needs to be easily accessible…"*

Similarly, Ayanda explained that the time-consuming nature of these services deters students from making use of them, saying:

> *"It's a hassle having to go… that entire process of, you have to sit there… you have to explain what's wrong before they send you to see a therapist. And it's like, wait; it's a long admin process."*

Some of the participants believed that the high demand for psychological help results in the unavailability of student mental health services, which in turn deters students from seeking help. Stephanie stated: *"So they'll never get an appointment, so they just, instead of going to see if they can, they just say no, but I'll never get one."* Some participants felt that these services do not consider students' schedules. Stephanie emphasised the mismatch between her schedule and the availability of student mental health services: *"…because people don't have time. So, you can't make a therapist appointment at eight at night…That's, ja I think that's it. Maybe they're just*

unavailable." Christopher echoed this perceived mismatch, stating: *"…I have lectures from 08:00 to 17:00 or 09:00 to 17:00 on most days. And the therapy isn't really available after hours …"*

1.5.2. Perceived stigma in seeking and receiving (psychological) help

The majority of participants mentioned the perceived stigma surrounding mental health, both in seeking and receiving psychological support. For some students, this stigma also extended to receiving psychotropic medication. The public nature of campus mental health services prevented Mari from accessing these services. She would feel ashamed if people saw that she needed help, as she thought that they would look down on her:

> *"…everyone walks past there… I know it shouldn't be a thing that you shouldn't feel embarrassed to go, but if you walk in there, like everyone, not that they are looking, but it does feel as if everyone is looking at you…you are less because everyone else can handle life, but you can't…"*

Anisha echoed the perception, saying: *"…that will be the only reason. Like people don't want to be seen going there…it's also because of the, almost like the stigma against going there?"* Although she overcame this barrier and sought help; she was seen as weak for seeking psychological help: *"... like people knew that I'd been to a psychologist. And they're just like more careful around you. Like, I'm not a fragile thing, you don't have to treat me like that."* Some participants were hesitant to seek help in fear of not being accepted by their peers: *"…So I think that's especially, I think, towards their first year where everyone is trying to make a good impression on the group and things like that."* Stephanie felt that some students viewed social acceptance to be more important than seeking help: *"That they would rather be a liked person, than the person who needs help."* Stephanie feared seeking help from her friends. She felt that they would view her as demanding, due to their ignorance of mental health:

> *"And a problem is always a burden, so you don't want your friends to know that you're a burden to them… it's also scary, because, you don't want to say it to someone and then they come back to you with some sort of response, like, no, you're being full of shit."*

Some participants described the barrier that shame posed in seeking and receiving help, as Rachel stated: *"… A lot of people don't want to, um go to a psychologist or psychiatrist because they see it as something embarrassing, almost like a black mark, on you, um, somehow…"* She goes on to explain how this shame might be the result of the ignorance surrounding mental health service use:

> *"… it shouldn't be something which you should be embarrassed about, and I think they, people who don't want to go see a psychologist or don't want to admit that they have depression or bipolar or whatever it is, um, need to have a more clearer explanation of seeing a psychologist."*

Katy went on to explain that the ignorance and stigma surrounding mental health made it difficult for her to disclose the distress she experienced during her first year; fearing being seen as less worthy for seeking help:

> *" You just want people to treat you like normally. Not like, oh be careful what you say around that person now…Coming out, I think the hardest part is that people are gonna like, kind of look down on you, treat you like a lesser…"*

Some participants felt that receiving psychotropic medication was disempowering, as it takes away their sense of autonomy, as Rachel states: *"… And also it's… I want to do it on my own in a sense, um, also I know that I don't need medication for the rest of my life…"* Furthermore, Kevin had the perception that going to see psychologist would mean that he would have to take psychotropic medication; this prevented him from seeing a psychologist initially:

> *"…that was the easy way out. If I just say, hey, I'm going through a rough time, can I get some pills for me to feel better? So that was another fear I had. I don't know if some people*

have that fear, maybe that's why they don't go to psychologists, 'cause they don't want to take the pill route."

2. Perceived user-friendliness of iCare

2.1. Absence of direct human interaction reduces the perceived stigma of utilising traditional mental health services

The absence of direct human interaction inherent to iCare enabled the majority of the participants to seek help and speak about their distress*: "…the impersonal aspect of not having to actually say it face-to-face to someone, that you're depressed, it's a lot easier..."* stated Stephanie. Mari found it easier to make use of iCare than traditional services as she believed that it is not as stigmatised: *"…because I mean it was easier to get me to do this than to go to someone…it is just easier to do an e-intervention, it does not have that same connotation to it…"* This enabled her to open up about her distress without feeling like a burden*: "And it is not that you necessarily put your problems on someone, yes there is someone that reads it, but you can just put your problems there…"* Similarly, Anisha found it easier to discuss her distress on iCare than in face-to-face therapy:"…*It was like, over the, like, computer, and I figured that's the easiest…To open up, yes. To open up easier…I have been to a psychologist, but I've never opened up…"*

2.2. Allows anonymity and enables emotional expression

The majority of the participants felt reassured by being anonymous and by the presence of an anonymous eCoach. This helped them to focus on themselves and be honest about their distress. Stephanie thought that she would not be as open if she knew the eCoach: *"... I might be more inclined to hide things instead of being completely honest. Yes. Easier to concentrate on myself as well. As opposed to concentrating on who I'm sharing it with."*

The majority of the participants found that iCare's anonymity enabled them to express their emotions, something they would not have been able to do face-to-face, as Ayanda stated:

> *"…It made it, made it really better. Because I find it extremely difficult to talk to anyone I know about feelings or emotions. So, the fact that it was over the internet… it's a person I don't know, it's like a total stranger…it was better for me, 'cause I was able, I, I could, like, express myself…"*

Christopher felt this mediated his fear of being judged, encouraging him to openly discuss his distress on iCare. However, he mentioned that not all participants would find the anonymity of the eCoach helpful:

> *"…I actually found it better, just because you have never met this person, you know that they can't judge you because they don't actually know who you are…I think it very much depends on who is using it. Some people would find it very nice because they can be open and some people will find it not useful…"*

Peter, for example, found it difficult to trust and open up towards the anonymous eCoach: *"I remember having a lot to say about each session, but not wanting to type every detail to a person I haven't met and don't trust."*

2.3. Perceived availability and accessibility of iCare

The majority of participants praised iCare's perceived availability and accessibility. Christopher emphasised iCare's availability compared to face-to-face therapy's perceived unavailability: *"…this is where this course has a big advantage. It's just this; you can go home, it's there, you don't have to drive anywhere, you don't have to book an appointment, it's available..."* Mari enjoyed accessing iCare at a time that fit her schedule: *"That was the nice thing about this intervention, like it was convenient, on your own time…"* Similarly, Stephanie enjoyed being able

to engage with the iCare content as long as she wanted to; in contrast to the limited availability and accessibility of face-to-face therapy:

> *"... it can be accessible to so many people, as opposed to just a therapist that you have an hour session with. And, I could spend as long as I want to on that, and still go access it afterward..."*

2.4. Perceived privacy provided

The majority of the participants felt that iCare provided them with the privacy they needed to access help; in contrast to the public nature of accessing campus mental health services. Stephanie felt that this enabled her to decide who is aware of her receiving help: *"...In like, private, and it, no one would've ever known that I'd done it unless I told them."* Mari would encourage her friends to use iCare as they will be able to access help privately: *"Yes, because you can do it in private, you know, without people knowing."* She goes on to describe the comfort that iCare's perceived anonymity and resulting privacy brought her:

> *"...like the anonymity helps to put you at ease because it is online, because, I mean, things can easily leak out... if it does, it is anonymous, so yes, password protected and all those things..."*

Mari thought that the benefit of iCare's privacy might be limited to students who can afford portable devices, such as laptops:

> *"... it was easy for me because I sat at my laptop, in my room when I had time. But I mean if you do not have access to a laptop or whatever then you had to go and sit in the library to do it. That is not something that you would want to do."*

2.5. Usefulness of feedback provided by eCoach

Some of the participants felt that the eCoach's individualised feedback mediated the absence of direct human interaction. Mari stated: *"…the feedback that you got, it was not the interaction as such, but it was still as if you were talking to someone…"* In addition, participants felt that the individualised feedback assisted them in navigating the session content, and reminded them of the content between sessions, as Stephanie stated: *"It was nice…if I hadn't gotten feedback, I wouldn't have continued thinking about it during the week."* Christopher emphasised how the individualised feedback made him benefit the most from the course:

> *"…having this person to, ja actually comment on your answers…all the responses were very much individualised which I very much liked…they do actually give advice on, just focus on this or maybe, you know, try be a bit more specific and things like that… I feel like that helped me get the most out of the course."*

3. Perceived positive impact of utilising iCare

3.1. Provided effective coping strategies

The majority of participants felt that they needed strategies to cope with specific difficulties, instead of receiving sympathy, as Anisha stated*: "… and they give you sympathy a lot when you're doing one-on-one, and I don't like that so much."* These participants felt that iCare provided such strategies:

> *"… my biggest thing is that I constantly have these problems and I don't need, I don't need sympathy or that, I just need to know the tools that I need to cope with it. And I feel like this intervention thing was very useful in that it gives you a lot of tools, a lot of guidelines and examples of situations and how they dealt with it, that you can try and apply to your own life..." (Christopher)*

The majority of participants felt that the optional modules were especially helpful in providing specific, solution-focused coping strategies:

> *"...you can choose also, they give you, um, sub-activities that you can choose as extra-curricular sort of vibes. So, like, you know, like that. Like what you're struggling with. So they give you tips on that. Like self-respect or s-, appreciation, like that then..." (Anisha)*

Participants felt that these modules covered a broad range of specific difficulties that any student could experience, as Stephanie stated: *"Because it covered, it covered lots of aspects of life. But then they were very specific, which was really, really nice."* These modules assisted her in dealing with her sleep hygiene and perfectionist tendencies: *"...And a thing on sleep, and a thing on, like, perfectionism, and those were really helpful, just to, like, remind you of what's normal, I guess..."*. Some participants appreciated and felt empowered by the option to tailor each session according to their needs at that time.

> *"...and the additional modules that you could do, that was nice because, like, that week I could decide, like, you know this was this type of week, so then I am going to do this module..." (Mari)*

The need for constantly available, specific, solution-focused, tailored coping strategies seemed to be especially important to Stephanie:

> *"... it felt like it ended too soon. 'cause there were all these optional modules. And it would've been nicer if I could've done those afterwards. 'Cause, once you've been doing that for a while, it becomes a weekly, crutch..."*

3.2. Enabled participants to reflect

All the participants felt that the biggest benefit of iCare was that it assisted them to reflect on their thoughts, feelings, and behaviours. Some participants found the student testimonials especially useful in this regard:

> *"…it guides you quite nicely through the student examples it provides, if you are not too sure what they are asking, it gives you an example. That is the nice thing about this program…" (Mari)*

Participants found it useful to reflect on their need to structure their time. Anisha became aware of the positive influence this had on her mood, leading her to study more efficiently: "*… they suggested putting up a study schedule and stuff like that there. And my marks improved and stuff. So I feel, maybe it, I, it helped…"* Ayanda expressed that iCare would have been more beneficial to her if it was made available earlier in the year; enabling her to reflect on the importance of a balanced university life:

> *"… 'cause, matric I did everything, and I handled it perfectly…not realising that there is a difference between matric and first year…had I had this whole intervention in the beginning… I would've realised earlier that I'm putting way too much strain on myself…"*

Participants expressed how they benefitted from reflecting on their emotional needs. Through iCare, Stephanie became aware of issues that she needed face-to-face help with:

> *"…I went after this to a therapist, because I realised that I needed that. Instead of, going straight to a therapist, and not knowing what was actually wrong. This was like a thing that helped me diagnose my problems, and figure out, where I stood…"*

The majority of participants felt that iCare enabled them to reflect on their thoughts and the impact that these thoughts had on their emotions, behaviours and relationships with others:

> *"…my anxiety has made it difficult for me to, not make friends, but to kinda keep the friendship…I find ways to, I don't want to say destroy, but, ja, kinda overthink it…" (Christopher)*

Anisha stated that iCare enabled her to identify when she engaged in negative thinking:

> *"… Aware of my thoughts and stuff…it makes you more aware, like it, like you know what, OK now you're just, like, wallowing in self-pity. You need to get out of this, do something productive instead."*

iCare made Stephanie aware of her possibly problematic drinking habits and her poor sleeping hygiene:

> *"… I'm not saying I have a drinking problem. I'm just saying that I did it. Yes, but then you realise, having done that, OK this isn't normal. Maybe I shouldn't. Or, the sleeping thing was a big thing for me as well. Realising that, only a few hours a night doesn't actually work…"*

Through iCare, Ayanda was able to reflect on her limited means of expressing her emotions. iCare made her aware of alternative ways to express her emotions, such as writing. She felt that she benefitted from her expanded repertoire of ways to express a range of emotions:

> *"… I understood that I could actually write in a journal to express the other emotions. So, it helped me express the other emotions that I'd been suppressing for so long… When I got angry, I just drew and so… but then, went through iCare, realised that I could write. So now I also write, and I draw… 'cause, bottling up emotions is so tiring. So I think it was the fact that I was able to express my emotions better... I think it helped, 'cause it wasn't bottled up…"*

3.3. *Promoted further help-seeking and breaking the stigma*

The opportunity to anonymously discuss their distress and express their emotions made some of the participants feel more prepared to seek face-to-face help. This made them overcome the self-stigma they had towards seeking psychological support, as Kevin stated:

> *"…sometimes you feel, uh, shy to go to a real psychologist. I think that, is almost like a sign of, defeat in a way… Ja. So, I think that the… the fact that it's online also just makes it, really, anonymous, and really, I think, helpful. Ja… And then you realise that it's for my own benefit. So, seeing a psychologist was no longer like a shameful thing for me."*

Similarly, Katy felt that iCare's anonymity would encourage participants to open up about and accept their distress. This would make it easier for them to seek face-to-face help:

> *"… going to somebody else is always difficult. So maybe if you like, had to do it on the, like, on your computer, go through this, then you've already kind of said it to someone? And then maybe going, to someone else, saying it face-to-face would be easier."*

3.4. Promoted acceptance of distress

The majority of the participants mentioned that iCare assisted them in accepting their distress, as Ayanda stated: *"As you learn how to deal with your emotions, you also learn to accept things. It becomes easier to accept things about yourself, so, it also helped with that."* iCare enabled Kevin to become aware of his fear of disappointing himself and others and to accept his current situation, empowering him to deal with his distress:

> *"… If you can remove fear, it'll remove the depression…the only way to remove that, is, to experience it and let it, ex-, to let yourself experience it but, don't let yourself be affected by it. And this is what, your program, allows to do… So, I mean I couldn't change the situation… I couldn't change what had happened. But I could change the fact that I didn't have to let it, let me feel down."*

4. Perceived limitations of iCare

4.1. Lack of direct human contact

4.1.1. Problematic and possibly harmful

Some of the participants felt that the absence of direct human contact could be problematic and potentially harmful. Mari and Anisha thought that the lack of direct human contact did not promote a strong sense of accountability towards the completion of the whole session, or implementing the strategies they learned. Mari stated:

> *"…it was easy to say, ag you know I did not actually do it, but it is okay. That is was I said a lot of the times. Um, and I think that maybe if you had to say it in front of a person, like, had to say it to a person, that's, um, that's different, yes."*

Mari felt that the danger in iCare lies in the lack of control over how a participant might react towards the content presented: *"… I think that is kind of the danger of a program as well. There is no control over how the person will react at that moment…"* Peter's experience is an example of the limitations posed by the absence of direct human contact; leading to misinterpretations and misunderstandings:

> *"Without someone saying something in a specific tone coupled with a facial expression, questions, or instructions aimed at private information can seem invasive or insincere. Basing the online platform on text, therefore, creates opportunities for misunderstandings or misinterpretations..."*

Peter experienced the session on the symptoms of depression as hostile, insincere, invasive and judgemental; as a result of the lack of direct human contact:

> *"The information on depression regarding the mental processes of someone suffering made it seem as if the program was making a mockery of the person reading the text, by proving the patient's mental processes summarised as a list of incorrect thinking patterns.*

> *Summarising something sensitive in an open view can seem extremely judgemental, and this is where the lack of face to face contact comes in the most. A psychologist could easily react to a patient's expression if something said was insincere/misunderstood and solve the problem, where if it were online, the patient would never have typed their actual response. Overall the session on depression made things worse rather than helping."*

However, Peter's experience of iCare's content is in contrast to the other participants' experience. Christopher felt that the material conveyed a sense of understanding:

> *"… because a lot of the content was, never hostile, never aggressive. It was actually understanding or as far as content can be, you know what I mean. It's, you don't feel excluded because of it. Um, and no, I was actually very happy with it."*

This said, the majority of participants acknowledged instances where the lack of direct human contact limited the perceived advantages of iCare. Although iCare enabled Mari to become aware of the difficulty she has in dealing with acceptance, the benefit of this newfound awareness was limited; she could not discuss this issue in more detail, something she needed:

> *"Yes, because, like, I think I needed to talk about it, like, I did not even know that it was an issue. And when I realised that is an issue, I had no one to discuss it with further, because the program only goes so far…I felt that I just wanted to talk about it a bit more…This is where the intervention is totally different from talking to someone. Like, it suggested solutions, but I did not necessarily always want a solution."*

Christopher felt that the help he could receive was restricted to the content and exercises contained in the sessions:

> *"…you can't really ask them for help outside of it, outside of the lessons…I think that if you had an actual person that you were talking to or that you needed help with something, you could actually go on a bit of a tangent and ask for help about a specific matter. And I think that that is where talking to a person is a lot more useful…"*

4.1.2. Hinders formation of a personal connection

The majority of the participants felt that severely depressed students would need to form a personal connection. Rachel felt that e-interventions seem impersonal: "*…whereas on a computer you kind of know that that is what they are saying to everyone, you know, like, it is the email they send to everyone…"* She felt that severely depressed individuals need to form a personal connection to alleviate their sense of loneliness; something that can only be fostered in a face-to-face relationship:

> *"…if, they are very depressed, like, internet intervention isn't enough. Um, just because it's, it's, you are still lonely, you know, it is still you and a screen…whereas when you, when you make that connection with someone, um, and you trust someone to, like, say all these things and have a, be completely not judged, um, it is a very different feeling and you don't feel so alone…"*

Rachel also experienced difficulty in building trust with the anonymous eCoach: *"...um, I can't speak to people that I have never met because, um, I'm quite reserved like I, I will slowly trust someone…"* However, she did not find the lack of face-to-face contact problematic; she experienced iCare as a tool for self-reflection and maintaining the benefit of therapy, rather than a means to form a personal connection:

> *"…but I was fine, like, doing the internet whole thing…because it is not like you are constantly talking to a person, it is just like exercises that you do, and like you read through some stuff. And I found that helped…and I am not at that bad stage and everything so, like, every week it's, um, nice to, like, almost keep track of it…almost like a mild therapy in a sense, um, where it doesn't really like feel like therapy. It's just like a reflection of yourself… it was nice to, like, have a structure."*

4.2. Not meeting expectations: reflectiveness and responsiveness of face-to-face therapy

It seems that some of the participants expected iCare to be similar to a face-to-face therapy session. Peter referred to himself as 'the patient', while Stephanie referred to the eCoach as the 'therapist': *"…The feedback that I got from the, uh, therapist was pretty average… that was a bit disappointing actually."* Stephanie's expectations seem to have influenced her experience of the responsiveness and reflectiveness of the eCoach's feedback. She expected the feedback to be more responsive: *"…so if, if the feedback for this EK (iCare) thing happened a lot quicker…"* She expected the eCoach to have analysed the content of her sessions: *"A bit more like, analysis of what I'd said…"* Stephanie needed more than just guidance and encouragement through the content: *"And it, it felt like, I could've had more. 'Cause I knew that I needed more."* She needed external insights as she felt that her own insights were not helpful:

> *"… Like he never, he never said anything about, looks like you're lacking here. And those are the things that I noticed myself, so I figured that, ja. That was my problem with that...instead of, maybe you should do this rather or, you're doing that wrong. 'Cause, obviously if I was doing something about my mental health, then that means I'm not very good at it."*

However, other participants did not expect iCare to fulfil the role of a person. Mari felt that the purpose of iCare was to promote participants' self-awareness rather than substitute the role of a person:

> *"Because I mean it is just an intervention to, like I said, I think it is good in getting you to that level where you are aware of what is going on. But I don't think that you will ever get it on that level where it will take over the role of a person."*

Similarly, Anisha felt that the purpose of iCare was to serve as an outlet for her emotions; she did not expect anything more: *"…I feel with the iCare; it's more about expressing your feelings and like getting it out there…like you know, just not bottling it up inside…"*

4.3. The un-relatability of the student testimonials

Some participants found the student testimonials helpful in assisting them to reflect. However, it seems that Stephanie had difficulty in reflecting, as she was not able to relate to these testimonials: *"…I often didn't know what I was supposed to write in the, uh, boxes…I looked at the examples, and the examples weren't relative to me whatsoever."* Therefore, she found it time-consuming to process and reflect on the sessions: *"…then you're given all this, new information, and, I'm someone who takes a while to think about things…."*

5. Reasons for attrition

5.1. Technical difficulties

The majority of the participants who did not complete all the iCare sessions experienced technical barriers to accessing iCare. Kevin, for example, had to deregister from the university soon after starting iCare. He moved back to Zimbabwe where he did not have internet access: *"…I'm just gonna do it in my head because I don't have, I didn't have internet at that time…"* Some of the participants experienced difficulties with their laptops; Katy lost all the data she had on her laptop, including her emails, and could not continue with the intervention: *"… my laptop crashed! So I've lost absolutely everything."*

5.2. Time constraints and time demands of the intervention

Rachel initially encountered technical difficulties. However, once these were resolved she decided not to continue with iCare; she experienced it to be too time-consuming during exams. She was under the impression that she had to complete a session every day:

> *"… eventually, um, I stopped doing it because my laptop wasn't working the one week and so then you just sort of left it, also that one they wanted you to do every day and, like, I didn't have, like, 40 minutes to spend every day on it…".*

Similarly, Ayanda mentioned that her lack of time was the only reason that she discontinued using iCare: *"… it was like literally the only reason that I did not have time. 'Cause I wanted to continue with it, but I never had time. And then when I did have time, I was so tired…"* She felt that she did not have time in between seeing various mental health professionals at the university's disability unit, and her academic responsibilities, to complete iCare. It would also seem that these experiences were emotionally taxing and affected her energy levels, as mentioned above:

> *"…'cause I couldn't speak for three weeks…. I went to see the disability unit….. It was during the intervention thing. And I was just, dealing with a lot of doctors and, dealing with my social worker, and dealing with school and, and, and…"*

5.3. Received necessary help: awareness of the importance of self-reflection

In addition to not being able to access iCare after moving back to Zimbabwe, Kevin thought that he had received the support he needed after the first two sessions: being made aware of the importance of self-reflection. Kevin felt empowered to deal with his depression after gaining this insight. For these reasons, Kevin did not complete iCare:

> *"…I was feeling this way, and, this is how this affected me. So your power is in yourself. That's why I give this a big thumbs up. … So there's no need for me. Then I also did other*

research, and I saw that there's that same pattern of self-consciousness. So I didn't finish the whole, the whole, thing."

6. Suggestions for improving format and content of iCare

6.1. Include indigenous languages and content

The majority of participants suggested the option to complete iCare in the participants' home language, as Christopher stated*: "I think definitely having the option there would be quite nice. I think especially in Stellenbosch, Afrikaans as a second language would be very good."* Mari, an Afrikaans home language speaker, did not find it problematic to complete iCare in English. However, she felt that it could be beneficial to students to access iCare in their home language; especially students who traditionally don't have access to psychological help in their home language:

"…definitely for one of the, like, Zulu or other languages. Because I mean it is a very personal thing and I think that it might just work better if you can do it in your own language. Like the English did not bother me at all, but I can imagine that it could be a bit of a barrier…I think is it not also one of the things with, like, the psychology practice in general, that people do not have access to someone that speaks their language?"

Ayanda, a Black female, felt that although she enjoyed iCare's content, it could be made more specific to the SA population, although, at the time, she could not think of ways this could be done:

"…the content was nice, the stories that they had, they were nice to read …there could be certain aspects that I'd change so that it's, like, more South African based? Not specifically Stellenbosch, but like South African based? So that it's more relatable. Ja. Hmm. I could email you some when I think of them."

6.2. Need for more engaging content and interactive format

Some participants felt that the videos lacked depth, as Christopher stated: *"…the videos were very good at getting you interested... But if you skipped them, you wouldn't have missed too much…"* Similarly, Stephanie felt that they were not suitable to young adults*: "…it didn't, it didn't feel grounded enough. It felt airy-fairy… They're very colourful and childish…"* Christopher felt that the written content was comprehensive and suggested that some of this should be added to the videos:

> *"… the contents in the passages and messages were often more in-depth than the videos…I do feel that the videos, ja, not word for word but maybe include just a little bit more info from the paragraphs there…"*

Rachel felt that presenting the content via video format would be more engaging to participants than a lot of reading. In addition, the sessions should not take longer than 30 minutes to complete:

> *"…um, a lot of reading, I wouldn't recommend for an internet-based therapy… But if you are trying to explain what's happening…let's say for, um, how to deal with anxiety, like, things to do, rather make, like, a short video with pictures or images or find one on YouTube that explains it, um, and you could still write it if you wanted to, but I think the video, more people would watch it.… I think, um, it mustn't be, like, over half an hour. Ja the ones I were doing took 40-45 minutes, and I would find that it was just, it was so long."*

She suggested that pop-up quotes could aid in promoting participants' engagement with iCare: *"... ja maybe like something random could be a quote every day that comes up, like, on the website…"* Other participants experienced iCare's format as static and expressed the need for more interactivity, possibly through the use of videos:

> *"…it's permanently they ask a question, you give an answer. Like I understand that, because you're gonna have to give your fe-, what you're feeling, 'cause it's all about that.*

> *But, I dunno, maybe a bit, something. A bit more stimulating…the reading work was fine…I feel maybe make the sessions a bit more interactive…Like, maybe more videos or something." (Anisha)*

Mari felt that the amount of reading work possibly contributed to the static feel; this might hinder some participants from engaging with the sessions. She suggested making use of more videos to reduce the amount of reading work, increase the interactivity of the sessions, and promote engagement:

> *"…because there is a lot of reading work… I know some of my friends won't like this; it is just a bit too static. Like, it is read, read, read, answer, answer, answer…The videos were cool, and I know that a lot of my friends will really like a more interactive thing… instead of reading the tips or the layout of the session, you have everything in a video. Because I know if there is too much reading work, then my friends would be put off by it."*

Kevin suggested that iCare should incorporate an additional aspect enabling synchronous, anonymous communication with the eCoach. Kevin thought this feature would be useful, although more expensive, as it would require more time from the eCoach:

> *" ...feedback, I think that really helps a lot or, if you'd even had that more frequent…sometimes you f-, you don't f-, you feel like you don't wanna talk. But then if there is someone to talk to, who actually isn't there. It makes it a lot easier. That's why people find it easier to, talk on social media…So we could take advantage of that and say, let's use that tool for people who actually, need it. So people who are depressed… And then that can be a platform to like, share, or how you're feeling. And you know it's confidential, you know that it's private. But obviously that would be more expensive, to, to, to organise that…"*

6.3. Adjust session frequency and length

Kevin suggested condensing the overall program, limiting the number of sessions to enable participants to realise the importance of self-reflection sooner. However, he felt that participants with severe depression would not benefit from a shorter version of iCare:

> *"… Another way you guys can improve is, maybe cramming it more... Like this is what this is: recognise a pattern, or, just be self-aware…depending on how deep someone is in how they're feeling. If I were, the point when I was like deep, deep, deep, I don't think, the condensed program would've worked. I probably needed like slow fishing out of that whole scenario."*

Kevin went on to suggest that the frequency of the sessions should be increased rather than condensing the programs:

> *"…doing it a couple of more times a day would make someone more conscious… I don't think squeezing it up would be the best, 'cause then s-, people might just rush through it and not actually take it all in."*

Ayanda also thought that condensed sessions would hamper self-reflection: *"… you need more time to spend with yourself. So, if the ses-, sessions become shorter, you don't get as much time to do some introspection…"*

7. Suggestions for implementing iCare

7.1. Make iCare available to all students

Some of the participants felt that all students could benefit from iCare, or an adapted version thereof, as Mari stated: *"… it has such a reflective nature, like, you can literally just go through it, yes, anybody can actually do it..."* She suggested one version of iCare for students who are experiencing distress or are aware that they need help; another for students in general. She felt that students' level of distress might impact on their level of engagement:

> *"…I think that the program should be adjusted a little bit to be used by anybody because I don't think that someone who does not realise that they have that problem, or that they are going through something will put in so much effort and time. So maybe an abridged version for everyone and then, you know, a deeper, longer and more intense one for others."*

Similarly, Christopher would recommend the current version of iCare to students experiencing symptoms of distress, such as MDD: *"Ja, if I knew anyone struggling just with depression or anything along those lines, I would definitely recommend it, ja."* Some participants mentioned the importance of marketing iCare, as Christopher stated: *"… as soon as, if you want to make it public you just have to promote it a lot more."* Stephanie felt that iCare should be made available on the campus mental health services website. In addition, she suggested that all students be informed of iCare via email:

> *"…Um, ja. I, I would just have it available always on, like, on the SSVO page for participants. And then, occasionally maybe some sort of correspondence sent out, of, like, hey do this, maybe it'll help you."*

Mari suggested that each optional module could serve as an intervention on its own. This would enable more participants to receive help on a wide range of difficulties:

> *"…with the optional modules and so, like I mean it can easily be a program on its own. Every module can be like a program on its own…Definitely, and I think it will enable more people to benefit from iCare and receive help…"*

7.2. Offer iCare as a first step in receiving help

The majority of participants felt that iCare is a good first step to receiving help, as Mari stated: *"…it is especially good, especially for participants to like, you know, like just to begin with it…"* iCare made Stephanie aware of her difficulties, improved her well-being and, as mentioned earlier, made her realise that she would benefit from seeking face-to-face therapy:

> *"…because, it was the starting point. Because it was the push in the right direction. And, my life, as a whole, has become a lot better since then. It, it, I mean, it might just be a coincidence, but it helps a lot."*

Some participants suggested that different forms of receiving psychological help have different roles to play, at different times. For example, Anisha felt that the benefit of group therapy lies in the support it offers, alleviating the feeling of struggling alone:

> *"Because like, like if you find people who are, like, suffering from like, like, like going through the same thing as you are…you, like, feel there's this, this bond almost like togetherness… somebody understands what you're going through. You're not alone in it."*

Mari felt that being part of a support group would act as a haven and bring a sense of hope in case of a relapse:

> *"And I think the group thing will also work in, like, the long term. Um, just to make sure you are… there is someone that can catch you…to remind yourself that, you know, if something happens it's okay, there are people that can help me…"*

These participants felt that iCare should, therefore, be implemented as part of a process to deliver psychological help according to students' needs. Anisha thought that she would first make use of group therapy before face-to-face therapy: *"…I think support group to, like, ease yourself into it, and then one-on-one."* On the other hand, Mari felt that she would start with the e-intervention, then take part in a support group and then go to one-on-one therapy: *"…Like, that is why I say iCare, face-to-face therapy, and then group therapy, I feel those steps could work quite well…"*

7.3. Implement iCare in combination with face-to-face therapy

Peter felt that e-interventions should be combined with regular face-to-face sessions. It would seem that iCare's lack of direct human contact did not fulfil Peter's need for the responsiveness and reflectiveness typically found in face-to-face therapy. He made suggestions to mediate the lack of

responsiveness and reflectiveness of iCare: *"…the same format as a program to improving yourself with step by step instructions, coupled with a face to face contact session on fixed dates/times…"*

7.4. Include online support groups as part of the intervention

Some participants suggested adding an online support group to iCare, as stated by Anisha:

> *"… Like I feel, like almost, like, how you have group chats and stuff like that there? So, like that. Would like, like group… support groups online."*

Stephanie suggested that these should be disorder-specific online support groups:

> *"… not like anxiety and depression together. 'Cause they're related, but they're not the same thing. And then, ja. I feel like, it would have to be quite specified."*

Stephanie goes on to state that one should be able to select which specific group you would want to join. She feels that the main benefit of these groups is that they will alleviate participants' sense of loneliness:

> *"So then you, like, choose, a drop-down list of all the things that you're suffering from. And then you can join those support groups. Just so that, it's known that there are other people, anonymously, but there are other people who are suffering from the same thing. 'Cause that's often a thing of, ja, but maybe I'm the only one."*

She suggested that these groups could either take the form of anonymous chat rooms or a blog that students can use as an artistic outlet. However, participants should not be able to comment on the blog. It would seem that even on an online support group, the fear of judgment is still prevalent:

> *"…thinking of it like a chat room, or like a, or just like a, a blog even. Where you can post essays… A lot of people find poetry…therapeutic, is the right word I guess... 'Cause you, then you're just sharing and maybe not allow a comment section. Just because of the worry of that" (Stephanie).*

7.5. Implement as a targeted e-intervention

Kevin suggested that iCare should be targeted towards participants who failed their first semester, as they are most at risk of developing symptoms of depression:

> *"She failed her first year, and she went through a depression all that…So, I mean if, if she had been noticed that, OK, this person had failed, um, and she's dropped out for second semester, she's coming back next year, then you could target resources to people like that…realising those people who are really, really in need of this…guys who actually do fail modules get hit hard …"*

7.6. Implement as a tool to prevent relapse

Rachel suggests that one should not terminate face-to-face therapy without having some form of help to maintain the benefit achieved in therapy and prevent relapse or '*slip*' as she stated. She feels that iCare and group therapy help in this regard, suggesting that these forms of therapy could assist in preventing relapse:

> *"… And then, like, all of a sudden as soon as you slip…like, I don't think it is a good idea to all of a sudden not have therapy… So I think, like ja, do personal therapy and then have some group and then stop personal therapy and then still go to group and then, um, if you want to, you can come out and go out of group. And then internet therapy, um, I think is similar to group, um, in a sense…like maintenance."*

Discussion

Participants experienced psychological distress related to the educational, social and emotional changes common to 'emerging adulthood' and entering higher education (Dyson & Renk, 2006; Prendergast, 1994; Sussman & Arnett, 2014). This highlighted the difficulty some first-year

university students experience in adapting to university life (Dyson & Renk, 2006). Some students are faced with increasing academic pressures, the impact of academic failure, a binge-drinking culture, and irregular sleeping patterns (Arnett, 2005; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Cuijpers, et al., 2018; Prendergast, 1994; Bruffaerts et al., 2018; Bantjes, Saal, et al., 2019). All participants were aware of their distress, which motivated them to make use of iCare. Some participants only became aware of their need for psychological help after receiving the screening survey feedback. It would seem that participants' perceived need for treatment facilitated their use of iCare; consistent with research indicating that a lack of perceived need of treatment prevents individuals from seeking treatment (Andrade et al., 2014; Mojtabai et al., 2011).

The transtheoretical model (TTM) for stages of change has been applied to psychotherapy and is useful in understanding the feedback above (Prochaska & Norcross, 2001; Prochaska & Velicer, 1997). According to the TTM, individuals need to progress through certain stages to achieve a change in behaviour, such as addressing their distress. Progression through these stages is facilitated by processes and principles of change specific to each stage (Norcross, Krebs, & Prochaska, 2011; Prochaska & Velicer, 1997). Pre-contemplation is the first stage; characterised by individuals who do not intend to seek help and are unmotivated or resistant to engage in therapy, typically unaware of their problems (Norcross et al., 2011; Prochaska & Velicer, 1997). The second stage, contemplation, is characterised by individuals who are aware of their need for help and intend to address their current difficulties (Norcross et al., 2011; Prochaska & Velicer, 1997).

Consciousness-raising is a process of change that assists individuals to progress from pre-contemplation to contemplation by increasing their awareness of their need for help and the benefits of seeking help (Norcross et al., 2011; Prochaska & Velicer, 1997).The screening survey feedback seemed to achieve this. Motivational interviewing (Rollnick & Miller, 1995) (used in

MET-TA, discussed in Chapter 5) might also be useful to facilitate consciousness-raising through exploring and resolving participants' resistance to address their distress (Norcross et al., 2011). In addition, this points to the possible benefits of targeting iCare to students in the contemplation stage, who may be more likely to take up iCare. For example, students already accessing the campus mental health services website, and students experiencing distress as a result of failing their first semester, as suggested by participants.

The perceived barriers reported by university students internationally (Mowbray et al., 2006) were also reported by participants in this study; importantly, stigma, which reduces help-seeking behaviour through 'label avoidance' (Corrigan, 2004). Individuals want to avoid being labelled as someone with a mental disorder, and therefore do not want to be seen accessing mental health services. Thus they avoid the perceived prejudice and discrimination associated with mental disorders, navigating the feelings of shame and embarrassment associated with self-stigma (P. Corrigan, 2004). Similar to other qualitative research of university students' experience and expectations of e-interventions (Chan, Farrer, Gulliver, Bennett, & Griffiths, 2016; Fleischmann et al., 2018), the participants in this study valued and benefited from the anonymity, privacy, availability, and accessibility provided by iCare. Although the aforementioned are essential to the acceptability of mental health services in general, the perceived helpfulness and credibility of these services seemed to influence the likelihood of their use (Musiat et al., 2014).

The TTM is also useful in understanding participants' experience of the eCoach and the positive impact of iCare. It is argued that interventions and the specific relational stance of the therapist should be targeted to the individual's specific stage of change (Norcross et al., 2011; Prochaska & Norcross, 2001). As mentioned before, it is possible that the majority of students were in the contemplation stage. The relational stance of a 'Socratic teacher' is important at this

stage. This relational stance encourages the individual to gain insight into their situation (Prochaska & Norcross, 2001). Participants experienced iCare as helpful in gaining insight into their emotions, thoughts, and behaviours. iCare provided them with an opportunity to reflect, which they experienced as beneficial. Similarly, students in Ly et al. (2015) experienced the awareness they achieved through the guided e-intervention for MDD as crucial to their improvement. Also similar to the current study, students in Fleischmann et al.'s study (2018) reported that they valued the motivational and repetitive function of the feedback provided by the eCoach, i.e. being reminded of the content of the sessions and the insights that they gained during them (Fleischmann et al., 2018). It is possible that the guiding role of the eCoach reflects that of a "Socratic teacher', therefore some participants (possibly in the contemplation stage) had a positive view of the eCoach's feedback.

Individuals will progress through the stages of change if the benefits of doing so increase, while the costs decrease. This is known as decisional balance (Hall & Rossi, 2008; Prochaska, 1994; Prochaska & Velicer, 1997). It is possible that experiencing the benefit of gaining insight into their distress and their needs, and being able to express their emotions, enabled participants to progress to the preparation stage, where individuals have started taking small steps to address their distress (Prochaska & Velicer, 1997). These steps may have included the use of the optional modules, which, as the participants stated, provided them with tailored strategies to cope with difficulties related to symptoms of anxiety and MDD. These modules seemed to have provided participants with specific coping tools, possibly giving them a sense of regaining control over their lives in deciding how to address the specific difficulties they faced (Wilhelmsen et al., 2013). These findings are in line with previous studies of guided e-interventions for university students with symptoms of MDD and stress (Fleischmann et al., 2018; Palacios et al., 2018).

An *experienced* coach is needed in the preparation stage to either provide the individuals with a plan of action, or review their own plan of action to address their distress (Prochaska & Norcross, 2001). Through decisional balance, some participants may have moved to the action stage, i.e. becoming actively engaged in addressing their distress. This stage entails observable behaviour changes which require significant time and energy. In the action stage, individuals need a 'consultant' to provide them with expert advice and support (Prochaska & Norcross, 2001). This could explain some participants' dissatisfaction with the eCoach's feedback, which they experienced as lacking the necessary responsiveness and reflectiveness. Similarly, Fleischmann et al. (2018) and Palacios et al. (2018) found that students were dissatisfied with the explanatory function of the feedback, expressing their need for feedback that was more tailored to their responses. Students in Palacios et al. (2018) mentioned that although they appreciated the presence and guidance of the eCoach, they felt a lack of personal connection with them.

It seems that participants experienced the anonymous eCoach and lack of direct human contact as beneficial in the early stages of iCare, which facilitated their engagement with iCare. However, as they experienced the benefit of gaining insight and taking small steps to address their distress, the role of the eCoach became limited; possibly incongruent with the specific stage of change that they progressed to. This does make sense in light of participants' suggestions to implement iCare as a first step in receiving help, aiding them in gaining insight into and addressing their distress, and experiencing the benefit of therapy before commencing with face-to-face therapy. Other participants suggested incorporating iCare with face-to-face therapy; known as blended care (Mitchell & Gordon, 2007; Topooco et al., 2017; Wilhelmsen et al., 2013). Wilhelmsen et al. (2013) suggest a blended care approach where individuals have brief face-to-face consultations with a psychologist at a clinic after completing each module of the iCBT. This

could potentially address participants' need for more responsive feedback and mediate the lack of direct human contact inherent to e-interventions. However, this may negatively impact the cost-effectiveness and flexibility associated with e-interventions.

iCare seemed to have exhibited the first process of the working alliance (WA), 'establishing a relationship', through its content, which some participants experienced as relatable and understanding, similar to other guided iCBTs (Barazzone et al., 2012). The eCoach's feedback seemed to have formed a collaborative framework between the participant and the eCoach. However, as with other guided iCBTs, iCare did not fully exhibit the second process of the WA, namely 'developing the relationship'; some students expressed a need for more detailed, responsive and tailored feedback, characteristic of this process (Barazzone et al., 2012; Cahill et al., 2008).

Loneliness is common among university students and positively associated with symptoms of MDD and anxiety among this group (Diehl, Jansen, Ishchanova, & Hilger-Kolb, 2018). The feeling of loneliness mentioned by some participants could explain their need for a personal connection and their suggestions to incorporate online support groups to provide a secure base from which they can navigate their experience of loneliness − although it does seem that iCare provided a secure base to a certain extent, providing a safe space to express emotions and receive help (Barazzone et al., 2012; Cahill et al., 2008). Similar to other guided iCBTs, 'maintaining the relationship', the final process of the WA, seemed to be absent from iCare (Barazzone et al., 2012; Cahill et al., 2008). Responsiveness and being able to repair ruptures in the WA are central to this process (Barazzone et al., 2012; Cahill et al., 2008), and some participants did express a need for more responsiveness. In addition, iCare's format was unable to detect or mediate the negative

experiences that one participant had, which is a concern also raised by students in Chan et al. (2016).

Participants' reasons for non-adherence and their suggestions to improve iCare can be understood using the working theory model of non-adherence (Johansson et al., 2015). Individuals decide to non-adhere when certain dimensions of the treatment process are perceived to be incompatible with their life conditions, capabilities, perceived needs, and characteristics. Thus, individuals' perception of the treatment should be compatible with their current life situation for them to adhere (Johansson et al., 2015). One participant non-adhered as she perceived iCare to be too time-consuming (she was under the impression that she had to complete a session every day, although this was not the case). Similarly, participants in Johansson et al. (2015) indicated that a lack of information about the treatment outline and content led them to non-adhere. Although adherence leads to increased benefits from iCBT, individuals who non-adhere may have done so *because of* the benefits they had experienced (Hilvert-Bruce, Rossouw, Wong, Sunderland, & Andrews, 2012), as one participant indicated. Johansson et al.'s (2015) model could explain participants' need for less text-intensive sessions and for using more videos to convey information. This would require less effort from participants to utilise iCare, thereby making it more engaging and compatible with their university life. Alfonsson, Olsson and Hursti (2016) found that experiencing iCBT as unengaging predicts non-adherence. Lastly, one participant expressed the need for information about the scientific basis behind iCare, similar to findings in Fleischmann et al.,(2018). Providing evidence for the scientific basis behind iCare and the modules on which it is based may increase the perceived credibility of iCare, and therefore its use (Musiat et al., 2014).

Taken together, these findings indicate that participants had an overall positive experience of iCare. iCare presented participants with an opportunity to seek help and gain insight into their

distress, while providing strategies to cope with their distress. In addition, iCare enabled participants to express their emotions and cope with the changes and challenges common to university life (Dyson & Renk, 2006; Prendergast, 1994; Sussman & Arnett, 2014). Although useful, participants acknowledged the limits inherent in guided e-interventions and provided suggestions which could improve e-interventions, especially in SA.

Conclusion

In this chapter I presented and discussed the findings of university students' experiences of iCare. These findings highlighted the barriers faced by students in seeking psychological help, suggesting that iCare may be appropriate to bridge these barriers and provide students with a first line of help. University students found iCare helpful in coping with their distress and increasing their self-awareness, and although the lack of direct human contact facilitated this, some participants expressed a need for more human contact. The chapter also highlighted how the TTM could be useful in understanding which students might use iCare and when they would find iCare most beneficial. Participants' suggestions to improve and implement iCare evidence the importance of ensuring compatibility between their perception of iCare and their current life situation. Recommendations based on these findings are presented in the next chapter.

CHAPTER 7: Conclusion

With this research, I sought to assess the feasibility of an iCBT for depressive symptoms, namely iCare. This was done in light of the need for evidence-based treatments among university students, where MDD is highly prevalent and associated with deleterious outcomes (Auerbach et al., 2016; Auerbach, Mortier, Bruffaerts, Alonso, Benjet, Cuijpers, et al., 2018). To aid in a deeper understanding of iCare's feasibility within this context, participants' experiences of and suggestions for improving iCare were also investigated. The findings of this research have important implications, which I summarise here in addition to the limitations and strengths of this research. To conclude, I make recommendations for future e-intervention research.

Implications of the present study

Firstly, this study provided important contributions to filling the gap in the literature on the use of e-interventions among SA university students. It is the first study to date that has piloted an e-intervention in this population. Secondly, the study identified key aspects (recruitment methods, utilisation and retention, specifically during-treatment drop-out) that need to be addressed to successfully scale this research to a larger RCT. Thirdly, the study provided suggestions on how to address these key feasibility areas, which may also be applicable to other e-intervention research. Lastly, the results of this research reflect iCare's real-world applicability (effectiveness), although the size of its effect was small to moderate (Cohen, 1988). iCare encouraged a small number of students to make use of mental health services. These students would otherwise not have made use of the traditional mental health services available to them. This indicates that there are a number of university students for whom e-interventions provide a first step to accessing mental health services.

Limitations and strengths of the present study

Limitations of the present study

Students could only be recruited after institutional permission was granted, which was after the mid-year break. They were therefore recruited and (eligible students) invited to enrol in iCare amid upcoming end-of-year exams. This could have affected the feasibility results obtained. In addition, only first-year university students were recruited. Students who have become more accustomed to the university context (such as final year or post-graduate students) might have used and experienced iCare differently. It is possible that higher completion rates may have been observed in older students (Williams & Andrews, 2013). Furthermore, only four participants who decided to drop out of iCare completed the post-intervention individual interview. The reasons for drop-out from iCare given by these participants may not be representative of all the participants (n=22) who chose to drop out of iCare. It may also have been useful to also gain an understanding of the reasons behind some eligible participants' decision not to take up iCare.

Finally, the reflexivity of the researcher is important to ensure the quality of the obtained qualitative data. The way I, as a researcher, made sense of this process may have influenced it. I started this research after completing an Honours degree in Psychology, and am therefore a novice researcher, especially in qualitative research. My Honours research project was purely quantitative; my only exposure to prior qualitative work had been the completion of a TA assignment as part of the Honours research module. The qualitative aspect of this research was a learning process in many respects. My inexperience in qualitative research may have influenced my approach to the research process. However, the numerous discussions with and guidance of my supervisor throughout the analysis process ensured that I approached the TA in a systematic and critical way. Although this study was not directly related to the stigma of living with a CMD

and seeking help, the majority of participants brought forward these topics. I believe that having previously been in a long-term romantic relationship with someone diagnosed with MDD enabled me to empathetically respond in the aforementioned instances. I conducted the majority of the interviews before I had gone through personal psychotherapy. It is possible that my preconceived ideas about therapy might have biased the way in which I approached and probed questions regarding the comparison of iCare to participants' previous experiences with mental health services. This may still have affected and biased the data collected, despite the steps taken to ensure credibility.

Strengths of the present study

Firstly, a substantially larger proportion of participants than typically associated with pilot studies was recruited. This subsequently enabled sample size estimations, through the use of ITTA-MI, that would ensure a sufficiently powered RCT. Secondly, five out of the six iCare completers agreed to be interviewed. These participants represented a small sample of the university population as a whole; however, they were largely representative of participants who completed iCare.

Recommendations to scale iCare and for future e-intervention research

To conclude this research thesis, I offer five recommendations for future research based on the findings presented in Chapters 5 and 6.

(1) The use of multiple recruitment strategies. Based on the findings by Krusche et al. (2014), I recommend using web-based and radio advertising in addition to invitational emails to recruit participants. Vignettes surrounding the perceived user-friendliness and positive impact of

iCare (Chapter 6) could be constructed and aired on the local student radio station and/or posted on the student portal of the university's website.

(2) The use of acceptance-facilitating interventions (AFIs). I recommend using AFIs based on the video format used by Ebert, Berking, Cuijpers, et al., (2015), incorporating the findings presented in Chapter 6, specifically the themes "perceived user-friendliness of iCare" and "perceived positive impact of utilising iCare".

(3) Identifying the stages of change. Identifying the specific stage of change that a student is at might prove useful. The use of trans-diagnostic Motivational Enhancement Therapy for Treatment Adherence (MET-TA), which is based on Motivational Interviewing (Mistler et al., 2016; Rollnick & Miller, 1995), could be used to not only encourage students to progress through the various stages of change, but also promote treatment adherence (Mistler et al., 2016; Rollnick & Miller, 1995).

(4) Investigating e-interventions based on artificial intelligence (AI). Some participants expected iCare to mimic the reflectiveness and responsiveness of face-to-face therapy. The majority expressed the need for more engaging content and an interactive format. E-interventions based on AI aim to address these needs. For example, Woebot is an iCBT developed for students, incorporating automated real-time engagement using AI (Fitzpatrick, Darcy, & Vierhile, 2017). Investigating the feasibility of e-interventions such as Woebot among university students in SA may be useful.

(5) Investigating the feasibility of a stepped care/blended care approach. Participants' suggestions for implementing iCare seemed to highlight the importance of future research to assess the feasibility of stepped care and blended care (Mitchell & Gordon, 2007; Topooco et al., 2017; Wilhelmsen et al., 2013).

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APPENDICES

APPENDIX A: Extension of ethical approval

UNIVERSITEIT
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Approval Letter
Progress Report

17/04/2019

Project ID: 1788

Ethics Reference #: M17/10/036

Title: Pilot study of an e-intervention for symptoms of depression among University students in South Africa

Dear Dr. Jason Bantjes,

At a review meeting of HREC2 on 17 April 2019, the following progress report was reviewed and approved:

Progress Report dated 17 April 2019.

The approval of this project is extended for a further year.

Approval date: 17 April 2019

Expiry date: 16 April 2020

Kindly be reminded to submit progress reports two (2) months before expiry date.

Where to submit any documentation

Kindly note that the HREC uses an electronic ethics review management system, *Infonetica*, to manage ethics applications and ethics review process. To submit any documentation to HREC, please click on the following link: https://applyethics.sun.ac.za.

Please remember to use your **Project ID [1788]** and **Ethics Reference Number [M17/10/036]** on any documents or correspondence with the HREC concerning your research protocol.

Yours sincerely,

Mr. Francis Masiye,

HREC Coordinator,

Health Research Ethics Committee 2 (HREC2).

National Health Research Ethics Council (NHREC) Registration Number:
REC-130408-012 (HREC1)·REC-230208-010 (HREC2)

Federal Wide Assurance Number: 00001372
Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number:
IRB0005240 (HREC1)·IRB0005239 (HREC2)

The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by the World Medical Association (2013). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects;the South African Department of Health (2006).Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2nd edition); as well as the Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2nd edition).

The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.

Page 1 of 2

APPENDIX B: Ethical approval

UNIVERSITEIT
STELLENBOSCH
UNIVERSITY

Approved

Response to Modifications

23/02/2018

Project ID: 1788

HREC Reference #: M17/10/036

Title: Pilot study of an e-intervention for symptoms of depression among university students in South Africa

Dear Dr. Jason Bantjes,

The **Response to Modifications** received on 14/02/2018 was reviewed by members of the **Health Research Ethics Committee (HREC)** via Minimal Risk Review procedures on 23/02/2018 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: This project has approval for 12 months from the date of this letter.

Please remember to use your Project Reference Number **(1788)** on any documents or correspondence with the HREC concerning your research protocol.

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

Please note that this decision will be ratified at the next HREC full committee meeting. HREC reserves the right to suspend approval and to request changes or clarifications from student applicants. The coordinator will notify the applicant (and if applicable, the supervisor) of the changes or suspension within 1 day of receiving the notice of suspension from HREC. 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 https://applyethics.sun.ac.za/Project/Index/1968 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.

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: https://applyethics.sun.ac.za/Project/Index/1968

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Francis Masiye,

HREC Coordinator,

APPENDIX C: Institutional permission

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jou kennisvennoot • your knowledge partner

INSTITUTIONAL PERMISSION:

AGREEMENT ON USE OF PERSONAL INFORMATION IN RESEARCH

Name of Researcher: **Dr Jason Bantjes**

Name of Research Project: ***Pilot study of an e-intervention for symptoms of depression among university students in South Africa***

Service Desk ID: **IRPSD-827**

Date of Issue: **22 June 2018**

You have received institutional permission to proceed with this project as stipulated in the institutional permission application and within the conditions set out in this agreement.

1 WHAT THIS AGREEMENT IS ABOUT	
What is POPI?	1.1 POPI is the Protection of Personal Information Act 4 of 2013. 1.2 POPI regulates the entire information life cycle from collection, through use and storage and even the destruction of personal information.
Why is this important to us?	1.3 Even though POPI is important, it is not the primary motivation for this agreement. The privacy of our students and employees are important to us. We want to ensure that no research project poses any risks to their privacy. 1.4 However, you are required to familiarise yourself with, and comply with POPI in its entirety.
What is considered to be personal information?	1.5 'Personal information' means information relating to an identifiable, living, individual or company, including, but not limited to: 1.5.1 information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person; 1.5.2 information relating to the education or the medical, financial, criminal or

	employment history of the person; 1.5.3 any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person; 1.5.4 the biometric information of the person; 1.5.5 the personal opinions, views or preferences of the person; 1.5.6 correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence; 1.5.7 the views or opinions of another individual about the person; and 1.5.8 the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.
Some personal information is more sensitive.	1.6 Some personal information is considered to be sensitive either because: 1.6.1 POPI has classified it as sensitive; 1.6.2 if the information is disclosed it can be used to defraud someone; or 1.6.3 the disclosure of the information will be embarrassing for the research subject. 1.7 The following personal information is considered particularly sensitive: 1.7.1 Religious or philosophical beliefs; 1.7.2 race or ethnic origin; 1.7.3 trade union membership; 1.7.4 political persuasion; 1.7.5 health and health related documentation such as medical scheme documentation; 1.7.6 sex life; 1.7.7 biometric information; 1.7.8 criminal behaviour; 1.7.9 personal information of children under the age of 18;

	1.7.10 financial information such as banking details, details relating to financial products such as insurance, pension funds or other investments. 1.8 You maymake use of this type of information, but must take extra care to ensure that you comply with the rest of the rules in this document.
2 COMMITMENT TO ETHICAL AND LEGAL RESEARCH PRACTICES	
You must commit to the use of ethical and legal research practices.	2.1 You must obtain ethical clearance before commencing with this study. 2.2 You commit to only employing ethical and legal research practices.
You must protect the privacy of your research subjects.	2.3 You undertake to protect the privacy of the research subjects throughout the project.
3 RESEARCH SUBJECT PARTICIPATION	
Personal information of identifiable research subjects must not be used without their consent.	3.1 Unless you have obtained a specific exemption for your research project, consent must be obtained in writing from the research subject, before their personal information is gathered.
Research subjects must be able to withdraw from the research project.	3.2 Research subjects must always be able to withdraw from the research project (without any negative consequences) and to insist that you destroy their personal information.
Consent must be specific and informed.	3.3 Unless you have obtained a specific exemption for your research project, the consent must be specific and informed. Before giving consent, the research subject must be informed in writing of: 3.3.1 The purpose of the research, 3.3.2 what personal information about them will be collected (particularly sensitive personal information), 3.3.3 how the personal information will be collected (if not directly from them), 3.3.4 the specific purposes for which the personal information will be used, 3.3.5 what participation will entail (i.e. what the research subject will have to do), 3.3.6 whether the supply of the personal information is voluntary or mandatory for

	purposes of the research project, 3.3.7 who the personal information will be shared with, 3.3.8 how the personal information will be published, 3.3.9 the risks to participation (if any), 3.3.10 their rights to access, correct or object to the use of their personal information, 3.3.11 their right to withdraw from the research project, and 3.3.12 how these rights can be exercised.
Consent must be voluntary.	3.4 Participation in the research project must always be voluntary. You must never pressure or coerce research subjects into participating and persons who choose not to participate must not be penalised.
Using the personal information of children?	3.5 A child is anybody under the age of 18. 3.6 Unless you have obtained a specific exemption in writing for your research project, you must obtain 3.6.1 the consent of the child's parent or guardian, and 3.6.2 if the child is over the age of 7, the assent of the child, before collecting the child's information.
Research subjects have a right to access.	3.7 Research subjects have the right to access their personal information, obtain confirmation of what information is in your possession and who had access to the information. It is strongly recommended that you keep detailed records of access to the information.
Research subjects have a right to object.	3.8 Research subjects have the right to object to the use of their personal information. 3.9 Once they have objected, you are not permitted to use the personal information until the dispute has been resolved.
4 COLLECTING PERSONAL INFORMATION	
Only collect what is necessary.	4.1 You must not collect unnecessary or irrelevant personal information from research subjects.

Only collect accurate personal information.	4.2 You have an obligation to ensure that the personal information you collect is accurate. Particularly when you are collecting it from a source other than the research subject. 4.3 If you have any reason to doubt the quality of the personal information you must verify or validate the personal information before you use it.
5 USING PERSONAL INFORMATION	
Only use the personal information for the purpose for which you collected it.	5.1 Only use the personal information for the purpose for which you collected it. 5.2 If your research project requires you to use the personal information for a materially different purpose than the one communicated to the research subject, you must inform the research subjects and Stellenbosch University of this and give participants the option to withdraw from the research project.
Be careful when you share personal information.	5.3 Never share personal information with third parties without making sure that they will also follow these rules. 5.4 Always conclude a non-disclosure agreement with the third parties. 5.5 Ensure that you transfer the personal information securely.
Personal information must be anonymous whenever possible.	5.6 If the research subject's identity is not relevant for the aims of the research project, the personal information must not be identifiable. In other words, the personal information must be anonymous (de-identified).
Pseudonyms must be used whenever possible.	5.7 If the research subject's identity is relevant for the aims of the research project or is required to co-ordinate, for example, interviews, names and other identifiers such as ID or student numbers must be collected and stored separately from the rest of the research data and research publications. In other words, only you must be able to identify the research subject.
Publication of research	5.8 The identity of your research subjects should not be revealed in any publication. 5.9 In the event that your research project requires that the identity of your research subjects must be revealed, you must apply for an exemption from this rule.
6 SECURING PERSONAL INFORMATION	
You are responsible for the confidentiality and	6.1 Information must always be handled in the strictest confidence.

security of the personal information	6.2 You must ensure the integrity and security of the information in your possession or under your control by taking appropriate and reasonable technical and organisational measures to prevent: 6.2.1 Loss of, damage to or unauthorised destruction of information; and 6.2.2 unlawful access to or processing of information. 6.3 This means that you must take reasonable measures to: 6.3.1 Identify all reasonably foreseeable internal and external risks to personal information in your possession or under your control; 6.3.2 establish and maintain appropriate safeguards against the risks identified; 6.3.3 regularly verify that the safeguards are effectively implemented; and 6.3.4 ensure that the safeguards are continually updated in response to new risks or deficiencies in previously implemented safeguards.
Sensitive personal information requires extra care.	6.4 You will be expected to implement additional controls in order to secure sensitive personal information.
Are you sending any personal information overseas?	6.5 If you are sending personal information overseas, you have to make sure that: 6.5.1 The information will be protected by the laws of that country; 6.5.2 the company or institution to who you are sending have agreed to keep the information confidential, secure and to not use it for any other purpose; or 6.5.3 get the specific and informed consent of the research subject to send the information to a country which does not have data protection laws.
Be careful when you use cloud storage.	6.6 Be careful when storing personal information in a cloud. Many clouds are hosted on servers outside of South Africa in countries that do not protect personal information to the same extent as South Africa. The primary example of this is the United States. 6.7 It is strongly recommended that you use hosting companies who house their servers in South Africa. 6.8 If this is not possible, you must ensure that the hosting company agrees to protect the personal information to the same extent as South Africa.

7 RETENTION AND DESTRUCTION OF PERSONAL INFORMATION	
You are not entitled to retain personal information when you no longer need it for the purposes of the research project.	7.1 Personal information must not be retained beyond the purpose of the research project, unless you have a legal or other justification for retaining the information.
If personal information is retained, you must make sure it remains confidential.	7.2 If you do need to retain the personal information, you must assess whether: 7.2.1 The records can be de-identified; and/or whether 7.2.2 you have to keep all the personal information. 7.3 You must ensure that the personal information which you retain remains confidential, secure and is only used for the purposes for which it was collected.
8 INFORMATION BREACH PROCEDURE	
In the event of an information breach you must notify us immediately.	8.1 If there are reasonable grounds to believe that the personal information in your possession or under your control has been accessed by any unauthorised person or has been disclosed, you must notify us immediately. 8.2 We will notify the research subjects in order to enable them to take measures to contain the impact of the breach.
This is the procedure you must follow.	8.3 You must follow the following procedure: 8.3.1 Contact the Division for Institutional Research and Planning at 021 808 9385 and permission@sun.ac.za; 8.3.2 you will then be required to complete the information breach report form which is attached as Annexure A. 8.4 You are required to inform us of a information breach within 24 hours. Ensure that you have access to the required information.
9 MONITORING	
You may be audited.	9.1 We reserve the right to audit your research practices to assess whether you are complying with this agreement.

	9.2 You are required to give your full co-operation during the auditing process. 9.3 We may also request to review: 9.3.1 Forms (or other information gathering methods) and notifications to research subjects, as referred to in clause 3; 9.3.2 non-disclosure agreements with third parties with whom the personal information is being shared, as referred to in clause 5.4; 9.3.3 agreements with foreign companies or institutes with whom the personal information is being shared, as referred to in clause 6.5.
10 CHANGES TO RESEARCH	
You need to notify us if any aspect of your collection or use of personal information changes.	10.1 You must notify us in writing if any aspect of your collection or use of personal information changes (e.g. such as your research methodology, recruitment strategy or the purpose for which you use the research). 10.2 We may review and require amendments to the proposed changes to ensure compliance with this agreement. 10.3 The notification must be sent to permission@sun.ac.za.
11 CONSEQUENCES OF BREACH	
What are the consequences of breaching this agreement?	11.1 If you do not comply with this agreement, we may take disciplinary action or report such a breach to your home institute. 11.2 You may be found guilty of research misconduct and may be censured in accordance with Stellenbosch University or your home institute's disciplinary code.
You may have to compensate us in the event of any legal action.	11.3 Non-compliance with this agreement could also lead to claims against Stellenbosch University in terms of POPI and/or other laws. 11.4 Unless you are employed by or studying at Stellenbosch University, you indemnify Stellenbosch University against any claims (including all legal fees) from research subjects or any regulatory authority which are the result of your research project. You may also be held liable for the harm to our reputation should there be an information breach as a result of your non-compliance with this agreement.

12 CONTACT US	
Please contact us if you have any questions.	Should you have any questions relating to this agreement you should contact permission@sun.ac.za.

Annexure 'A'

Instruction:

Please send this Notice to permission@sun.ac.za. If you have any difficulty completing the Notice, please contact the Division for Institutional Research and Planning at 021 808 9385. You must confirm that the Notice was received.

NOTIFICATION OF INFORMATION BREACH

Name of Researcher: _____

Name of Research Project: _____

Service Desk ID: _____

A security breach happens when you know (or you **reasonably believe)** that there has been:

(a) loss of Personal Information ("PI")
(b) damage to PI
(c) unauthorised destruction of PI
(d) unauthorised access to PI
(e) unauthorised processing of PI

Date and time of security breach:	
Brief description of the security breach (what was lost and how). Please identify the equipment, software and/or physical premises and whether it is by hacking, lost device, public disclosure (email), theft or other means:	
Name of the person/s responsible for the security breach (if known):	
Is the security breach ongoing?	
Describe the steps taken to contain the security breach:	
What steps are being taken to investigate the cause of breach?	

APPENDIX D: Recruitment email invitation to complete an online survey on your current mental health

Dear first-year student,

Re: CARING UNIVERSITIES - World Student Health Survey

You are being invited to take part in a study to examine health and mental wellbeing among university students. The purpose is to study issues related to mental health (i.e., depression), so that we can better understand the support needs of students. The survey will also be used to identify students who may benefit from interventions to reduce symptoms of depression. Students who report mild to moderate symptoms of depression will have the opportunity to be included in a pilot study of an e-intervention (internet based intervention) to reduce symptoms of depression. Students who report severe symptoms of depression will be helped to access appropriate treatments. We are asking you to complete a short online confidential survey which will take between 10 and 15 mins.

All SU students who are entering university for the first time have been invited to complete the survey. Participation is voluntary. You may withdraw from the study even if you initially agreed to take part. Declining to take part or withdrawing from the study will not affect you negatively in any way.

Although participating in the study will not benefit you directly, it will give you the opportunity to reflect on your mental health. The study will also help us to better understand students' psychological and support needs.

The survey will close at the end of July.

If you have any queries or difficulties accessing the survey please contact Dr Jason Bantjes (jbantjes@sun.ac.za)

Please click on the link below for more information or to start the survey.

https://sunsurveys.sun.ac.za/Survey.aspx?s=10da3b23829b48bfb975d7be8f5512c8&i=52b5566efd3b4ee287ab441f7b575359

Yours sincerely

The Caring Universities Research Team

APPENDIX E: Participant information leaflet and consent form

TITLE OF THE RESEARCH PROJECT: Pilot study of an e-intervention for symptoms of depression among university students in South Africa

REFERENCE NUMBER: #1788

PRINCIPAL INVESTIGATOR: Dr Jason Bantjes

ADDRESS: Department of Psychology, Stellenbosch University

CONTACT NUMBER: 083 234 5554

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

This survey is part of a study to identify students' mental health care needs and to pilot e-interventions for mood and depression problems. In this study we want to find out: whether university students with mild to moderate symptoms of depression will utilize an e-intervention and how students experienced the usability of online treatments for mental health problems.

Why have you been invited to participate?

You are being invited to patriciate in this online survey because you are a first year student from Stellenbosch University.

What will your responsibilities be?

If you agree to take part in this online survey you will be asked to complete a short 10 – 15 min online survey about your current level of psychological health.

Will you benefit from taking part in this research?

There is no direct benefit to participating in the survey. However, if you have symptoms of depression you will received feedback about suitable treatment options and you may have the opportunity to enrol in a pilot study of a new e-intervention for depression.

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

The content of the screening survey will not pose any direct risk for injury or distress. However, it is possible that some students who complete the survey may already be distressed from their own personal experiences. In cases where it is evident that any student may be experiencing

distress, the student will be contacted by the research team who will offer support and advice regarding relevant services that might be helpful.

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

Participation in this study is optional and there are no consequences for choosing not to participate.

Who will have access to your data?

Your responses to the online survey will be kept completely confidential and the information collected will be stored in such a way that your identity is protected, so that no one will know you particular answer to questions or your personal information.

All the collected information will be password protected and will be accessed only by authorized personnel. The authorized personnel are researchers, masters students, and PhD students from this University as well as collaborators from outside Stellenbosch University or South Africa who are working on this study. The data will only be used for the purpose of this study and will be destroyed after a three-year period. Scientific publications or presentations on the results will only report analyses on an aggregated level.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

There is no risk for direct injury related to your participation in this study.

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

No you will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- You can contact Dr Jason Bantjes at jbantjes@sun.ac.za if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.

Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled *Pilot study of an e-intervention for symptoms of depression among university students in South Africa*

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2018.

…….. ……..

Signature of participant **Signature of witness**

Declaration by investigator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2018.

…….. ……..

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* ……..…… declare that:

- I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) ……..…….. using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

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

....

Signature of interpreter **Signature of witness**

APPENDIX F: Survey Questionnaires

DEMOGRAPHIC CHARACTERISTICS

Gender:	Male		Female		Genderfluid		Gender neutral	
	Gender queer		Transgender		Nonbinary		Polygender	
	Other (Specify)							

Age:	

Ethnicity:	Black African		Coloured		Indian / Asian		White	
	Other (Specify)							

Home language:	Afrikaans		IsiXhosa		English		IsiZulu	
	Other (Specify)							

Faculty registered:	AgriSciences		Economic & Management Sciences		Engineering		Science	
	Arts & Social Sciences		Education		Law		Theology	
	Health Sciences							

Type of accommodation:	University residence		Private Halls of Residence/Communal Blocks		Private renting	
	Living with parent		Living in a parent-owned house		University accommodation other than residence (flats/house)	

Sexual orientation	Heterosexual				Homosexual	
	Bicurious				Bisexual	
Feelings of sexual attraction to women	Very sexually attracted		A good deal sexually attracted		Somewhat sexually attracted	
	A little sexually attracted		Not at all sexually attracted			
Feelings of sexual attraction to men	Very sexually attracted		A good deal sexually attracted		Somewhat sexually attracted	
	A little sexually attracted		Not at all sexually attracted			
In the past 5 years, who have you had sex with?	Men only		Woman only		Both men and women	
	I have not had sex					

NOTE: We use the word "sex" to mean any kind of sexual contact (not just sexual intercourse, but also, for example, oral sex or masturbation).			

Access to medical aid:	Yes		No	

Previous psychological treatment:	Yes		No	

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ - 9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use "✓" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all ☐	**Somewhat difficult** ☐	**Very difficult** ☐	**Extremely difficult** ☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use "✓" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

HEALTH QUESTIONNAIRE EQ-5D-5L

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

MOBILITY

I have no problems in walking about □

I have slight problems in walking about □

I have moderate problems in walking about □

I have severe problems in walking about □

I am unable to walk about □

SELF-CARE

I have no problems washing or dressing myself □

I have slight problems washing or dressing myself □

I have moderate problems washing or dressing myself □

I have severe problems washing or dressing myself □

I am unable to wash or dress myself □

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

I have no problems doing my usual activities □

I have slight problems doing my usual activities □

I have moderate problems doing my usual activities □

I have severe problems doing my usual activities □

I am unable to do my usual activities □

PAIN / DISCOMFORT

I have no pain or discomfort □

I have slight pain or discomfort □

I have moderate pain or discomfort □

I have severe pain or discomfort □

I have extreme pain or discomfort □

ANXIETY / DEPRESSION

I am not anxious or depressed □

I am slightly anxious or depressed □

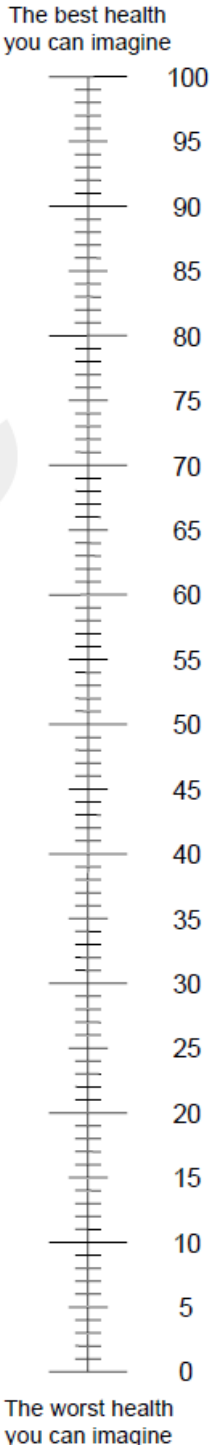
I am moderately anxious or depressed □

I am severely anxious or depressed □

I am extremely anxious or depressed □

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine. 0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



CLIENT SATISFACTION WITH TREATMENT QUESTIONNAIRE – 8 (CSQ-8)

Purpose	To assess client satisfaction with treatment.
Scoring	The CSQ-8 is easily scored by summing the individual item scores to produce a range of 8 to 32, with high scores indicating greater satisfaction.
Description	The CSQ-8 is an 8-item, easily scored and administered measurement that is designed to measure client satisfaction with services. The items for the CSQ-8 were selected on the basis of ratings by mental health professionals of a number of items that could be related to client satisfaction and by subsequent factor analysis. The CSQ-8 is unidimensional, yielding a homogeneous estimate of general satisfaction with services. The CSQ-8 has been extensively studied, and while it is not necessarily a measure of a client's perceptions of gain from treatment, or outcome, it does elicit the client's perspective on the value of services received. The CSQ-8 seems to operate about the same across all ethnic groups. This also is true for a version of the CSQ-8 that was translated into Spanish.
Primary reference	Larsen, D.L., Attkisson, C.C., Hargreaves, W.A., and Nguyen, T.D. (1979). Assessment of client/patient satisfaction: Development of a general scale, Evaluation and Program Planning, 2, 197-207. Instrument reproduced with permission of C. Clifford Attkisson.
Availability	Dr. C. Clifford Attkisson, Professor of Medical Psychology, Department of Psychiatry, Box 33-c, University of California, San Francisco, CA 94143.

CLIENT SATISFACTION QUESTIONNAIRE Please help us improve our program by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much; we really appreciate your help.

Select your answer:

1. How would you rate the quality of service you have received?			
Excellent 4 □	Good 3 □	Fair 2 □	Poor 1 □
2. Did you get the kind of service you wanted?			
No, definitely 1 □	No, not really 2 □	Yes, generally 3 □	Yes, definitely 4 □
3. To what extent has our program met your needs?			
Almost all of my needs have been met 4 □	Most of my needs have been met 3 □	Only a few of my needs have been met 2 □	None of my needs have been met 1 □
4. If a friend were in need of similar help, would you recommend our program to him or her?			
No, definitely 1 □	No, not really 2 □	Yes, generally 3 □	Yes, definitely 4 □
5. How satisfied are you with the amount of help you have received?			
Quite dissatisfied 1 □	Indifferent or mildly dissatisfied 2 □	Mostly satisfied 3 □	Very satisfied 4 □

6. Have the services you received helped you to deal more effectively with your problems?			
Yes, they helped a great deal 4 □	Yes, they helped 3 □	No, they really didn't help 2 □	No, they seemed to make things worse 1 □
7. In an overall, general sense, how satisfied are you with the service you have received?			
Very satisfied 4 □	Mostly satisfied 3 □	Indifferent or mildly dissatisfied 2 □	Quite dissatisfied 1 □
8. If you were to seek help again, would you come back to our program?			
No, definitely 1 □	No, I don't think so 2 □	Yes, I think so 3 □	Yes, definitely 4 □

Thank you for participating in the iCare study! We would appreciate hearing from you, so please let us know about your experience. Comments (optional):

APPENDIX G: Usual Care email

Dear NAME,

Thank you for completing the Stellenbosch University Survey on university Adjustment. The levels of psychological distress you reported were high enough that you might benefit from speaking to a counselor. As you know, Stellenbosch University has counseling resources available to students experiencing distress. The phone number to make an appointment is 021 808 4707 or for the 24 hour crisis service contact 082 557 0880. Please consider making an appointment and speaking to a counselor.

Alternatively, you could contact a private practitioner in the Stellenbosch area:
JP Theron 082 8811340;
Muriel Brent 021 882 8343;
Corne' Waldeck 074 404 1023;
Maxine Spedding 0 82 929 0184
Lisa Padfield 072 922 6322
Welgevallen community psychology Clinic
https://www.sun.ac.za/english/entities/welgevallen-community-psychology-clinic/appointments

Jason Bantjes, Ph.D.
Course Co-ordinator: Masters Degree in Clinical Psychology and Community Counselling, Stellenbosch University
Phone: 083 2345 554
Email: jbantjes@sun.ac.za

APPENDIX H: Recruitment email for the iCare group

Dear NAME,

Thank you for completing the Stellenbosch University Survey on university Adjustment. The levels of psychological distress you reported were high enough that you might benefit from speaking to a counselor on campus (to make an appointment contact 021 808 4707) or participating in an internet-based program we developed to help students manage their distress. Our internet-based program is anonymous, easy to use through a smartphone, tablet, or computer, and can be accessed 24 hours a day, 7 days a week. If you are interested in trying this program, which is completely free, please click the link below to sign up.

[https://www.minddistrict.com/professional/]

Jason Bantjes, Ph.D.
Course Co-ordinator: Masters Degree in Clinical Psychology and Community Counselling, Stellenbosch University
Phone: 083 2345 554
Email: jbantjes@sun.ac.za

APPENDIX I: Participant information leaflet and consent form (ICare intervention)

TITLE OF THE RESEARCH PROJECT: Pilot study of an e-intervention for symptoms of depression among university students in South Africa

REFERENCE NUMBER: #1788

PRINCIPAL INVESTIGATOR: Dr Jason Bantjes

ADDRESS: Department of Psychology, Stellenbosch University

CONTACT NUMBER: 083 234 5554

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

In this study we want to find out: whether university students will utilize the ICare e-intervention for symptoms of depression. We are interested in learning more about the students mental health care needs and the acceptability of e-interventions to treat mild to moderate symptoms of depression.

Why have you been invited to participate?

You are invited to participate in this e-intervention because your online mental health survey response indicated that you are currently experiencing mild to moderate levels of depression. We know from previous research that students who have mild to moderate levels of depression can benefit from participating in online interventions and that this helps reduce their symptoms of depression.

What will your responsibilities be?

If you elect to take part in this study, you will have the opportunity to complete an online e-intervention for depression, over the course of 8 weeks. At the end of the 8 week intervention, you will be asked to complete another short (15 min) assessment of your mood and you will be invited to patriciate in a focus group discussion.

The focus group discussion will be voluntary but if you choose to participate in this group you will be asked to share your experiences of the ICare intervention and make suggestions for how the intervention might be adapted for ongoing use among SA university students.

Will you benefit from taking part in this research?

There is no direct benefit to participating in the study, beyond the possibility that the e-intervention might help you to feel better by alleviating the symptoms of depression you are currently experiencing. Your participation in the study may also assist researchers to better understand the mental health care needs of students and the effectiveness of alternative interventions for treating depression.

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

There are no direct risks involved in your participation in the intervention. We will also continue to monitor your mood during this intervention and refer you to appropriate services if needed.

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

Participation in this study is optional. If you would not like to participate you still have the option of contacting the student counselling and community based treatment facilities or private practitioners to access alternative treatments.

Who will have access to your data?

All your personal information will be kept confidential and will be stored in such a way that your privacy is protected.

Alphanumeric ID will be assigned to ensure privacy: DataStat, Inc. will use email addresses provided by the University. For students who report mild/moderate depression, they will receive an email link inviting them to the treatment. The treatment is provided on the MindDistrict platform. Thus the email link provided by DataStat to MindDistrict will use REST API. The REST

API will provide an alphanumeric ID (i.e., a key) that is hard-locked into MindDistrict. Thus, data from DataStat and MindDistrict will only be linked on this de-identified, anonymous alphanumeric study ID. At the study completion, the email addresses will be destroyed. Only the alphanumeric IDs will be used with these data (acquired on DataStat and MindDistrict).

During your participation you will be assigned a ICare intervention coach who will offer support and answer any questions you may have. All communication will be completed through the MindDistrict platform. This ensures the anonymity of both you and your.

All the collected information will be password protected and will be accessed only by authorized personnel. The authorized personnel are researchers, masters students, and PhD students from this University as well as collaborators from outside Stellenbosch University or South Africa who are working on this study. The data will only be used for the purpose of this study and will be destroyed after a five-year period. Scientific publications or presentations on the results will only report analyses on an aggregated level.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

There is no risk for direct injury related to your participation in this study.

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

No you will not be paid to take part in the study. You will receive a R200 gift voucher as compensation for your time if you elect to take part in the one-on-one interview at the end of the study. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- You can contact Dr Jason Bantjes at jbantjes@sun.ac.za if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I ……..……. agree to take part in a research study entitled *Pilot study of an e-intervention for symptoms of depression among university students in South Africa.*

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2018/19.

…… ……

Signature of participant **Signature of witness**

Declaration by investigator

I *(name)* ……..…… declare that:

- I explained the information in this document to ……..
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use a interpreter. (*If a interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2018.

…… ……

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* ……..…… declare that:

- I assisted the investigator (*name*) ……. to explain the information in this document to (*name of participant*) ……..…….. using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

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

....

Signature of interpreter

APPENDIX J: Severe depression email

Dear NAME,

Thank you for completing the post-ICare assessment. The levels of psychological distress you reported were high enough that you might benefit from speaking to a counselor. As you know, Stellenbosch University has counseling resources available to students experiencing distress. Please consider making an appointment and speaking to a counselor. The phone number to make an appointment is 021 808 4707 or for the 24 hour crisis service contact 082 557 0880. Please consider making an appointment and speaking to a counselor.

Alternatively, you could contact a private practitioner in the Stellenbosch area:
JP Theron 082 8811340;
Muriel Brent 021 882 8343;
Corne' Waldeck 074 404 1023;
Maxine Spedding 0 82 929 0184
Lisa Padfield 072 922 6322
Welgevallen community psychology Clinic
https://www.sun.ac.za/english/entities/welgevallen-community-psychology-clinic/appointments

Jason Bantjes, Ph.D.
Course Co-ordinator: Masters Degree in Clinical Psychology and Community Counselling, Stellenbosch University
Phone: 083 2345 554
Email: jbantjes@sun.ac.za

APPENDIX K: Suicide risk email

Dear NAME,

Thank you for completing the Stellenbosch University Survey on university Adjustment. The levels of psychological distress you reported were high enough that you might benefit from speaking to a mental health professional. Below is a list of websites that can refer you to local providers. In addition, we encourage you to call a friend or family member, to call the CSCD 24 hour crisis number 082 557 0880; or ER24 010 205 3032, or to visit the emergency department of a local hospital if you are feeling like you cannot keep yourself safe

Emergency contact number:

- CSCD (SSVO): 082 557 0880
- South African Depression and Anxiety Group (SADAC): 0800 567 567 or

  0800 12 13 14 (24hour crisis line)
- Lifeline: 021 461 1113

Suicide Prevention Websites:
www.suicidepreventionlifeline.org/
www.suicide.org/suicide-hotlines.htm
suicidehotlines.com/

Jason Bantjes, Ph.D.
Course Co-ordinator: Masters Degree in Clinical Psychology and Community Counselling, Stellenbosch University
Phone: 083 2345 554
Email: jbantjes@sun.ac.za

APPENDIX L: Recruitment Email for Individual Interview

Dear NAME,

Thank you for completing the Stellenbosch University Survey on university Adjustment. Would you be willing to participate in an individual interview describing their experience of participating in the intervention?
During this interview, you will have the opportunity to share experience of the intervention and comment on the cultural acceptability and relevance of the intervention.

Jason Bantjes, Ph.D.
Course Co-ordinator: Masters Degree in Clinical Psychology and Community Counselling, Stellenbosch University
Phone: 083 2345 554
Email: jbantjes@sun.ac.za

APPENDIX M: Interview Schedule for Individual Interviews

M.1. Can you tell us about your decision to make use of the iCare intervention?

M.2. Can you tell us about your experience of using the iCare intervention?

Potential probes:

M.2.1. What did you like about it?

M.2.2. What didn't you like about it?

M.2.3. What made it easy / difficult to engage with?

M.2.4 Why did you decide not to continue with iCare? (if participants indicated that they did not complete all eight sessions)

M.2.5. What was your experience of the interaction with the eCoach?

M.3. How does this intervention compare with any other experiences you have had of mental health treatments / counselling (if you have had any before)?

Potential probes:

M.3.1. Other students have access to the SSVO/CSCD but do not use it. What do you think are the reasons for this?

M.4. Would you recommend it to other people?

Potential probes:

M.2.1. Why/why not

M.2.2. Whom (what kinds of people) do you think would like this kind of intervention?

M.5. What suggestions would you have to make the intervention more appealing to SA students?

Potential probes:

M.2.1. What did you think about the appeal of iCare's content?

M.2.2. What did you think about the way in which the information was presented in iCare?

M.2.3. What did you think about iCare's format?

M.6. How can iCare be made more culturally appropriate for use in SA?

M.7. Do you have any other comments or suggestions about the intervention?

APPENDIX N: Formulas used in data analyses

N.1. Calculating the one proportion z-test

The formula for the one-proportion z-test is expressed as follows (Gauvreau, 2006, p.1546) :

$$\mathrm{z} = \frac{\hat{p} - p_0}{\sqrt{\frac{p_0(1-p_0)}{n}}};$$

Where,
$\hat{p} = sample\ proportion$
$p_0 = population\ proportion$
$n = number\ of\ participants\ in\ sample$

The one-proportion z-test assumes that the binomial distribution is approximately normal (Gauvreau, 2006). This assumption is met when: $n(\hat{p}) \geq 5$ and $n(1 - \hat{p}) \geq 5$ (Pagano & Gauvreau, 2018, p.324); which was met. Therefore, at a significance level of 0.05 (p=0.05) in a two-tailed hypothesis test, the critical z-value is 1.96; which means that 2.5% of the values lie below the critical z-value of -1.96 and 2.5% lie above 1.96 (Gauvreau, 2006). Thus, if the z-statistic was found to lie below or above these respective values, the null hypothesis (that the sample proportion on the respective demographic variables are the same) was rejected. The obtained z-statistic was used to find the significance value (p-value) in the z-table by looking up the smaller proportion of the z-statistic in this table and multiplying it by two (as it was a two-tailed hypothesis test) to get the p-value (Field, 2009, p. 887).

N.2. Calculating converted z-scores to assess the assumption of normality

Normality was assessed using converted z-scores (obtained through the following formulae (Kim, 2013, p.53; Field, 2009, p.184):

N.2.1. Skewness values converted to z-scores

$$Z_{skewness} = \frac{Skew\ value}{Standard\ error\ of\ skew\ value}$$

N.2.2. Excess kurtosis values converted to z-scores

$$Z_{kurtosis} = \frac{kurtosis\ value}{standard\ error\ of\ kurtosis\ value}$$

N.3. Constructing 95% CI's around proportions

The following formula was used to construct the 95% CI's around the participation rates. (Hazra, 2017, p.4127):

$$p \pm (z - value)\sqrt{(p)\frac{(1-p)}{n}}\ ;$$

Where,
p = sample proportion.
n = number of participants in sample (n = 91 as mentioned in table 2).
Critical z − value = 1.96 (for 95% CI).

N.4. Calculating generalised eta-squared (ηG²) for a single-factor repeated measures design

The formula presented in Bakeman (2005, p.381) for a single-factor repeated measures design to calculate generalised eta-squared (ηG²) is presented below:

$$\eta G^2 = \frac{SSp}{SSp + SSs + SSps};$$

Where,

SSp = Sum of Squares of the factor (also called the model of sum squares, denoted as SSm).

SSs = Sum of Squares of the subjects.

SS_{ps} = Sum of Squares for the interaction between factor and subjects (also called the residual sum of squares, denoted as SSR).

N.5. Calculating the bias-corrected omega-squared (ω^2)

I calculated the bias-corrected omega squared ($\boldsymbol{\omega^2}$) using the formula provided by Field (2009, p. 567):

$$\omega^2 = \frac{\frac{k-1}{n\mathrm{k}}(MS_M - MS_R)}{MS_R + \frac{MS_B - MS_R}{k} + [\frac{k-1}{nk}(MS_M - MS_R)]}$$

Where,

K = number of conditions (assessment times) in the experiment (in this case, k=3).

n = number of participants (n = 19 and n = 18 participants completed all three assessments for the PHQ − 9 and GAD − 7 respectively).

MS_M = Mean Square for the model (the average amount of variation explained by the model; systematic variance)

MS_R =Residual Mean Square (the average amount of variation explained by external variables; unsystematic variance).

MS_B = Between − participants Mean Sum of Squares.

N.5.1. Calculating the between-participants mean sum of squares ($\boldsymbol{MS_B}$)

The between-participants mean sum of squares (MS_B) cannot be directly obtained from the SPSS output and has to be calculated separately using the following three steps in Field (2009, p. 567).

N.5.1.1. Calculating the total Sum of Squares (SS_T)

Firstly, the Total Sum of Squares (SS_T) should be calculated using the following formula (Field, 2009, p.551):

$$SS_T = S^2_{Grand}(\text{N-1});$$

The grand variance (S^2_{Grand}) refers to the variance of all the scores across the three assessment points. In other words, the scores are treated as if they were obtained at a single point in time, on each respective outcome measure. Thus, the N in the above formula refers to the total number of scores used to generate the aforementioned grand variance (S^2_{Grand}). In other words, for the PHQ-9 measure, N = 57 (3 assessment points, times 19 available participants) and for the GAD-7 measure, N=54 (3 assessment points, times 18 available participants).

N.5.1.2. Calculating the between-participants sum of squares ($\boldsymbol{SS_B}$)

Secondly, the between-participants sum of squares (SS_B) was calculated using the following formula (Field, 2009, p.551) :

$$SS_B = SS_T - SS_M - SS_R ;$$

Both the model of sum squares ($\boldsymbol{SS_M}$) and the residual sum of squares (SS_R) can be obtained directly from the SPSS output (as used earlier in the formula to calculate generalised eta-squared) (Bakeman, 2005; Field, 2009, p.567).

N.5.1.3. Calculating $\boldsymbol{MS_B}$

Finally, the total sum of squares (SS_T) and the between-participant sum of squares (SS_B) were used in the formula below to calculate the between-participants mean sum of squares(MS_B). Where N refers to the total number of participants in the analysis on each respective outcome measure (in other words, for the PHQ-9, n=19 and for the GAD-7, n=18).

$$MS_B = \frac{SS_B}{N-1} ;$$

N.6. Calculating Glass's d and its associated 95% CI's

I calculated Glass's d (Glass et al., 1981) with its associated 95% CI's using the following formulae in Bonett (2015, pp.367-369).

N.6.1. Calculating Glass's d

$$\text{Glass's d} = \frac{\hat{\mu}_1 - \hat{\mu}_2}{\hat{\sigma}_1} ;$$

Where,

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\mu}_1$ = Mean score of the sample on the respective outcome measures at baseline.

$\hat{\mu}_2$ = Mean score of the sample on the respective outcome measures at the respective post − treatment follow − up assessments.

N.6.1.1. Constructing the 95% CI's around Glass's d

The following three steps were followed to construct the 95%CI's around the Glass's d (Bonett,2015, pp.367-369).

N.6.1.1.1. Calculating the sample variance of the difference scores

Firstly, I calculated the sample variance of the difference scores using:

$$\hat{\sigma}_d^2 = \hat{\sigma}_1^2 + \hat{\sigma}_2^2 - 2\hat{p}\,\hat{\sigma}_1\,\hat{\sigma}_2 ;$$

Where,

$\hat{p}$ = the correlation between the scores obtained from the SPSS output.

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\sigma}_2$ =SD of the respective posttreatment follow up scores on the respective outcome measures.

N.6.1.1.2. Calculating the approximate variance of Glass's d

Secondly, I calculated the approximate variance of Glass's d:

$$\widehat{var}(Glass's\ d) = \frac{Glass's\ d}{2(\mathrm{df})} + \frac{\hat{\sigma}_d^2}{\hat{\sigma}_1^2(df)};$$

Where,

df = Degrees of freedom expressed as $\mathrm{N} - 1$.

$\hat{\sigma}_d^2$ = Sample variance calculated in step 1, above.

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

N.6.1.1.3. Constructing the 95% CI's around Glass's d

Thirdly, I calculated the upper and lower 95% CI's for Glass's d using:

$$Lower\ 95\%\ CI = Glass's\ d - z_{\alpha/2}\sqrt{\widehat{var}(Glass's\ d)};$$

$$Upper\ 95\%\ CI = Glass's\ d + z_{\alpha/2}\sqrt{\widehat{var}(Glass's\ d)};$$

Where,

$z_{\alpha/2}$ = two − sided critical zvalue for the 95% CI, which is 1.96 (Hickey et al., 2018)

$\widehat{var}(Glass's\ d)$ = approximate variance of Glass's d calculated in step 2, above.

N.7. Calculating Cohen's d_{av} and its associated 95% CI's

I calculated Cohen's d_{av} and its associated 95%CI's using the following formulas in Bonett (2015, pp.367-369).

N.7.1. Calculating Cohens d_{av}

$$\text{Cohen's } d_{av} = \frac{(\hat{\mu}_1 - \hat{\mu}_2)}{\sqrt{\frac{(\hat{\sigma}_1{}^2 + \hat{\sigma}_2{}^2)}{2}}}$$

Where,

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\sigma}_2$ = SD of the scores on the respective outcome measures at the respective follow − up assessments.

$\hat{\mu}_1$ = Mean score of the sample on the respective outcome measures at baseline.

$\hat{\mu}_2$ = Mean score of the sample on the respective outcome measures at the respective post − treatment follow − up assessments.

N.7.1.1. Constructing the 95% CI's around Cohens d_{av}

The following three steps were followed to construct the 95%CI's around Cohens d_{av} (Bonett,2015, pp.367-369).

N.7.1.1.1. Calculating the sample variance of the difference scores

Firstly, I calculated the sample variance of the difference scores using:

$$\hat{\sigma}_d^2 = \hat{\sigma}_1^2 + \hat{\sigma}_2^2 - 2\hat{p}\,\hat{\sigma}_1\,\hat{\sigma}_2\ ;$$

Where,

$\hat{p}$ = the correlation between the scores obtained from the SPSS output.

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\sigma}_2$ = SD of the respective post − treatment follow up scores on the respective outcome measures.

N.7.1.1.2. Calculating the approximate variance of Cohen's d_{av}

Secondly, I calculated the approximate variance of Cohen's d_{av}

$$\widehat{var}(Cohen's\ d_{av}) = \frac{(Cohen's\ d_{av})^2\left(\hat{\sigma}_1^4+\hat{\sigma}_2^4+2\hat{p}^2{\hat{\sigma}_1}^2{\hat{\sigma}_2}^2\right)}{8(df)(\sigma^4)} + \frac{\hat{\sigma}_d^2}{\sigma^2(df)}$$

Where,

$\sigma^4 = \left[\frac{\hat{\sigma}_1^2+\hat{\sigma}_2^2}{2}\right]^2$

$\sigma^2 = \frac{\hat{\sigma}_1^2+\hat{\sigma}_2^2}{2}$

df = Degrees of freedom expressed as N-1.

$\hat{\sigma}_d^2$ = Sample variance calculated in step 1, above.

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\sigma}_2$ = SD of the respective post − treatment followup scores on the respective outcome measures.

N.7.1.1.3. Constructing the upper and lower 95% CI's around Cohen's d_{av}

Finally, I calculated the upper and lower 95% CI's for Cohen's d_{av}

$$Lower\ 95\%\ CI = Cohen's\ d_{av} - z_{\alpha/2}\sqrt{\widehat{var}(Cohen's\ d_{av})}\ ;$$

$$Upper\ 95\%\ CI = Cohen's\ d_{av} + z_{\alpha/2}\sqrt{\widehat{var}(Cohen's\ d_{av})}\ ;$$

Where,

$z_{\alpha/2}$ = two − sided critical zvalue for the 95% CI, which is 1.96 (Hickey et al., 2018)

$\widehat{var}$(Cohen's dav)=approximate variance of Cohen's dav calculated in 7.1.1.2, above.

N.8. Hedges' correction

Hedges' correction is calculated as follows (Hedges, 1981, p. 114), where *df* refers to the degrees of freedom (and is calculated as n - 1). This correction was applied to both (a) Glass's $d_{;}$ and (b) Cohen's $d_{av.}$ Thereafter referred to as (a) Glass's d_{unb}; and (b) Cohen's d_{avunb}

$$1\text{-}\frac{3}{4(df)-1}$$

N.9. Calculated the standard deviations (SD's) from the intention-to-treat analysis using multiple imputations (ITTA-MI)

I calculated the SD's from the ITTA-MI using the formula by Altman & Bland (2005, p.903) presented below. This is based on sample size (n=91) and the pooled (standard errors) SE's obtained from the ITTA.

$$SE = \frac{SD}{\sqrt{n}};$$

Thus,

$$SD = SE(\sqrt{n});$$

Where,

n= sample size (n=91)

N.10. Sample size estimation of a paired-samples design using the safeguard power analysis

$$n = \frac{\left(z_{1-\alpha/2}+z_{1-\beta}\right)^2}{d^2} + \frac{\left(z_{1-\alpha/2}\right)^2}{2};$$

Where,

$n = estimated\ sample\ size.$

$z_{1-\alpha/2} = 1.96\ (for\ \alpha\ set\ at\ 0.05, according\ to\ convention).$

$z_{1-\beta} = 0.842\ (for\ power\ set\ at\ 0.8, according\ to\ convention).$

$d = lower\ bound\ of\ the\ 60\%\ CI\ of\ Cohen's\ d_{avunb}$ calculated from the ITTA.

N.11. Sample size estimation of an independent samples design using the safeguard power analysis

Firstly, I present the formula for sample size estimation assuming equal group sizes in the intervention and control group (Campbell et al., 1995, p.1148).

$$n = \frac{(2)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{d^2} + \frac{\left(z_{1-\alpha/2}\right)^2}{4}$$

$n = estimated\ sample\ size\ per\ group$

$z_{1-\alpha/2} = 1.96\ (for\ \alpha\ set\ at\ 0.05, according\ to\ convention).$

$z_{1-\beta} = 0.842\ (for\ power\ set\ at\ 0.8, according\ to\ convention).$

$d = lower\ bound\ of\ the\ 60\%\ CI\ of\ Cohen's\ d_{avunb}$ calculated from the ITTA.

N.11.1. Adjusting sample size estimation according to the allocation ratio

Secondly, I present the formula that adjusts each respective group (calculated above) according to the allocation ratio (Campbell et al., 1995, p.1148).

$$n' = \frac{r+1}{2r}(n);$$

Where,

$n' = adjusted\ group\ sample\ size\ (i.e. sample\ size\ of\ second\ group)$

$n = estimated\ sample\ size\ of\ first\ group$

$r = allocation\ ratio\ (in\ this\ study\ r = 2)$

N.12. Calculating the clinically meaningful effect

I calculated the clinically meaningful effect using formulas to calculate Cohen's d_{avunb} (formula 7.1 and formula 8) and the criteria established by McMillan et al. (2010) for RCSC on the PHQ-9. Thus:

$$\text{Cohen's } d_{avunb} = \frac{(\hat{\mu}_1 - \hat{\mu}_2)}{\sqrt{\frac{(\hat{\sigma}_1{}^2 + \hat{\sigma}_2{}^2)}{2}}} \times \left(1 - \frac{3}{4(df)-1}\right);$$

Where,

$(\hat{\mu}_1 - \hat{\mu}_2)$ = the mean PHQ − 9 score change of 5 – 10 points, respectively, on the PHQ as suggested by McMillan et al., (2010)

$\hat{\sigma}_1$ = SD of the baseline scores on the respective outcome measures.

$\hat{\sigma}_2$ = SD of the scores on the respective outcome measures at the respective follow − up assessments (calculated using formula 9)

df = degrees of freedom (and is calculated as n − 1).

N.13. Conducting a clinically meaningful effect sample size estimation

Firstly, I estimated the sample size for an independent design assuming equal group sizes in the intervention and control group (Campbell et al., 1995, p.1148).

$$n = \frac{(2)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{d^2} + \frac{\left(z_{1-\alpha/2}\right)^2}{4}$$

$n = estimated\ sample\ size\ per\ group$

$z_{1-\alpha/2} = 1.96\ (for\ \alpha\ set\ at\ 0.05, according\ to\ convention).$

$z_{1-\beta} = 0.842\ (for\ power\ set\ at\ 0.8, according\ to\ convention).$

$d = minimal\ clinically\ significant\ effect$

N.13.1. Adjusting sample size estimation according to the allocation ratio

Secondly, I adjusted each respective group (calculated above) according to the allocation ratio (Campbell et al., 1995, p.1148).

$$n' = \frac{r+1}{2r}(n);$$

Where,

$n' = adjusted\ group\ sample\ size\ (i.e. sample\ size\ of\ second\ group)$

$n = estimated\ sample\ size\ of\ first\ group$

$r = allocation\ ratio\ (in\ this\ study\ r = 2)$